Submission No 19

INQUIRY INTO NANOTECHNOLOGY IN NEW SOUTH WALES

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CSIRO

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The Director
Standing Committee on State Development
Parliament House
Macquarie St
Sydney NSW 2000

28 March 2008

The Director

Re: Inquiry into Nanotechnology in NSW

We thank you for the opportunity to provide a submission on nanotechnology in New South Wales. CSIRO believes that Australia needs a strong research base in nanotechnology to capture the very significant opportunities that the technology presents to improve Australia's well being while ensuring we can identify, understand and appropriately manage any possible harmful consequences of nanotechnology.

To this end, CSIRO is actively conducting research in nanotechnology with the recently established Niche Manufacturing Flagship spearheading the research effort.

Our comments are written with an understanding that we are active in the area of nanotechnology research and that the research we conduct is of benefit to both the Australian and International scientific community as well as for the public good.

Specific comments pertaining to the terms of reference for the inquiry are attached.

Yours sincerely

Stephen Morton

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CSIRO Submission 07/271

Inquiry into Nanotechnology in NSW

March 2008

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Terms of Reference

That the standing committee on State Development inquire into and report on nanotechnology in New South Wales, in particular:

a. Current and future applications of nanotechnology for NSW industry and the NSW community

b. The health safety and environmental risks and benefits of nanotechnology

c. The appropriateness of the current regulatory frameworks in operation for the management of nanomaterials over their life-cycle

d. The adequacy of existing education and skills development opportunities related to nanotechnology

e. The adequacy of the National Nanotechnology Strategy in the NSW context

f. The level of community understanding of nanotechnology and options to improve public awareness of nanotechnology issues

Contents

Executive Summary

CSIRO believes that Australia needs a strong research base in nanotechnology to capture the very significant opportunities that the technology presents to improve Australia's wellbeing while ensuring we can identify, understand and appropriately manage any possible harmful consequences of nanotechnology.

Terms of reference "a": Current and future applications of nanotechnology for NSW industry and the NSW community

Thirty to forty percent of Australian companies that provide services, processes or products based on nanotechnology currently have addresses in NSW. Future opportunities leveraged from CSIRO research could develop from interactions with CSIRO's Niche Manufacturing Flagship or the Australian Growth Partnerships program. Opportunities exist in biomedical devices, electronics, drug delivery, and advanced materials.

Term of reference "b": The health safety and environmental risks and benefits of nanotechnology

Nanoparticles have unique properties that may be used to advantage for human health and environmental applications, but there also are potential risks. Preliminary toxicity studies on cells and model animals indicate that some nanoparticles may be toxic to humans. Long-term studies to assess chronic exposure to nanoparticles in the workplace and to nanoparticles in products are required. The risk of human exposure to nanomaterials must be kept in context, for example by comparing the measured level of nanoparticle toxicity with exposure to particulates in exhaust fumes. There are many gaps in our knowledge of the environmental fate and toxicity of nanoparticles. There is growing evidence of nanoparticle toxicity to aquatic organisms. Data on toxicity to higher aquatic organisms are lacking. Data on toxicity to terrestrial organisms are very limited.

Term of reference "c": The appropriateness of the current regulatory frameworks in operation for the management of nanomaterials over their life-cycle

Current Commonwealth Regulations for both Hazardous Substances and Dangerous Goods can be used to ensure that employees, other people and property are safe from the possible risks of nanoparticles. However, we do not have a complete understanding of the toxicity of various nanoparticles at present, complicating the implementation of the current legislative framework as it pertains to nanoparticles. This is one important aspect of nanotechnology that CSIRO is currently researching.

Term of reference "d": The adequacy of existing education and skills development opportunities related to nanotechnology

Creative people with expertise in physics, chemistry, medicine, biology, materials science, environmental science and many other disciplines can all contribute to different areas of nanotechnology. As a result, the needs for nanotechnology education are met by having a strong and effective general science and engineering education system.

Term of reference "f": The level of community understanding of nanotechnology and options to improve public awareness of nanotechnology issues

Public understanding of nanotechnology is low. Public engagement in nanotechnology research and development could be helpful in encouraging interest in this emergent. As such credible sources to inform the public about developments in science and technology are vital. CSIRO is widely regarded as such a source of credible information, (it has been the leading message about CSIRO in CARMA media analysis reports for many years) and in recent public fora organised by the Australian Office of Nanotechnology, a CSIRO scientist has spoken at each.

Preamble

CSIRO is internationally recognised as a research and development organisation in the field of nanotechnology. It developed the world's first biosensor using the nanotechnology principle of self-assembling components. This work was reported in the high-profile journal *Nature*)[1]. It led to the formation of the company Ambri, which is focused on developing biosensor products for medical and industrial applications and which was initially established in Sydney, NSW.

To date, CSIRO has supported nanotechnology-based projects in diverse areas of application such as drug delivery, medical imaging, electronics, sensors, biomedical materials, environmental toxicology, nanocomposite materials, liquid and gas separation, and photocatalysis. A nanotechnology audit conducted in 2006, covering research activities 1998-2006, revealed a total of 280 equivalent full-time staff working in 69 nanotechnology projects in CSIRO. On the basis of this number, CSIRO was investing about $70M per year in nanotechnology research at the time of the audit. Approximately one half of these resources were dedicated to basic material science and measurement, about 15% to fabrication of devices, and around 30% to dealing with specific applications of nanotechnology. Between 1998 and 2006, CSIRO scientists co-authored 12,232 scientific papers in peer-reviewed journals. Of these more than 4,400 contained one or more of a set of 28 keywords designed to identify papers relating to nanotechnology. Analysis of the titles and abstracts of these 4,400 papers revealed a total of 779 publications that could be further classified as falling within the broad area of "nanotechnology", based on the nature of the work, and its potential application.

CSIRO's Position Statement on Nanotechnology

Recognising the current and future importance of nanotechnology to Australian industry and the public, CSIRO has developed a position statement on nanotechnology (attachment 1). "CSIRO believes that Australia needs a strong research base in nanotechnology to capture the very significant opportunities that the technology presents to improve Australia's well being while ensuring we can identify, understand and appropriately manage any possible harmful consequences of nanotechnology".

CSIRO's Niche Manufacturing Flagship

As part of the National Nanotechnology Strategy announced in 2007, the Federal Government provided additional funding of $36.2 million over 4 years for CSIRO to establish a Flagship to support the development of niche manufacturing businesses based on nanotechnology in Australia. The new Niche Manufacturing Flagship covers research and development in electroactive polymers, therapeutic delivery, applications of spun carbon-nanotube yarns, and sensors for use at point of sampling (point of care). In parallel, the Niche Manufacturing Flagship is developing a Nanosafety research program to ensure that CSIRO's Health, Safety and Environmental (HSE) standards are met for the Flagship's research, and to gather research-based evidence on the safety issues surrounding the nanomaterials and nanomaterial-containing products being used and developed by other projects in the Flagship.

Nanosafety researchers are interacting closely with Government agencies with the aim of transferring information from the HSE research to national and international regulators, to assist in the development of guidelines for safe work practices involving nanomaterials, for safe use of products containing nanomaterials, and for assessing the impact of nanotechnology developments on the environment. This HSE information will also be made publicly available through publication in peer-reviewed journals, open seminars, and press releases.

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[1] Cornell B, Braach-Maksvytis V, King L, Osman P, Raguse B, Wieczorek L, and Pace R. "A biosensor that uses ion-channel switches" *Nature* (1997), *387*, 580

The Niche Manufacturing Flagship is a world leading model as demonstrated by testimony to the United States House of Representatives Committee on Science and Technology Hearing on "Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation under the National Nanotechnology Initiative" in October 2007, Dr Andrew Maynard, Chief Science Adviser with the project on emerging technologies at the Woodrow Wilson Centre, stated: "Building a top-down strategic nanotechnology EHS research plan around these goals, challenges and elements, is essential to providing a framework for generating the information that regulators, industry, consumers and others need to develop and use nanotechnologies as safely as possible. As an example of what is possible, Australia recently announced the formation of an AU$36.2 million initiative to develop nanotechnologies for niche markets – the Niche Manufacturing Flagship. What sets this initiative apart is an integrated approach to EHS research from the start, an approach that will lead to products that have been researched and designed with safety in mind. And while the Niche Manufacturing Flagship approach represents just one component on an effective strategic research framework, in the long run, it is products arising from programs like this that are most likely to be embraced by consumers and industry alike."

CSIRO's position as an independent voice

CSIRO "recognises and respects the public's interest in and concerns about nanotechnology and acknowledges the rights of the public to receive open and disinterested information on these topics and on the research that CSIRO is performing" (CSIRO position statement, attachment 1). While CSIRO research is often supported by co-investment from companies, it should be recognised that CSIRO staff personally do not benefit financially from this funding arrangement, nor do they benefit from patents arising from their research as patent ownership is transferred to CSIRO. It is important to understand that while the private sector can pay do for the research, this does not compromise the results of the research and the results of the research are independent of funding sources, not least because they are subject to peer review. The same arrangements do not necessarily exist at all research institutions receiving funding from external sources.

What is nanotechnology?

The term "nanotechnology" covers a diverse range of technologies, and it is more accurate to use the word "nanotechnolgies" when describing the field in general terms. However, given the general accepted usage of the term nanotechnology, as well as the specific use of the term for this inquiry, "nanotechnology" is still used where appropriate in this submission. When considering the risks and benefits of products and uses derived from these nanotechnologies, it is necessary to perform a risk-benefit analysis specific for that product or use. In this way, the product, and the specific nanotechnology used to develop that product, is uncoupled from the broad "nanotechnology" umbrella. For example, some nanotechnology applications have very low risk to human safety, such as the use of silver nanoparticles in refrigerator walls to kill bacteria and keep food fresh for longer. Other nanotechnology applications may have a higher inherent risk to human health, but the benefit may far outweigh the potential risk, such as the use of nanometre-sized self-assembled liposomes to control the delivery of drugs for medical applications. Still other applications may have little apparent benefit and there may be uncertainty as to whether they might present a risk to human health, such as the inclusion of nanoparticles in food simply to enhance its appearance.

There are many definitions of the term nanotechnology; some of these have been compiled in Attachment 2. The definition of nanotechnology used by the journal *New Scientist*, and more accessible than some others, is "nanotechnology is science and engineering at the scale of atoms and molecules. It is the manipulation and use of materials and devices so tiny that nothing can be built any smaller." http://technology.newscientist.com. Much of nanotechnology takes place at the interface of two or more scientific disciplines, which include, but are not limited to, biology, physics, chemistry, mathematics, computing and materials science.

It is important to note that nanotechnology is not new. Unknowingly, the ancient Greeks and Romans used a hair-dying recipe that involved the generation of lead sulphide nanoparticles in hair shafts and caused the hair to darken)[2]. Silver has been known as a bactericide for over a thousand years, and colloidal silver has been drunk to treat infectious diseases. Nanoparticles are generated from a variety of sources including volcanic eruptions and bush fires, and are they are present in vehicle exhaust. However, only in the past 20-30 years have we had microscopes and other instruments that have allowed us to “see” and detect nanoparticles in naturally occurring and manufactured samples. The current situation is that the deliberate production of manufactured nanoparticles is being scaled up, and many new types of nanoparticles are being made.

Attachment 1: CSIRO’s position statement on nanotechnology

Attachment 2: Nanotechnology definitions

[2] Walter P, Welcomme E, Hallégot P, Zaluzec NJ, and Deeb C. “Early use of PbS nanotechnology for an ancient hair dyeing formula” *Nano Lett*., (2006) 6, 2215-2219.

Responses to the Terms of Reference of the Inquiry

a. Current and future applications of nanotechnology for New South Wales industry and the New South Wales community

General Comments:

Nanotechnologies are already in the market place and used in various industries in NSW. In some cases, the industries have been using technologies that have been redefined as “nano” to provide recognition of nano-components. Nanotechnology has the potential to provide disruptive technologies to create entirely new industries, make existing industries more efficient and environmentally sustainable and provide more effective, cheaper and energy efficient products and services. (Note: Social and safety issues and risks are discussed in TOR b).

To date, nanotechnologies introduced into processing and products provide new materials properties and products that are:

- Stronger
- Lighter
- Chemical resistant
- More durable
- Energy saving
- Offering a previously unavailable functionality.

Examples include: paint that is a colloidal combination of nanoparticles and fluids, homogenized milk which has nano-sized fat globules distributed evenly throughout the milk (to make the milk more palatable for the consumer), antimicrobial sensors and coatings (to prevent food poisoning and increase shelf life of food products), printable Radio-Frequency Identification (RFID) tags using printable nanoparticle inks (for improved tracking of documents, clothing in laundries, distribution of products), functional foods (for improved digestion and absorption of nutrients from food) and nanocomposite materials in car components that are scratch resistant, rust proof and light weight (reducing fuel consumption, increasing component life time and reducing maintenance).

The benefit of nanotechnology in the NSW context

Potential nanotechnologies of benefit to NSW industries are categorized into different groups:

- Nano-sized materials (usually the building blocks of nano-structured materials, coatings and thin films)
    - Nanoparticles
    - Nanocrystals
    - Nanotubes
- Bulk materials which use nano-sized materials as a component:
    - Nano-composites
    - Nanostructured materials
    - Nanoclays
- Thin films and coatings
    - Nano-composite coatings
- Nanostructures, devices and components including quantum electronics, sensors and detectors
- Nanobiotechnology

Industry Sectors

The industry sectors that are using or could benefit from using nanotechnologies include:

- Biomedical devices and health
- Electronics, information technology and communications
- Packaging, logistics
- Food and agribusiness
- Automotive
- Power, energy
- Environment monitoring and maintenance
- Mining, mineral exploration and mineral processing
- Scientific instruments
- Security, Defence
- Cosmetics
- Sporting equipment
- Clothing
- Building and built environment
- Consulting and training

There is no definitive list of companies that provide services, processes or products based on nanotechnology. There are several sources that provide examples or a sub set of nanotechnology companies.

- Of the 40 private sector companies listed in the Warren Centre Directory (The Warren Centre for Advanced Engineering, U. Syd. June 2004, ISBN 1864876336) of nanotechnology service providers 18 companies (45%) had addresses listed in NSW.
- Another list giving examples of nanotechnology Employers in Australia, provided by the Australian Government, has 35 companies listed of which 12 (35%) are identified as operating form NSW.
- The PMSEIC nanotechnology report (11 March 2005 p. 28) provides a list of 24 nanotechnology companies of which 7 (29%) are operating in NSW.

Attachment 3 provides a list of nanotechnology applications and opportunities in Australian industry, while attachment 4 provides a short summary of state based nanotechnology interests.

CSIRO Nanotechnology Research

Nanotechnology research in CSIRO: In an audit undertaken in CSIRO in 2006, CSIRO was investing $70M per year in nanotechnology research (280 Full Time Equivalent (FTE) employees, calculated from $0.25M per FTE) and in the period of 1998 to 2006 CSIRO had invested more than $520M.Of this research 11.4% was in the biotechnology area. Table 1 summarizes some of the major nanotechnology projects in CSIRO.

Table 1. Some major nanotechnology research projects in CSIRO are:

Project	FTEs	Application Area
Creation of new functional enzymes	17	Proteins/enzymes/bio
ESI Environmental Nanovectors	5.5	Risk Assessment
ESI- 3D Hierarchical materials	5.3	Drug delivery/ sensors/energy/materials
GPCR Transductsomes	11.6	Sensors
Biomimetic nanosprings	5.5	G Protein/Enzymes/bio
Multifunctional polymers using nano additives	11.2	Various

Nanoparticles for printable electronics	5.65	Electronics and sensors
Multifunctional nanoparticles and nanocomposites	5.65	Materials Nanocomposites
ESI - Synchrotron	8.3	Characterisation/Metrology
Functional proteins	14.5	G Protein/Enzymes/bio

Current examples of CSIRO research that have led to NSW-based nanotechnology industries are:

- ***CAP-XX Pty Ltd:*** CAP-XX (http://www.cap-xx.com/) is an Australian company incorporated in 1997. It focuses on developing and commercialising advanced supercapacitors (high-powered energy storage devices). Supercapacitors work by employing nanostructured colloidal carbon electrode materials, which help to store energy by way of nanometre-wide pores. As a result of their leading technology and high quality product, CAP-XX is expected to dominate the supercapacitor market, which some forecasters predict will eventually exceed US$6 billion. CAP-XX is expanding globally and has sales staff based in the USA and Taiwan. CAP-XX is recognised as a world-leading nanotechnology company and employs 70 people and has manufacturing sites in Lane Cove and Penang. In 2006 it had raised ca. $60 million from investors. The technology development has involved 7 Divisions of CSIRO (35 CSIRO scientists and engineers) as well as CAP-XX staff.

- ***Ambri Ltd Ion Channel Switch (ICSTM):*** The Ambri ICSTM is the first purpose built nano-machine operating with nano-scale moving parts. The ICS consolidates more than a decade of research by the Australian Membrane and Biotechnology Research Institute (AMBRI), CSIRO and the University of Sydney. The company, Ambri Ltd is incorporating this technology into a reader and a series of test-specific, single-use disposable cartridges for point of care diagnostics, as well as other markets. The company was originally located at Chatswood, NSW but moved to Queensland in recent years.

Other companies using CSIRO developed Nanotechnologies in Australia but not located in NSW are:

- Boeing fireworthy nylon nanocomposites. This is a Boeing funded project ($1.6M) since 2001 which develops fireworthy nanomaterials (international patent filed) with unprecedented fire performance, cost effectiveness, good mechanical properties, moisture and gas barrier properties, and processing ability. The technology is now being scaled up for the new Boeing 787, and has great potential for other applications, e.g., ships, automotive fuel line, buildings.
- Electrical conductive composites/nanocomposites for electronic detonation (Orica). This project started in 2004 ($610k). The technology developed won the 2005 Orica Mining Services Division's Innovation Award. It is currently being scaled up and commercialised.
- Transparent and UV resistant nanocoatings developed to preserve the quality of food and beverage products packaged in glass bottles. The technology is being commercially pioneered by Bottle Magic Australia Pty, Ltd.
- Starpharma Dendrimer Products (http://www.starpharma.com/framemaster.htm). The idea originated from George Holan and Barry Matthews in CSIRO Molecular and Health Technologies and the intellectual property was developed when they were seconded to the Biomedical Research Institute (BRI). Starpharma is recognised globally as a nanotechnology company commercialising dendrimer technology for pharma applications. They are in clinical phase trials for some products.
- Surfactant Self-Assembly Drug Delivery Vehicles. A chemotherapy drug delivery system was developed by CSIRO Molecular and Health Technologies and Mayne Pharma. A controlled release infusion substitute system (CRISS) system has been developed. *In vitro* tests have been completed and Mayne Pharma is conducting animal studies.

- Ciba Vision Night and Day and O2Optix Contact lenses. http://www.cibavision.com/about_worldwide/milestones. html CSIRO Molecular and Health Technologies, CRC for Eye Technology and UNSW collaboration. CSIRO role was nano-scale surface modification, through plasma polymerisation and surface chemical reactions to attach polymer brushes, which led to lenses with good comfort and low protein fouling characteristics.
- BarOmegaTM Drilling Fluids: Environmentally friendly water-based drilling fluids for oil wells. The drilling fluid active ingredient was developed by CSIRO Petroleum and Molecular Science. New "green" drilling fluids are being marketed by Baroid Drilling Fluids (subsidiary of Halliburton). The fluid functions by a self-assembly process on the nano-scale that penetrates the surrounding shale formation and provides support during drilling to prevent bore hole collapse.
- LANDTEM SQUIDs for mineral exploration: a high temperature superconducting SQUID system has been licensed to Outer Rim Developments and 12 systems have been manufactured for rent and sale. It is being used in both eastern and western Australia, Canada, USA and Africa. It has led to the discovery of several significant nickel sulphide deposits and other conducting minerals worth over $6B dollars.

Future Opportunities for Nanotechnology Industries in NSW

In 2007 using new funding, CSIRO established a new “Niche Manufacturing Flagship”, focusing on nanotechnology. This will use nanotechnology to create a new wave of niche industries and add value to existing high-value segments of the manufacturing sector.

The Niche Manufacturing National Research Flagship's goal is to support the development of niche manufacturing businesses based on nanotechnology, to be worth in excess of A$3 billion per year by 2020. In addition, CSIRO has a number of other programs (e.g., the Australian Growth Partnerships program) providing small and medium enterprises (SMEs) access to CSIRO research capabilities, funding and support.

Australian Growth Partnerships (AGP) is a new, competitive, merit-based pilot funding program managed by CSIRO. CSIRO has been allocated funds by the Commonwealth Government to provide funding through the program, to high potential, technology-receptive SMEs in order that they can access CSIRO research and development (R&D) capability and intellectual property.

Other areas: NSW is well placed to capitalise on future quantum electronics development and associated industries, building on the research at the Australian Centre for Quantum Computing Technologies (ACQCT).

Research underway in CSIRO that has anticipated impact on NSW industries or providing investment opportunities are in:

- Biomedical devices
    - Electronics
    - RFID tags based on printed nanoparticle conducting inks
- Molecular electronics
- Health drug delivery platforms
- Advanced materials
    - Ultra light/ultra strong
- Automotive components

Attachment 3: Nanotechnology applications and opportunities in Australian Industry

Attachment 4: State based nanotechnology interests across Australia

b. The health, safety and environmental risks and benefits of nanotechnology

General comments:

Nanoparticles have unique and novel properties that may be used to advantage for human health and environmental applications. However, as with all technologies, the benefits of using these novel properties in products come with associated risks, as nanoparticles are likely to interact with living systems in new ways. Scientists have been leading the call for studies on their potential toxicity and altered bioavailability to organisms[3].

Benefits and risks of nanotechnology

The examples given below are not comprehensive but representative of the many current and potential applications of nanotechnology for human health, safety and the environment.

Biosensors – benefits: The development of bio-sensors for diagnosing human and environmental health is shifting from the concept of sending samples for analysis on large expensive machines located in centralised laboratories to immediate information obtained from small, light-weight, hand-held sensors used at the site of medical care or in the field. Nanotechnology will play a large part in the development of such sensors, with the scope for miniaturising the size and weight of the sensors, and for utilising properties of the nanoparticles for the transduction signal. An example is the colour change observed when a red-coloured solution of gold nanoparticles (modified with diagnostic single-strands of DNA) may change to blue when a DNA sample of interest is added. The change from red to blue occurs if the sample has DNA molecules with sequences complementary to the diagnostic DNA on the gold nanoparticles, as this sample DNA is then able to bind to diagnostic DNA on different gold nanoparticles and bring the nanoparticles in close proximity, thus altering the surface plasmon resonance and hence the colour of the solution[4].

Risks: Adverse impacts associated with the development of small and inexpensive sensors for use in the field are likely to be on ecosystems resulting from inappropriate disposal of very large numbers of these sensors.

Skin care products – benefits: Sunscreens and skin-care products containing nanoparticles of zinc oxide and titanium dioxide are available commercially in Australia. These inorganic nanoparticles are the active ingredients that prevent sunburn. They absorb UVA and UVB radiation over a wider range of wavelengths than chemical absorbers such as octylmethoxycinnamate or butylmethoxydibenzoylmethane, with ZnO nanoparticles in particular having excellent absorption of UVA radiation which is mainly responsible for skin damage.

Risks: Associated with the benefits of preventing sunburn are the unknown effects of potential dermal absorption of the nanoparticles, production of free radicals upon absorption of UV radiation by the nanoparticles, and release of significant quantities of the nanoparticles to aquatic systems upon use of sunscreens by swimmers. In this respect it should be noted that use of sunscreens containing chemical absorbers (not nanoparticles) has been linked with allergic reactions in humans, and with bleaching of coral reefs by promoting viral infections[5].

Drug delivery – benefits: Drug delivery and *in vivo* imaging are two potential medical applications of nanotechnology which are attracting attention, as many nanoparticle properties are highly

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[3] Maynard, A.D., Aitken, R.J., Butz, T., Colvin, V., Donaldson, K., Oberdorster, G., Philbert, M.A., Ryan, J., Seaton, A., Stone, V., Tinkle, S.S., Tran, L., Walker, N.J., Warheit, D.B. (2006) Safe handling of nanotechnology. Nature 444, 267-269.

[4] Elghanian, R., Storhoff, J.J., Mucic, R.C., Letsinger, R.L., Mirkin, C.A. (1997) Selective colorimetric detection of polynucleotides based on the distance-dependent optical properties of gold nanoparticles. Science 277, 1078-1081.

[5] Danovaro, R., Bongiorni, L., Corinaldesi, C., Giovannelli, D., Damiani, E., Astolfi, P., Greci, L., Pusceddu, A. (2008) Sunscreens cause coral bleaching by promoting viral infections. Environmental Health Perspectives 116, 441-447.

suited for these applications. The small sizes of nanoparticles potentially enable them to pass through cell membranes. The nanoparticles may have accompanying molecules encapsulated, or physically or chemically attached to their surfaces, and these may be released upon binding to cell membranes or upon entry to the cell. The accompanying molecules may be drugs, or imaging agents. Alternatively, the nanoparticle itself may have imaging properties, such as fluorescence from quantum dots, or the nanoparticle may consist of drug molecules assembled in such a way to form the nanoparticle.

Risks: Current regulations for any materials proposed for medical applications require extensive testing in animal and human trials, and these regulations also will be applicable to nanoparticles. Therefore, knowledge of the risks associated with nanoparticle use for these applications will be at the same level as for other current technologies. Although the risks may be known, they are not negligible, as most pharmaceuticals and medical procedures have side-effects, and generally their use is approved when the perceived benefit justifies the risk.

Food packaging & ingredients - benefits: There are two potential areas where consumers may be exposed to nanotechnology in the food chain; food packaging, and food ingredients. The enhanced barrier properties of nanocomposite packaging films provide a better protection from oxygen for our foods and keep foods such as meats and vegetables fresher for longer, potentially reducing the amount of food wasted. The health risk posed by such technology is likely to be low because the nanoparticles used are embedded in a polymer matrix. Legislation similar to that in the US, requiring the addition of a polymer layer between the nanocomposite film and the food, would provide enhanced consumer protection. In the area of nano-ingredients, the goal is to increase nutrient bioavailability by increasing solubility and by protecting the nutrients from degradation.

Risks: The health risk posed by these ingredients is likely to be low because they are created from digestible soluble food ingredients. However, increasing the scope of novel food legislation to include aspects of size might be warranted to provide enhanced consumer protection.

General comments relating to potential nanoparticle toxicity

Here we provide comments to assist with understanding the potential risks to human health and ecosystems from exposure to nanoparticles. As experimental data on the actual toxicity are gathered for each type of nanoparticle in its various forms, the knowledge may be used to adjust the properties of these nanoparticles to reduce or eliminate any adverse impact. At this stage, little is known about the toxicity (if any) of nanoparticles for human health and ecosystems. Experiments with cells *in vitro* indicate there is cause for concern, but experiments with isolated cells are not always predictive of the actual effects in animals and humans. Initial experiments with animal models have strengthened the concern for human health, at least for some types of nanoparticles (for example, carbon nanotubes, although at this stage the experimental results are conflicting).

The physical and chemical properties of nanoparticles that may be implicated in toxicity and altered bioavailability include:

- Size (particle diameter)
- Number
- Shape
- Chemical composition
- Internal structure
- Aspect ratio (ratio of length to width of the nanoparticle)
- Contaminants
- Surface area
- Surface charge
- Surface coating
- Aggregation state

- Chemical and photo-reactivity
- Oral digestibility

It is not yet known for certain which of these metrics, or combinations of metrics, may be responsible for adverse biological impacts for any class of nanoparticles.

For bulk materials, the number of molecules within any large particle is very much greater than the number of molecules at the surface of the same particle, and so the bulk properties of the material dominate. If the same material is prepared as very tiny particles, the numbers of molecules on the surfaces increase exponentially when particle size decreases to below 100 nm, as can be seen from Figure 1, and for this situation the surface properties dominate. Figure 1 illustrates why surface area and other surface properties are thought to be implicated in any increased chemical and biological activities of nanoparticles, compared to an identical mass of the same material in bulk form.

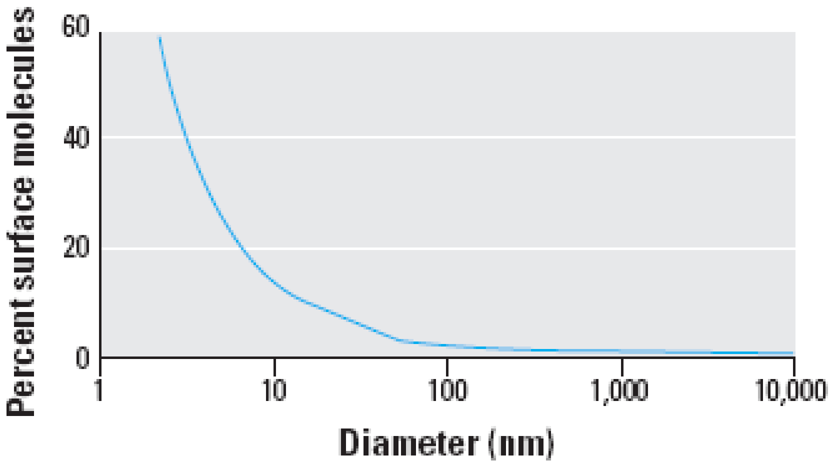

Figure 1. Surface molecules as a function of particle size[6].

Nanoparticles may exert their toxicity when they become attached to cell membranes, or following entry into the cell via mechanisms such as endocytosis. The size, shape, surface coating and charge of any nanoparticle may affect its ability to penetrate cell membranes. The mechanisms of nanoparticle toxicity are thought to involve:

- Disruption or damage of cell membranes
- Oxidative stress caused by the generation of free radicals and reactive oxygen species
- Release of toxic dissolved species inside or in close proximity to the cell

The properties of nanoparticles may change when they are placed in a biological or environmental system. For example, the surfaces may become coated with biomolecules or humic materials, the nanoparticles may dissolve, or there may be chemical changes such as oxidation. In many situations, the aggregation of nanoparticles can be quite significant. Such transformations of nanoparticles in biological systems and environmental matrices create problems in determining the physico-chemical properties responsible for toxicity and understanding dose response relationships. In addition, it is extremely difficult to find nanoparticles and to characterise their properties *in vivo*, but this information is needed to understand the mechanisms of nanoparticle toxicity. CSIRO research, by means of the Niche Manufacturing Flagship is specifically addressing this issue.

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[6] Oberdorster, G., Oberdorster, E., Oberdorster, J., (2005) Nanotoxicology: An emerging discipline evolving from studies of ultrafine particles. Environmental Health Perspectives. 113, 823-839.

Potential nanotoxicity and human health

Nanoparticles may enter the human body by inhalation, ingestion, or absorption through the skin.

The greatest risk for human exposure is from nanoparticle “dust” that may be inhaled or, less likely, ingested or dermally absorbed. The risk is highest in the workplace during the manufacture of nanoparticles in dry form, and subsequent processing and handling of these materials. The risks are minimised by following the “hierarchy of control” as described later in TOR “c”. The risks may also be minimised by using alternative production methods that result in manufactured nanoparticles in liquids with limited risk of forming aerosols.

There is a lower risk for human exposure when nanoparticles are suspended in liquids, although exposure could occur by inhalation of aerosols, and by dermal absorption or ingestion if splashed on the skin, eyes or lips. In the case of consumer use of liquid-based products containing nanoparticles, such as skin-care products or sunscreens containing nanoparticles of titanium dioxide, zinc oxide or iron oxide, there is potential for dermal absorption following normal use. Although the majority of publications studying *in vitro* dermal absorption of these products conclude that nanoparticles do not penetrate the *stratum corneum*, an Opinion published in December 2007 by the European Commission on the Safety of Nanomaterials in Cosmetic Products concluded that the standard device for estimating percutaneous absorption is not ideal and that, at present, there is inadequate information on nanoparticle uptake in physiologically normal and compromised human skin (http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf). There is also the possibility of exposure by ingestion through licking lips to which the products have been applied.

The risk of human exposure to nanoparticles embedded in a solid matrix is very low, if the matrix is not volatile or is not rubbed with harsh abrasives. An example would be the incorporation of silver nanoparticles in the surfaces of refrigerator walls; in such products, the silver nanoparticles kill bacteria resulting in food being kept fresher for longer. Another example is the use of nanocomposite materials in the aircraft industry where very strong and light-weight materials are required.

It is likely that indigestible or insoluble nanoparticles will pose a much higher potential risk to human health than digestible or biodegradable nanoparticles. Nanoparticles made from insoluble minerals or polymers may persist within the human body increasing the potential for harm. Nanoparticles that are soluble or digestible may pose less of a risk because the body is able to degrade the nanoparticle into its molecular components. Many natural digestible nanoparticles are already present in our foods and widespread consumption has shown them to be innocuous. An example is milk, which is made up of whey proteins, which are about 3-6 nanometers in size, and casein, which is an assembly of proteins and minerals about 200 nanometers in size. The nanostructure of milk efficiently delivers nutrients and minerals to our bodies.

The disposal of nanoparticles, and products containing nanoparticles, may result in the release of nanoparticles to the environment which could then further impact on human health following entry by various routes to the body. The release of nanoparticles embedded in solid matrices could occur if the products are sent to rubbish dumps where they are degraded by exposure to UV. Nanoparticles may be generated if materials are incinerated.

Thus far, international research on the toxicity of nanoparticles has been *ad hoc* in nature. Most experiments have been designed to study the effect of nanoparticles on cells *in vitro*, with a few studies in animals, mainly mice. There have been limited studies on humans. Further, results from experiments to study the effect of potential therapeutic molecules on cells are not always predictive for the effect observed in animals, and it is likely that results from toxicity studies of nanoparticles on cells will not always be predictive of toxicity to animals and humans.

Most toxicity studies measure exposure to nanoparticles over short times. Longer-running experiments are needed to assess the impact of chronic exposure to nanomaterials.

There are large gaps in knowledge for what is required to define regulations for safe work practices.

Potential nanotoxicity and the environment

There are many potential nanotechnology applications that could benefit the environment. These include:

- Nanoparticulate formulated fertilizers and pesticides that allow targeted delivery
- Nanoparticulate iron based tools for groundwater remediation
- More efficient combustion catalysts that reduce volatile contaminant emissions
- Nanomaterial based wastewater treatment systems
- Development of nanotechnology based sensors for more effective environmental monitoring

In order to clearly understand the impact of nanoparticles on the environment it is necessary to (i) characterise the toxicity of such materials to a wide range of organisms and (ii) characterise the concentrations of manufactured nanomaterials in environmental samples and understand the physicochemical transformations that affect their bioavailability and toxicity. Most environmental studies to date have focussed on aquatic systems, with some very limited attention to the fate of nanoparticles in terrestrial environments.

Information on the ecotoxicity of nanoparticles is limited but growing steadily. Earlier studies were confounded by methodological problems and are of limited use. Concerns arose about methodology used to obtain toxicity information. This has led to a better understanding of the need to develop appropriate toxicity testing protocols, namely:

- Toxicity studies require a thorough understanding of the physics and chemistry of nanoparticles in aqueous solutions:
    - particle size/morphology
    - solubility or other chemical transformations (e.g. oxidation)
    - photochemistry (production of reactive species)
- Use of environmentally-relevant forms of nanoparticles and concentrations
- Importance of proper controls – dissolved and bulk material plus solvent/solubilising agent control
- Controls must also assess the effects of solubilising agents if used (e.g. solvents)
- Characterisation of initial nanoparticle form/concentration and transformations over the time course of the toxicity test (e.g. dissolution, aggregation)

Long-term toxicity studies are needed to address the issue of whether nanoparticles are cumulative poisons that may accumulate in target organs over the lifetime of the organism.

The analysis of manufactured nanoparticles in environmental samples such as water, soils, sediments, and in organisms, is currently in its infancy. There are currently no standardised methods for detecting nanoparticles in such complicated matrices. The use of stable and radioactive isotope tracer-labelled nanoparticles is currently the best approach for understanding nanoparticle transport and fate in model studies, as tagging the surfaces with other markers may alter their properties.

Given the challenges in the area of environmental analysis, predictive modelling of fate and transport of nanoparticles is a high priority.

CSIRO research activities: the Niche Manufacturing Flagship – Nanosafety research theme

As indicated previously, CSIRO's Niche Manufacturing Flagship was formed in 2007 with the goal of providing transformational innovation for the Australian manufacturing industry by taking advantage of recent advances in nanotechnology. Integrated into the business plan of the Flagship is a Nanosafety research theme to ensure that research and product development is carried out in a safe and socially responsible way. The goal of the Nanosafety research theme is to assess and understand the impacts on human health and the environment of nanomaterials, and products containing them, which are used or developed in other Flagship projects. In addition, the Nanosafety theme aims to develop rapid and inexpensive bio-assays to monitor human exposure to nanomaterials in the workplace, and to determine the impact on ecosystems from exposure to these nanomaterials.

The Nanosafety theme has a comprehensive engagement strategy with national and international regulatory agencies through its direct involvement with the Australian Office of Nanotechnology's Health, Safety and Environmental Working Group for Manufactured Nanomaterials. Information from CSIRO's research on specific nanomaterials regarding their fate and transport in the laboratory, factory and environment, their dose-dependent toxicity, their mechanism of toxicity, and the physical and/or chemical metrics responsible for toxicity, will be transferred through this link to assist in the work of the appropriate regulatory agencies.

The Nanosafety theme in the Niche Manufacturing Flagship starts its research on the toxicity of any nanoparticle with a life-cycle analysis of that nanoparticle destined for use in a specific product, for example the use of zinc oxide nanoparticles in sunscreens. The life-cycle analysis determines the areas of highest risk associated with that nanoparticle, and research projects are focussed on the high-risk areas. Risks to both human health and the environment are considered.

The task to determine safe work practices, dose-related toxicity for humans, and impact on ecosystems for a specific nanoparticle is immense, and so the Nanosafety Theme will initially focus on nanoparticles of interest to the Niche Manufacturing Flagship. Currently, the focus is on metal oxides, particularly zinc oxide, and on special multi-walled carbon nanotubes that have properties suitable for spinning into yarns, and which are being developed in another Flagship activity. Although work will be focused on these two nanomaterials, the capabilities and bioassays developed will be applicable to subsequent investigations of other nanoparticles, and will be transferable to other laboratories.

The life-cycle analyses have resulted in proposed projects studying exposure to carbon nanotubes and zinc oxide nanoparticles in the workplace, and exposure to zinc oxide nanoparticles from use of sunscreens. Research on the environmental risks of nanotechnology will initially concentrate on the environmental fate and toxicity of carbon nanomaterials and metal oxides (eg zinc oxide) in soil and water.

Prior to the establishment of the Niche Manufacturing Flagship, studies on the environmental fate of nanoparticles have been conducted within CSIRO's Centre for Environmental Contaminants Research (CECR) since early 2006. CECR research focussed mainly on (1) understanding the fate of metal oxide (particularly zinc oxide) and silver nanoparticles in aquatic systems and characterising their toxicity to a unicellular algal species (as a model test organism), and (2) developing analytical techniques (field flow fractionation) for the detection of manufactured nanoparticles in soil samples. Publications arising from these studies are attached at the end of this document The CECR group are also currently preparing one book chapter on the ecotoxicity of nanoparticles in the environment (Apte, Rogers and Batley) and contributing to one critical review on nanoparticles in the environment (both to be published later this year)[7,8]. Drafts of

[7] Apte, S.C., Rogers, N.J. and Batley, G.E. (2008) Ecotoxicology of manufactured nanomaterials. Chapter 7 in Environmental and human health effects of nanoparticles. Publisher: Wiley-Blackwell. Manuscript in preparation.

both of these contributions can be made available to the NSW government in April 2008. CECR have recently been commissioned by the Federal Government's Department of Environment, Water, Heritage and Art to conduct a desktop research project into the fate of manufactured nanomaterials in the Australian environment. This will be completed by June 2008. In July 2008, all of this research will be transferred to the Nanosafety theme of the Niche Manufacturing Flagship.

The impacts to be realised by the Nanosafety theme are as follows:

- Robust measurement and characterisation methods developed for nanomaterials and their physico-chemical properties by 2010
- Ecotoxicological information on the toxicity of metal oxide nanoparticles and carbon nanotubes in soil and water matrices generated and disseminated by 2010
- Generic environmental assessment protocols for nanomaterials developed by 2012
- Inexpensive and high-throughput bio-assays developed to monitor and assess the effects of human exposure to nanoparticles by 2013
- Models developed to evaluate and predict toxicity and biological response based on physico-chemical properties by 2018

Concluding remarks

There is some information available on nanoparticle toxicity to cells, and in some cases to animals, but there have been very few studies on humans. The most toxic nanomaterials are likely to be carbon nanotubes, which have the capacity to form aggregates that mimic the shape of asbestos fibres. Long-term studies to assess chronic exposure to nanoparticles in the workplace and to nanoparticles in products are required. The risk of human exposure to nanomaterials must be kept in context, for example by comparing the measured level of nanoparticle toxicity with exposure to particulates in exhaust fumes.

There are many gaps in our knowledge of the environmental fate and toxicity of nanoparticles. There is growing evidence of nanoparticle toxicity to aquatic organisms but more work is needed. Data on toxicity to higher aquatic organisms are lacking. Data on toxicity to terrestrial organisms are very limited.

Individual scientists mostly do not have the expertise to single-handedly research the safety aspects of nanoparticles. The breadth of expertise required is too large. For designing the most relevant experiments and to achieve timely impact, multi-disciplinary teams are needed with expertise covering materials science, chemistry, physics, molecular, cell and animal biology, metrology, human and environmental toxicology, computer modelling, and knowledge of occupational health and safety issues. There needs to be excellent communication between team members, and a comprehensive understanding of the difficulties involved in handling nanomaterials, in measuring their properties, and in the use of appropriate experimental controls.

High-level coordination of these types of multi-disciplinary research activities is necessary to avoid the continuation of *ad hoc* data collection, and to aid international linking of coordinated research groups. Substantial funding is necessary to enable the integration of appropriate nanosafety research programs within commercially focussed projects. In the long term, products that have been researched and developed with safety in mind are the ones most likely to be accepted by consumers. The Flagship is proving to be a unique and ideal vehicle in meeting these demands.

Recent CSIRO publications

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[8] Klaine, S., Alvarez, P.J., Batley, G,E, Lead, J.R., Fernandes, T., Handy R., Weeks, J. (2008) Critical review of Nanomaterials in the Environment. Environmental toxicology and Chemistry, manuscript in preparation.

(documents attached)

Franklin, N. M., Rogers, N. J., Apte, S. C., Batley, G. E., Gadd, G. E., Casey, P. S., (2007) Comparative Toxicity of Nanoparticulate ZnO, Bulk ZnO, and $ZnCl_2$ to a Freshwater Microalga (*Pseudokirchneriella subcapitata*): the Importance of Particle Solubility. Environmental Science and Technology, 41, 8484-8490.

Rogers N.J, Franklin N.M., Apte S.C., Batley G.E. (2007). The importance of physical and chemical characterization in nanoparticle toxicity studies. *Integrated Environmental Assessment and Management* 3:303-304.

c. The appropriateness of the current regulatory frameworks in operation for the management of nanomaterials over their life-cycle

CSIRO's response to this question considers the adequacy of current occupational health and safety legislation in the context of working with nanomaterials. Nanoparticles vary greatly across the entire chemical spectra and even within certain compounds of varying size and structure. The toxicity of a multi-walled carbon nanotube will not be the same as a particle of titanium dioxide. The toxicity of coarse or large particles of zinc oxide of 100 microns is presumably not the same as zinc oxide particles of 20 nm. The toxicity of rutile titanium dioxide is different to anatase titanium dioxide. It would therefore seem inappropriate to regulate simply on size alone.

CSIRO is a Commonwealth employer and as such must comply with Commonwealth laws. CSIRO do have interactions with State based organisations and as such, occasionally need to deal with two sets of regulations. However, this has not been the case in this instance. Fortunately Hazardous Substances and Dangerous Goods Regulations in all States and Territories and the Commonwealth follow the National Model Regulations.

Safe Handling and Disposal of Nanomaterials

A recent publication from the British Standards Institute (31 Dec 2007) entitled *BSI PD 6699 Nanotechnologies – Part 2: Guide to safe handling and disposal of manufactured nanomaterials* outlines a sound approach to the management of hazards (potential or otherwise) pertaining to nanotechnologies and

BSI PD 6699 describes five different types of nanomaterials:

1. Fullerenes
2. Carbon Nanotubes
3. Nanowires
4. Quantum Dots
5. Other Nanoparticles including; metals, oxides, ceramics and organic materials

There is not a complete understanding of the toxicity of various nanoparticles at present and so it is difficult to determination about whether a substance is toxic or not. Therefore this is one important aspect of nanotechnology that we are currently researching. A prudent approach is to consider all nanomaterials as potentially hazardous (def. used by CSIRO is set out below) until research provides definitive data. Any potential exposure should be limited to levels that are as low as is reasonably practical to achieve. This is known as the 'ALARP' principle.

The definition of a Hazardous Substance as used by CSIRO is a substance that is described in the 'Hazardous Substances Information System'. These substances are classified in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004] *3rd Edition* and/or have National Exposure Standards declared under the NOHSC *Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment*

[NOHSC:1003(1995)]. The Approved Criteria sets out a standard for determining if a substance is hazardous or not. Currently it is the duty of a supplier or manufacturer to make this determination and to alert the authorities if the substance is hazardous if it is not already on the list. Suppliers also have a duty to supply a Material Safety Data Sheet (MSDS) that outlines the risks of using, handling and storing substances including emergency information and information regarding environmental considerations.

Fire and Explosion Risks

Finely divided particles can form explosive dust clouds. This can occur with many organic materials, metals and non-metallic particles. Smaller particles have a greater surface area and can result in a more violent explosion. Nanoparticles should be stored in accordance with the storage requirements of other finely divided materials in order to reduce the potential of an explosive cloud forming and igniting.

BSI PD 6699 discusses a starting point for assessing the hazards associated with the various types of nanomaterials, the types of nanomaterials are:

- ***Fibrous*** a high-aspect ratio insoluble nanomaterial;
- ***CMAR*** any nanomaterial which is already classified in its larger particle form as carcinogenetic, mutagenic, asthmagenic or a reproductive toxin;
- ***Insoluble*** insoluble or poorly soluble nanomaterials not in the fibrous or CMAR category;
- ***Soluble*** nanomaterials not in fibrous or CMAR category.

Using these four categories, we can begin to assess the risks of using and handling nanomaterials in the workplace environment and applying the current Commonwealth Regulations for both Hazardous Substances and Dangerous Goods in order to ensure that employees, other people and property are safe.

Hazardous Substance Regulations are designed to protect workers from chronic health and safety issues e.g. Glutaraldehyde is a sanitising substance which is a known sensitiser. Immediate risks fall more under the category of Dangerous Goods. For example, if the risk is that the substance is highly flammable, explosive, highly toxic (eg Hydrogen Cyanide) or highly acidic (eg Hydrochloric acid) the substance can cause acute injuries or pose an immediate risk to health and safety etc., it is classified as a Dangerous Goods and is regulated under the Dangerous Goods Regulations. It is possible that some nanomaterials will fall under the criteria assigned to hazardous substances and some will fall under the criteria assigned to dangerous goods via the Australian Dangerous Goods Code. It is also conceivable that some nanomaterials will be both hazardous substances and dangerous goods.

The regulations in their current form work well for substances where the toxicity of the substance is consistent across varying characteristics of the substance; however we know that this is not the case for substances approaching the nanoscale. The challenge may well be in determining at which point the substance changes from a non-toxic substance to a point somewhere on a scale between ‘sensitiser’ to ‘very toxic.’ To comply with the Hazardous Substance Regulations, suppliers and manufacturers may have to test a variety of different particles with varying sizes, shapes, surface areas, etc to make the determination against the Approved Criteria. The place to start would be determining the toxicity of the specific products that a manufacturer supplies i.e. they do not have to have to provide for every different combination or permutation of size, shape, etc. of any one particular compound or element.

The next most important step in the Hazardous Substance Regulations is supplying a Material Safety Data Sheet (MSDS). The MSDS contains important safety information about the use, handling and storage of the product, including required Personal Protective Equipment (PPE) and emergency response information. There are Codes for the preparation of MSDS that manufacturers of Hazardous Substances must follow. It is not uncommon at present to be given an MSDS for a substance in the bulk or coarse form for a substance supplied at the nanoscale. The manufacturer in this case is making the assumption that the safety information pertaining to the coarse form of the product is the same as the nano form and we know that this is not necessarily correct. If it can be shown that the safety information is different for the two forms then it could be argued that the manufacturer is in breach of the Hazardous Substance Regulations. The regulations make an allowance for using substances when an MSDS is not available; in this case the HSE regime must be based on a risk assessment of known information and stipulate other precautions to be followed. This could apply to substances at the nanoscale as part of the OHS management practice which aims at reducing the risk to levels as low as is reasonably practicable (ALARP).

The Hazardous Substances Regulations include provisions to ensure that hazardous substances are labelled. The label must include information about the hazard, the supplier, ingredients and risk and safety phrases consistent with the National Code for labelling. Although the labelling of nano products is a contentious issue, a label should be placed on containers of nanoparticles determined to be hazardous under the approved criteria – this would not necessarily extend to consumer products where the hazardous material is a minor component of the final product. The regulations also cover training, risk control, atmospheric monitoring and health surveillance according to the outcomes of a mandatory risk assessment. These aspects form part of a comprehensive health and safety management system and are appropriate for working with nanomaterials.

The Regulations are expanded to include special provisions for working with scheduled carcinogens and some specific substances such as asbestos and lead and certain other substances contained in the regulations. This would also apply to any substance at the nanoscale.

BSI PD 6699 makes suggestions regarding workplace exposure limits (WEL). These recommendations are based on the potential toxicity of the four nanoparticle characteristics outlined above and draw parallels between similarly categorised substances that currently have a WEL. BSI PD 6699 suggests that the WEL for Fibrous nanoparticles is the same as the WEL for asbestos; that the WEL for CMAR particles is 0.1 x the WEL of the material to allow for a safety margin due to potential increased bioactivity of the nanoparticle. Insoluble particles have a suggested WEL of 0.066 of the material WEL and soluble nanoparticles have a WEL of 0.5 x the WEL of the material.

Managing Health and Safety

Health and safety risks should be identified based on known risks associated with the material and the characterisation of the particle in terms of size, shape, surface area, charge, solubility, chemistry, quantities used, frequency and potential routes of exposure. These risks can then be assessed using known information based on the four particle categories.

The control of health and safety aspects of working with nanomaterials should follow the 'Hierarchy of Control' set out in NATIONAL CODE OF PRACTICE FOR THE CONTROL OF WORKPLACE HAZARDOUS SUBSTANCES [NOHSC:2007(1994)]:

- Eliminate
- Substitute
- Isolate
- Engineering Controls
- Safe Work Practices
- Personal Protective Equipment

Personal Protective Equipment

Personal protection is a last option or a supplemental option to help support all of the other methods of exposure control.

- ***Protection from inhalation exposure*.** There is some recent evidence that fibrous filters (HEPA) are more efficient for nanoparticles compared with larger particles. Fibrous filters appear to be least effective for particles around 300nm and become more efficient with both larger and smaller particles. (See Nanosafe Efficiency of fibrous filters and personal protective equipments against nanoparticles January 2008 DR-325/326-200801-1). A high efficiency P3 respirator meeting the relevant Australian Standard should provide adequate protection from inhalation exposure. All users must be trained to ensure that the face-fit and application of the filter is correct and that the filter system is properly maintained.

- ***Protection from dermal exposure*.** Non woven materials such as Tyvek and Tychem seem much more efficient (air tight) against nanoparticle penetration. The risk assessment might indicate a need for protective gloves, protection goggles with side protection and protective clothing. Nanoparticles may penetrate commercially available gloves and at least two layers of gloves should be used.

Disposal of Nanomaterials

CSIRO is in the process of implementing a policy where all nanomaterial wastes, including incidental wastes such as cleaning cloths and disposable laboratory garments are double bagged and stored in fume cupboards before being transferred to specially marked and colour coded (burgundy) waste receptacles for disposal via appropriately licensed waste management contractors. Nanomaterials contaminated with biological materials will be treated in the same way that current biological wastes are managed.

Conclusion

CSIRO is not aware of any scientific evidence that the current occupational health and safety legislative framework; in particular the current Hazardous Substance and Dangerous Goods Regulations, are not sufficiently robust enough to cover the health and safety aspects of working with nanomaterials in the workplace environment. There are however, still significant gaps in our knowledge regarding the health and safety aspects of nanomaterials that makes implementation of the legislative framework problematic. CSIRO continues to work closely with the appropriate regulatory agencies and share it relevant research with them to address this problem.

d. The adequacy of existing education and skills development opportunities related to nanotechnology

In considering this issue it is important to recognise that nanotechnology in effect encompasses a very broad range of disciplines and technologies. Most practitioners in the area do not have direct qualifications in ‘nanotechnology’ and experts across a very broad range of fields can contribute to the development of nanotechnologies. A broad understanding of the underlying concepts and an ability to translate these into new ideas, opportunities and outcomes while working across disciplines is often more valuable than specialised qualifications. Creative people with expertise in physics, chemistry, medicine, biology, materials science, environmental science and many other disciplines can all contribute to different areas of nanotechnology. As a result, the needs for nanotechnology education are met by having a strong and effective general science and engineering education system. The current skills base underlying nanotechnology is illustrated by CSIRO’s staffing experiences with relation to nanotechnology based positions. During the period from 01 July 2006 to 28 February 2008, CSIRO advertised 9 positions that specifically mentioned nanotechnology in the advertisement title for which 213 applications were received.

As an example of the range of disciplines that can contribute to particular nanotechnologies, it is instructive to consider CSIRO's work in exploring applications of carbon nanotubes. These have the potential to create textiles that can conduct heat and electricity as well as having many other applications. In addition to drawing upon expertise in physical organic chemistry and atomic force microscopy, this work also draws upon CSIRO's experience and expertise in areas such as fibre physics and yarn structure and properties – areas that helped support the more traditional textile industries. In other words, the potential development of new, innovative and very high-technology products is receiving support from expertise developed to support what many would consider a relatively low technology sector. This provides an excellent demonstration of how it is possible to transfer existing skills base to new problems and may help explain why CSIRO has had no problems in finding the skilled scientists it needs for its nanotechnology research.

CSIRO itself contributes to nanotechnology skills development through providing post-doctoral positions and has the ability to provide PhD training in cooperation with universities. At present we have 294 post-doctoral researchers, 582 supervised- and 276 sponsored PHD students.

e. the adequacy of the National Nanotechnology Strategy in the New South Wales context

No Comment

f. the level of community understanding of nanotechnology and options to improve public awareness of nanotechnology issues.

Public input and deliberation into emerging sciences, like nanotechnology, is becoming a global norm and there is an abundance of examples of public engagement from around the world (Appendix 3).

Credible sources to inform the public about developments in science and technology are vital. CSIRO is widely regarded as a source of credible information, (it has been the leading message about CSIRO in CARMA media analysis reports for many years) and in recent public fora, organised by the Australian Office of Nanotechnology, a CSIRO scientist has spoken at each.

CSIRO already has some information about its work on nanotechnology on its website, (http://www.csiro.au/science/Nanomaterials.html) and plans to post its position statement on nanotechnology (Appendix 1) and other information of interest to the public in due course. It is currently discussing a number of models of community engagement on the issue.

Former community engagement

In 2004 CSIRO conducted two small-scale social research projects to facilitate public deliberation on nanotechnology. The first workshop, held in Bendigo, brought together 22 people consisting of a range of stakeholders living and working in and near Bendigo (a regional city in Victoria), government agency representatives, and CSIRO scientists and social scientists. Together, participants began to map some of the significant considerations pertinent to decision-making on nanotechnology research proposals and programs. (See Mee et al, 2004 for a full discussion of the outcomes of the Bendigo workshop)[9].

Typical issues raised during the Bendigo workshop related to the question of who would benefit from the technology, concerns about the purposes for which nanotechnologies are being

[9] Mee, W., Lovel, R., Solomon, F., Kearns, A., Cameron, F., and Turney, T. (2004) *The Bendigo Workshop*. Melbourne: CSIRO Minerals DMR 2561.

developed, as well as their possible effects. For example, participants questioned whether nanotechnologies would be developed solely for consumption purposes (such as 'self-cleaning' fabrics) or whether they would address social and environmental concerns, such as more sustainable forms of energy. One outcome of the workshop was a checklist of community issues that could be used by nanotechnologists for research planning[9].

Participants also quizzed the organizers as to the purpose of the workshop: was CSIRO genuinely interested in what the participants had to say or were they doing market/push research? They openly stated their expectation that research institutions like CSIRO address potential conflicts between public and commercial interests in their research and reporting, and articulated a desire that CSIRO's research activities reflect perceived public needs.

The second public engagement project, held in Melbourne, took the form of a 17-member Citizens' Panel. Building on the outcomes of the Bendigo workshop, activities within the Melbourne Citizens' Panel were structured to consider five key contexts of nanotechnology development – commercialization, environmental impacts, social impacts, regulation and ethics. (See Katz et al, 2005 for a full discussion of the Melbourne Citizens' Panel)[10]. The participants consisted of an expert from each of these contexts, and members of the public, including people active in non-government organizations eg Greenpeace/ Genethics, and media representatives.

The Melbourne Citizens' Panel highlighted the following issues as important:

- accountability and transparency in nanotechnology research and development;
- the health and safety of those working in the production of nanoparticles;
- the health of the natural environment;
- the potential for growth of industrial applications of nanotechnology;
- that such developments should be used to decouple resource consumption from economic growth;
- the development of an Australian nanotechnology industry that would allow local industry and smaller players to survive and develop rather than see the industry dominated by large multinational corporations;
- that nanotechnologies <u>not</u> be developed for the purposes of war;
- concern re the ownership and control of the new technologies;
- the adequacy of current international regulations for nanomaterials;
- the ramifications of intellectual property laws for Australia and for developing countries;
- the social divides that nanotechnologies might generate or exacerbate; and
- the public to have opportunities to engage with the development of the technologies before they became too entrenched in everyday life.

As a result of the CSIRO social research on nanotechnology in 2004 CSIRO was invited to present the findings at several national and international public and policy domains (e.g. Katz 2006; Mee et al, 2006; National Nanotechnology Task Force, 2006; Solomon & Katz 2006; Solomon 2005; PMSEIC, 2005)[11,12,13,14,15,16].

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[10] Katz, E., Solomon, F., Mee, W. and R. Lovel (2005) *Citizens Panel on Nanotechnology: Report to Participants.* CSIRO Minerals DMR 2673.

[11] Katz, E. (2006) Panel member, "Should Australia have a process for the social and ethical evaluation of new technologies?" Science meets Parliament, February 2006. - Federation of Australian Science and Technology (FASTS).

[12] Mee, W., Katz, E., Solomon, F. and Lovel, R. (2006) "*Social perspectives on nanotechnology research and development: a view from Australia*," paper given at the PATH (Participatory Approaches in Science and Technology) Conference, presented by the Macauley Institute. Edinburgh, June 2006.

Analysis of the research findings included the question of rationales for public engagement in nanotechnology R&D. Two different perspectives emerged – a nanoscientist one, and a social scientist one, both reflecting the expertise in their fields, and both from CSIRO.

The starting point of the CSIRO nanoscientist was a focus on the benefits of nanotechnology, using public engagement as an educative opportunity to reassure participants that risks are minimal. While the revolutionary potential of nanotechnology was highlighted, at the same time natural corollaries were emphasized e.g. the water-capturing surface of the fused overwings (elytra) of the desert beetle is an example of nanotechnology in Nature.

The starting point of the CSIRO social scientist was that past experience has shown how the very success of a particular technology can bring problems in its wake. In particular, the effects of a particular technology are not the same for everyone, e.g. while computer technologies are now part of everyday life for many people, their use raises issues such as employment, privacy, and a new societal information divide.

These two "starting points" lead to different evaluations of nanotechnology research and development and highlight the differing rationales that shape and influence public engagement: the first focuses on the technology itself and the possible effects as a side issue, whereas the second is a precautionary approach that focuses primarily on the possible effects upon people, communities, society and institutions. The two perspectives are not mutually exclusive and do suggest that for both approaches public engagement in nanotechnology research and development could be helpful in encouraging interest in and discussion about this emergent field.

Working with the Australian Office of Nanotechnology

The Australian Office of Nanotechnology is charged with implementing the Australian National Nanotechnology Strategy announced by the former Minister for Industry, Tourism and Resources in October 2007. One key initiative in the Strategy is a Public Awareness and Engagement program. As part of this program, a series of public fora have been planned for major cities in Australia to raise public awareness of nanotechnology. The format adopted has three people speaking about nanotechnology, followed by questions and comments from the audience. CSIRO has participated in the three fora held so far, in November 2007 in Darwin and Brisbane, and in February 2008 in Melbourne at the ICONN 08 Conference. A CSIRO scientist will also be a panel member for the forum scheduled for Sydney in April 2008.

Responses from audiences at these public fora have been substantially different in each city. The small Darwin audience had a reasonably good understanding of nanotechnology, and participated in a self-initiated ideas session with panel members following the formal proceedings. The small Brisbane audience was interested to find out how nanotechnology could be of benefit, particularly in medical applications; a representative from a non-government organisation who tried to dominate the discussion was not well accepted by this audience. The questions and comments from the Melbourne audience were wide ranging, and covered the potential benefits of nanotechnology, the trivial nature of many currently available

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[13] National Nanotechnology Taskforce (2006) "*Options for a National Nanotechnology Strategy*" Report to the Minister Industry, Tourism and Resources, June 2006.

[14] Solomon, F. and Katz, E. (2006) "*Nanotechnology and Society: Experiences of Public Dialogue at CSIRO*" International Conference on Nanoscience and Nanotechnology (ICONN06), Brisbane, 3-7 July.

[15] Solomon, F. (2005) "*Engaging Stakeholders in Dialogue*," International Conference on Engaging Communities, Brisbane, Australia.

[16] PMSEIC (2005) "Nanotechnology: Enabling Technologies for Australian Innovative Industries" March 2005.

nanotechnology-based products, potential adverse impacts on health, ethical considerations, and impact on societies; the views of a non-government organisation were welcomed at this forum.

Speakers in Darwin:

- Associate Professor Joe Shapter, Flinders University
- Dr Maxine McCall, CSIRO
- Professor Paul Mulvaney, University of Melbourne

Speakers in Brisbane:

- Associate Professor Joe Shapter, Flinders University
- Dr Maxine McCall, CSIRO
- Professor Matt Trau, University of Queensland

Speakers in Melbourne:

- Dr Andrew Maynard, Woodrow Wilson International Centre for Scholars, USA
- Dr Dong Yang Wu, CSIRO
- Professor John Weckert, Charles Sturt University

The Australian Office of Nanotechnology has conducted two surveys of 1000 people in 2005 and 2007 to assess their attitudes to nanotechnology. Only 2% volunteered nanotechnology when asked to name a recent development in science and technology, but when prompted in the 2007 survey, 63% had heard of nanotechnology, compared to 51% in 2005. However, their knowledge of nanotechnology was very limited with only 5% claiming detailed understanding.

In spite of this there was cautious optimism about its potential, with over eight in ten people in both 2005 and 2007 (81% and 83% respectively) being “hopeful” and “excited” by the potential implications of nanotechnology. Around one in ten people were concerned or alarmed by nanotechnology (14%), however caution is expressed about nanotechnology applications in food products (and this caution has continued from 2005.)

http://www.innovation.gov.au/Documents/MARSreport20070801094555.pdf

Attachment 5: Examples of public input to nanotechnology R&D.

CSIRO’s Position Statement on Nanotechnology

Objectives

To help Australia capture the benefits of nanotechnology in a safe and socially responsible way in which appropriate risk management strategies are in place for research, manufacturing, consumer use and environmental impact.

To ensure that government decisions and community perceptions of nanotechnology result from the careful and rational consideration of the available evidence.

To ensure that all CSIRO communications about nanotechnology have a sound base on peer-reviewed research and are open about any potential or perceived conflicts of interest.

To help CSIRO become the most trusted source of information on nanotechnology.

Preamble

Australia cannot ignore nanotechnology. Global investment is already high and its results will inevitably affect Australia, both directly and indirectly. Moreover, nanotechnology products are already in the market.

There is no question that nanotechnology can offer a wide range of economic, social and environmental benefits. For example, it has the potential to provide new, significantly improved ways to supply safe water, reliable energy and health care. Innovations arising from nanotechnology will create new technologies and transform current technologies in areas such as manufacturing, electronics and communications.

However, along with its potential benefits, the use of nanotechnology raises issues about possible health, safety and environmental impacts. At a very small scale the properties of materials can change, sometimes in unexpected ways. These novel characteristics can generate exciting opportunities but at the same time raise concern that they might have unknown and adverse consequences on people and the environment.

Position

CSIRO:

- Believes that Australia needs a strong research base in nanotechnology to capture the very significant opportunities that the technology presents to improve Australia’s wellbeing while ensuring that we can identify, understand and appropriately manage any possible harmful consequences of nanotechnology.

- Will continue to perform research and participate in domestic and international research collaborations aimed at using nanotechnology in a socially responsible manner to improve Australia’s wellbeing and to provide technical solutions to domestic and global problems.

- Recognises and respects the public's interest in and concerns about nanotechnology and acknowledges the rights of the public to receive open and disinterested information on these topics and on the research that CSIRO is performing.

- Will publish the results of its nanotechnology research in scientific journals and prepare plain English publications for wider distribution as appropriate.

- Will give health and safety issues a high priority in its own research and set high internal safety standards that as a minimum comply with all relevant government legislation and guidelines and aim to achieve world best practice.

- Will ensure that its science planning processes explicitly require nanotechnology research proposals to consider potential health, safety and environmental issues relating to proposed research and its application; and that the proposals identify any actions that might be necessary to respond to the issues they identify.

- Will use a whole of life approach to assess the risks of products that it might consider developing through its research programs.

- Will continue to perform research to identify potential health, safety and environmental issues associated with CSIRO research involving nanoparticles or products that incorporate them, and to develop ways of eliminating or managing any risks that exist.

- Will work with other Australian government organisations (State and Federal) under the umbrella of Australia's National Nanotechnology Strategy to: provide balanced and factual information that will raise public awareness of the risks and benefits of nanotechnology; facilitate informed public debate about nanotechnology; seek to understand and respond to public concerns about nanotechnology; and ensure its scientists are aware of public concerns and take note of them in planning their research.

- Will support Australian and international bodies developing and implementing regulations and guidelines for nanotechnology research and the use of products created by or incorporating nanotechnology.

- Will make appropriate use of the domestic and global IP systems to ensure that Australia can capture the benefits of its publicly funded research

- Will ensure that CSIRO conducts research paid for by the private sector using the same rigorous standards and with an uncompromising commitment to safety both of our workforce and of the public.

Attachment 2

Nanotechnology Terminology Listing – January 2008

Commonly used terminology	Definitions for commonly used terminology according to accredited sources			
	ASTM Terminology for Nanotechnology E2456-06 (1)	PAS 71:2005 Vocabulary — Nanoparticles (2)	Australian Safety and Compensation Council (ASCC) (3)	Other Definitions as Noted
Nanoscience	n—the study of nanoscale materials, processes, phenomena, or devices.	The study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale.	The study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale.	The study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale. *The Royal Society 2004* The study of phenomena on the nanometer length scale. *ICON*
Nanotechnology	A term referring to a wide range of technologies that measure, manipulate, or incorporate materials and/or features with at least one dimension between approximately 1 and 100 nanometers (nm). Such applications exploit the properties, distinct from bulk/macroscopic systems, of nanoscale components.	Design, characterization, production and application of structures, devices and systems by controlling shape and size at the nanoscale.	…those purposefully manufacturing nanoparticles, nanostructures or nanoconstructs with at least one dimension less than 100 nm and with an expected end use in mind.	are the design, characterisation, production and application of structures, devices and systems by controlling shape and size at nanometre scale. (100nm – 0.2nm) *The Royal Society 2004* Nanotechnology is a collective term comprising a broad range of technologies for which the unifying themes are the control of matter on the atomic and molecular scale, approximately 1 to 100 nanometres, and the fabrication of structures, devices and systems with critical dimensions that lie within that size range. Nanotechnology is the engineering of functional systems at the molecular scale. (*Definition from the Centre for Responsible Nanotechnology* *http://www.crnano.org/whatis.htm* Nanotechnology is technology distinguished

				primarily by the scale at which it acts: one billionth of a metre, or one ten-thousandth the width of a human hair. Nano-scale activities are essentially those that involve individual atoms or molecules. Nanotechnology is therefore artificial manipulation of atomic or molecular objects or processes. In the simplest terms, nanotechnology is engineering at the atomic or molecular scale. *NanoVic (www.nanovic.com.au)* Nanotechnology is the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale. *National Nanotechnology Initiative (USA) http://www.nano.gov/html/facts/whatIsNano.html* Nanotechnology is the art and science of manipulating matter at the nanoscale (down to 1/100,000 the width of a human hair) to create new and unique materials and products. *Woodrow Wilson Centre Project on Emerging Nanotechnologies*http://www.nanotechproject.org/topics/nano101/ Applications developed using materials that have at least one critical dimension on the nanometer length scale. *ICON*

Nanomaterials		Material with one or more external dimensions, or an internal structure, on the nanoscale, which could exhibit novel characteristics compared to the same material without nanoscale features NOTE Novel characteristics might include increased strength, chemical reactivity or conductivity.	Contain only a few thousand or tens of thousands of atoms, rather than the millions or billions of atoms in particles of their bulk counterparts.	Have structured components with at least one dimension less than 100nm. Materials that have one dimension in the nanoscale (and are extended in the other two dimensions), are layers, such as a thin films or surface coatings. Some of the features on computer chips come in this category. Materials that are nanoscale in two dimensions (and extended in one dimension) include nanowires and nanotubes. Materials that are nanoscale in three dimensions are particles, for example precipitates, colloids and quantum dots (tiny particles of semiconductor materials). *The Royal Society 2004* A material that has engineered properties because of nanometer-scale structuring. *ICON* Materials composed of interacting nanoscale objects embedded in a solid matrix as in nanocomposites or bonded together in simple assemblies (random as in aggregates and agglomerates and periodic as in nanocrystals of fullerenes and carbon nanotubes) and complex assemblies (as in multifunctional nanoscale particles such as virosomes). Quantum dots, fullerenes and colloidal particles are confined to three dimensional nanometric domain. Nanotubes, nanowires, nanofibres and nanofibrils have two nanometric dimensions, while nanoscale surface coatings, thin films and layers have only one nanometric dimension.

				NANO TC 229 Draft (7)
Nanoparticles	n—in nanotechnology, a sub-classification of ultrafine particle with lengths in two or three dimensions greater than 0.001 micrometer (1 nanometer) and smaller than about 0.1 micrometer (100 nanometers) and which may or may not exhibit a size-related intensive property. DISCUSSION—This term is a subject of controversy regarding the size range and the presence of a size-related property. Current usage emphasizes size and not properties in the definition. The length scale may be a hydrodynamic diameter or a geometric length appropriate to the intended use of the nanoparticle	Particle with one or more dimensions at the nanoscale NOTE 1 Also referred to as nanoparticulate, although this term is more often used adjectivally. NOTE 2 Novel properties that differentiate nanoparticles from the bulk material are typically developed at a critical length scale of under 100 nm.	An engineered form of matter having at least one dimension (length, breadth or width) in the nanometre scale (<100 nm). Nanoparticles are considered distinct from UFPs (q.v.) for the purposes of this report only insomuch that UFPs are derived from "accidental" sources (human or natural).	Materials that are nanoscale in three dimensions are particles, for example precipitates, colloidsand quantum dots (tiny particles of semiconductor materials).*The Royal Society 2004* Nanoparticles are particles having a diameter between 1 and 100 nm. Nanoparticles may be suspended in a gas (as an nanoaerosol), suspended in a liquid (as a colloid or nano-hydrosol), or embedded in a matrix (as a nanocomposite). The precise definition of "particle diameter" depends on particle shape as well as how the diameter is measured. Particle morphologies may vary widely at the nanoscale. For instance, carbon fullerenes represent nanoparticles with identical dimensions in all directions (i.e., spherical), whereas single-walled carbon nanotubes (SWCNTs) typically form convoluted, fiber-like nanoparticles with a diameter below 100 nm. Many regular but nonspherical particle morphologies can be engineered at the nanoscale, including "flower" and "belt"-like structures. For examples of some nanoscale structures, see www.nanoscience.gatech.edu/zlwang/research.html *NIOSH (6)* A particle that is 1-100 nm in diameter. *ICON*
Nanoscale	adj—having one or more dimensions	Having one or more dimensions of the order of	1 to 100 billionths of a metre.	Between 1 and 100 nm *NANO TC 229 Draft*

	from approximately 1 to 100 nanometers (nm)	100 nm or less NOTE Also referred to as nanosize.		
Engineered Nanoparticle		Manufactured to have specific properties or a specific composition	Nanoparticles between 1 nm and 100 nm manufactured to have specific properties or composition.	Engineered nanoparticles are intentionally produced, whereas incidental nanoscale or ultrafine particles are byproducts of processes such as combustion and vaporization. Engineered nanoparticles are designed with very specific properties (including shape, size, surface properties, and chemistry), and collections of the particles in an aerosol, colloid, or powder will reflect these properties. Incidental nanoscale particles are generated in a relatively uncontrolled manner and are usually physically and chemically heterogeneous compared with engineered nanoparticles. *NIOSH* Objects enclosed by interfaces limiting their size to nanoscale (ie between 1 and 100 nm) in one (nanoslab), two (nanocylinder) or three (nanosphere) dimensions. *NANO TC 229 Draft*
Agglomerate	n—in nanotechnology, a group of particles held together by relatively weak forces (for example, Van der Waals or capillary), that may break apart into smaller particles upon	Group of particles held together by relatively weak forces, including van der Waals forces, electrostatic forces and surface tension	Group of particles held together by relatively weak forces, including van der Waals forces, electrostatic forces and surface tension.	An agglomerate is a group of particles held together by relatively weak forces, including van der Waals forces, electrostatic forces and surface tension [ISO 2006]. *NIOSH*

	processing, for example.			
Aggregate	n—in nanotechnology, a discrete group of particles in which the various individual components are not easily broken apart, such as in the case of primary particles that are strongly bonded together (for example, fused, sintered, or metallically bonded particles).	Heterogeneous particle in which the various components are not easily broken apart NOTE 1 Strongly bonded aggregates are called agglomerates.	Heterogeneous particle in which various components are not easily broken apart.	An aggregate is a heterogeneous particle in which the various components are held together by relatively strong forces, and thus not easily broken apart [ISO 2006]. *NIOSH*
Nanostructured	adj—containing physically or chemically distinguishable components, at least one of which is nanoscale in one or more dimensions. DISCUSSION—While many conventional nanomaterials are distinguished by physical or chemical characteristics, biological recognition may also be the basis for defining a nanostructure. Though this concept is formally contained by the word 'chemically' such a feature would lead to a distinctive type of	Having a structure at the nanoscale NOTE Agglomerates and aggregates of nanoparticles are examples of nanostructured particles.	Nanometre sized objects. Chemically,nanostructures are molecular assemblies of atoms numbering from 103 to 109 and of molecular weights of 104 to 1010 Daltons. Thus, they are chemically large supramolecules. To molecular biologists, nanostructures have the size of objects such as proteins or viruses and cellular organelles. Material scientists and electrical engineers view nanostructures as the current limit of nanofabrication.	

	nanostructured system.			
Ultrafine Particle	n—in nanotechnology, a particle ranging in size from approximately 0.1 micrometer (100 nanometers) to 0.001 micrometers (1 nanometer). DISCUSSION—The term is most often used to describe aerosol particles such as those found in welding fumes and combustion by-products. The length scale may be measured by a particle's geometric, aerodynamic, mobility, projected-area, or hydrodynamic dimension.		An anthropogenic or natural form of nanoparticle which is usually derived from combustion processes. UFPs are distinguished by large variations in size and composition.	The term "ultrafine particle" has traditionally been used by the aerosol research and occupational and environmental health communities to describe airborne particles typically smaller than 100 nm in diameter. Although no formal distinction exists between ultrafine particles and nanoparticles, the term "ultrafine" is frequently used in the context of nanometer-diameter particles that have not been intentionally produced but are the incidental products of processes involving combustion, welding, or diesel engines. Likewise, the term "nanoparticle" is frequently used with respect to particles demonstrating size-dependent physicochemical properties, particularly from a materials science perspective, although no formal definition exists. As a result, the two terms are sometimes used to differentiate between engineered (nanoparticle) and incidental (ultrafine) nanoscale particles. It is currently unclear whether the use of source-based definitions of nanoparticles and ultrafine particles is justified from a safety and health perspective. This is particularly the case where data on non-engineered, nanometer-diameter particles are of direct relevance to the impact of engineered

				particles. An attempt has been made in this document to follow the general convention of preferentially using the term “nanoparticle” in the context of intentionally-produced or engineered nanoscale particles and the term “ultrafine” in the context of incidentally-produced particles (e.g., combustion products). However, this does not necessarily imply specific differences in the properties of these particles as related to hazard assessment, measurement, or control of exposures, and this remains an active area of research. “Nanoparticle” and “ultrafine” are not rigid definitions. For example, since the term “ultrafine” has been in existence longer, some intentionally-produced particles with primary particle sizes in the nanosize range (e.g., TiO_2) are often called “ultrafine” in the literature. *NIOSH*

Attachment 3

Nanotechnology applications and opportunities in Australian Industry (updated from PMSEIC Report on Nanotechnology, 11 March 2005). Companies in NSW are in red.

Sector	Company	Current Applications	Future Opportunities (5-10 years) for the Sector
Mining & Agri-business	• Advanced Nanotechnology • Mindata • BHP Billiton; • Rio Tinto	• Alumina platelets • Separation • Bioextraction; applications for particles, oxide powders	• Bio-leaching processes; mining without surface disturbance • Processes to eliminate tailings and mine wastes • Food process control systems to eliminate contamination • New taste and nutritional delivery systems
Energy & Environment	• Very Small Particle Co. • Advanced Nanotechnology • Ceramic Fuel Cells • Cap-XX • Memcor • Nanoquest Pty Ltd • Pacific solar • Sustainable technology • Skycool	• Industrial catalysts • Fuel additives • Solid oxide fuel cells • Supercapacitors • Membrane separation • Water/air purification, fuel cells/hydrogen technologies	• Artificial photosynthesis; efficient energy from light • Paint-on solar cells • Membranes for bulk water desalination & purification • Particles to rapidly purify air • Silica membranes for H_2 separation, photocatalysis
Health & Medical	• AMBRI • Starpharma • Eiffel Technologies • pSivida • MiniFAB • Proteomic Systems • Vita medical • Sirtex	• Diagnostic markers • Dendrimer drug delivery • Particle engineering • Biosilicates for tissue • engineering • Lab-on-a-chip devices • Bio markers • Nanoparticle delivery of nuclear medicine	• Real-time ultra-sensitive diagnostic devices • Point-of-care medicine • Personal monitoring • In-vivo applications: new surfaces and materials to replace or repair tissues
Materials & Manufacturing	• Orica • Bottle Magic • Advanced Nanotechnology • Micronisers • Intellegent manufacturing • Quantum technologies	• Coatings; catalysts • Coatings for food protection • ZnO in paints, sunscreens • ZnO in sunscreens • Polymer Braille cells	• Advanced sensory and control processes for manufacturing systems • Textiles with electronic and new mechanical properties

			• High-performance structural materials • New abrasives, lubricants • Intelligent packaging
Electronics & ICT	• Peregrine Semiconductors • Wriota • Quantum Precision Instruments • Advanced Display Technology • Qucor • Pro-M technologies • Canon/Cisra • Fujitsu • Bluglas	• Semiconductors • Memory applications • Positioning devices • Flexible displays • Atom-scale • Nanoelectronics • Device manufacturing	• Organic computers; • integration of IT and • biological systems • Parallel computing capacity • Computing and telecommunications systems • Energy-conversion and lighting systems with greater efficiency • Quantum Computer
Automotive and Aerospace	• Boeing	• Aerospace and network enabled systems	• Scratch resistant, self repairing vehicles • Thermoelectric airconditioning • Zero emission transport
Security and Defence			• Gas sensing • superlattice-based structures for infrared detectors; • resonant-cavity enhanced structures for tunable infrared detectors; • quantum effects and transport properties of two-dimensional electron gas; • photonic bandgap structures for wide bandwidth improved mirrors • Invisibility cloak
Scientific Instruments	• Warsaw Scientific • Carl Zeiss • ATA Scientific • SMR Scientific	• Nanometrology	• Quantum metrology • Nanoparticle NMR
Cosmetics	• L'Oreal	• "Age defying" creams	•
Sporting equipment		• Carbon nanotube golf clubs	• Non-stain cricket balls
Clothing			• Self cleaning • Improved performance of protective clothing • Embedded sensors
Building and Built	• Lehman Pacific	• Nanoparticle	• Energy efficient

Environment	Solar • Nanotec • V-Kool Holdings • Optically active glass • Pilkingtons	coatings for metal roofs • Self cleaning windows and surfaces • Nano particle embedded coatings for windows	house • Cold lighting systems • Low emission house
Consulting and Training	• Ecosteps • Future Materials • N-able nanotechnology • Ashwyn Innovation		• Nanosafety

State based nanotechnology interests across Australia (from www.anbf.com.au).

State	Nanotechnology Sector
Queensland	Bioengineering
	Particle manufacturing
	Polymer development
	Energy technologies
	Australian Institute for Bioengineering and Nanotechnology
Victoria	Manufacturing hub
	Biotechnology
	Materials manufacturing
	Drug design
	7 Universities and the Synchrotron
South Australia	Biotechnology
	Minerals processing
	Solar cells
	The Wark Institute
	Flinders University
Western Australia Nanoparticles	Biosilicates
	Magnetic materials
	UWA
Tasmania	Australian Innovation Research Centre
	Analytical Chemistry
	Intelligent Island program
	Tasmanian Electronic Commerce Centre
ACT	Photonics and solar cells
	ANU, ARCNN
Northern Territory	Centre for Appropriate Technologies
	Charles Darwin University

Examples of public input to nanotechnology R&D.

Project title/ institution/author /date	Country	Type of public engagement	Some selected findings
Citizens' Attitudes Towards Nanotechnology EUROPTA Project 1988-1999 Danish Board of Technology	Several countries in Europe	2 international workshops and 16 case studies	- The EUROPTA project "Participatory Methods in Technology Assessment and Technology Decision-Making" is a comprehensive look at participatory technology assessment (PTA) - While not specifically on nanotechnology it has been influential in early forms of public engagement around technologies. http://www.tekno.dk/subpage.php3?article=345&language=uk&category=11&toppic=kategori11
Wising Up: The public and new technologies CSEC Lancaster University: Grove-White, Macnaghten &Wynne 2000	UK	Interviews with 'information providers' and discussions with 'lay' people (p.6)	- Found that most people rely on 'trusted others' when making decisions about new technologies like nanotechnology - There is an urgent need for industry and government to initiate new patterns of interactive understanding between themselves and people at large, concerning the potential social implications of new technologies.
Nanotechnology Revolutionary Opportunities and Societal Implications Boubour, University of Denmark in Roco and Tomellini (eds) 2002	Europ'n Commissi on (EC)	3rd JOINT EC-NSF Workshop on Nanotechnology. Data on public perceptions from survey by French Ministry of Education, January 2001	- Early stage of nanotechnology development means data on public understanding of nanotechnology not yet available - Comparison of levels of public trust and skepticism between Germany, France, UK and USA. - Recommended a multidisciplinary 'think-tank' in nanotechnology
Bringing Visibility To the Invisible: Towards a Social Understanding of Nanotechnology Gotteborg University Fogelberg and Glimell, 2003	Sweden	Compilation of a number of exploratory papers	- An influential and wide-ranging report into the social understandings of nanotechnology field - Highlighted constructive technology assessment (CTA) use in the National Nanotechnology Initiative (USA) - Emphasized the interdisciplinary and open-ended hybrid character of this emerging field
Future Technologies, Today's Choices: Nanotechnology, Artificial Intelligence and Robotics; A technical, political and institutional map of emerging technologies Greenpeace: Arnall	UK	Commissioning of report prompted by a series of four debates in April and May 2002 on the impacts of new technologies entitled Science, Technology and the Future	- Debates found low levels of understanding and nothing on potential impacts. - Nanotechnology R&D seen as an opportunity to rectify gaps in R&D approaches concerning social considerations, possible impacts and public concerns.

2003			
The Big Down: From Genomics to Atoms Atomtech: Technologies Converging at the Nano-scale ETC Group January 2003	Canada	Review of reports and texts of those opposed to nanotechnology research	- Found a lack of knowledge about risks of nano-particles - Impact of converging technologies is either unknown or underestimated in intergovernmental forums - Recommends an international convention for the evaluation of new technologies - Calls for a moratorium on commercial production of new nanomaterials
The Social and Economic Challenges of Nanotechnology Economic and Social Research Council (ESRC) – Wood, Jones & Geldart 2003	UK	Did not use direct public engagement processes, but assessed the social and economic literature on nanoscience and nanotechnology, and emphasized the diversity and interdisciplinary nature of the field	- Influential report that argues for a social science agenda on nanotechnology broader than the public-science interface. - Suggests governance of technological change needs to go beyond the incorporation of concerns and perceived needs into the process of technical development, and aim for greater understanding of the drivers and processes of decisions at the various choice points in the social process of technological development.
Societal Implications of Nanoscience and Nanotechnology National Science Foundation Roco & Bainbridge 2001- 2003	USA	Workshops with industry, government, academia and other professional communities	- Recommends education and training of scientific workforce - Found disagreement over ability to predict societal implications or future advances in nanotechnology - Found agreement that research should support development of models of public engagement.
Nanotechnology Dialogues Meridian Institute 2003 and 2004	USA	Dialogues, round tables and workshops	- Aims to encourage a proactive approach to regulatory issues on the part of government, industry, and other nongovernmental organizations. - Global dialogue on nanotechnology implications for the poor.
The National Nanotechnology Initiative Strategic Plan Committee on Technology National Science and Technology Council December 2004	USA	Sponsored 17 topical workshops focused on nanotechnology applications, societal implications, and regional, state and local initiatives September 2004 NNI Research Directions 11 Workshop	- Generated NNI goals, one of which is to support responsible development of nanotechnology - Future plan includes targeting investments towards opportunities identified by the community via NNI-sponsored workshops - Identifies economic, education, workforce, ethical and legal aspect as potential areas of society that may be affected by nanotechnology - https://www. nano.gov
Nanoscience and Nanotechnologies	UK	Working group of experts in science, engineering,	- Found that public awareness of nanotechnology low in UK - Most thought nanotechnology would improve life, e.g. advances in medicine

The Royal Society and Royal Academy of Engineering July 2004		social sciences and ethics, and two major public interest groups. Two in-depth workshops, plus oral submissions from wide range of stakeholders from UK and overseas. Literature review and commissioned new research into public attitudes.	and the creation of new materials. - Concern about financial implications, impacts on society, the reliability of new applications, long-term side effects and whether the technologies could be controlled. - Issue of whether institutions could be trusted to ensure that n/t R&D would be beneficial. - Comparisons made with GMOs and nuclear power. - This report has been and continues to be highly influential. The UK government's response to the report was deemed by the Royal Society to be 'disappointing' for ignoring the Report's recommendation for public engagement to occur 'upstream' of nanoscience and technology (Macnaghten et al 2005).
Nanotechnology: Views of the General Public BMRB: 2004	UK	Two evening workshops and a face-to-face omnibus survey	- Respondents' decisions about whether a technology is "good" or "bad" depended on its purpose and use - Most thought its potential benefits and drawbacks would only become clear over time.
Public Perceptions about Nanotechnology: Risks, Benefits and Trust Journal of Nanoparticle Research 6: 395-405 Cobb & Macoubrie 2004	USA	National telephone survey	- Public knowledge about nanotechnology is limited and general belief that potential benefits will be greater than risks. - Most preferred benefit is medical, while most important risk identified is losing personal privacy due to nanotech surveillance devices.
Citizens' Attitudes Towards Nanotechnology Teknologiradet-Danish Board of Technology: Vincentsson 2004	Denmark	Group interviews of 29 citizens from Copenhagen area	- Found citizens positively disposed to nanotechnology and want Denmark to initiate research into risks and ethics involved. - Public benefit should define the purpose of nanotechnology research, e g. fight pollution, prevent climate change, develop new energy sources, and improve condition of developing countries, healthcare and more knowledge. - Opposed to the use of nanotechnology to prolong life span or to improve consumer durables. - Worry about private sector being controlled by financial profit instead of what is beneficial to society.
Nanotechnology in Focus Rathenau Institute 2003-2004	Holland	Public meeting which included the Technology Policy Theme Committee of the Dutch House of Representatives	- Found that rather than a broad public debate, participants preferred discussions initiated by other parties and carried out on the basis of specified applications.
Report on the Potential Health, Environmental and	Japan	Joint workshop of 51 participants from UK and	- Found public concern exists over potential negative impacts of nanomaterials on health and the

Societal Impacts of Nanotechnologies The Royal Society and Science Council of Japan July 2005		Japan, and including representatives from the EU and the US	environment. - Little evidence from Japan, UK or USA of the outcome of public engagement activities impacting on decision-making. - Governments are more willing to take risks and to disregard stakeholder opinion if economic advantage is at stake. - Recommended stakeholder requirements be mapped, including the degree of power and interest of each stakeholder group. Reason why stakeholders are being engaged needs to be made explicit. - To date in Japan there has been little public engagement on technologies.
Survey on Nanotechnology Governance International Risk Governance Council (IRGC) on Nanotechnology 2005	Switzerland	Survey questionnaire 11 countries participated	- Survey on Nanotechnology Governance found little mention of public input in the national nanotechnology governance strategies of these countries. - Exceptions: Italy conducted a census in 2004 for a national database; 2005 France initiated a public debate concerning nanoparticle risk for health and safety; and the NSF in the USA which created nanotechnology networks to address the best mechanisms for communicating with the public (p. 17). - The majority of survey respondents wanted wide stakeholder engagement. - Some saw need for public input at early stage of R&D process (p. 18).
Nanotechnology: The Bendigo Workshop October 2004 Citizens' Panel on Nanotechnology: Report to Participant April 2005 Nanotechnology and Society: Integrating Social Issues in R&D Governance November 2005 Mee, Lovel, Solomon & Katz CSIRO Australia and La Trobe University, 2003-2005	Australia	Two public participatory workshops; third workshop was with nanotechnologists and social scientists within the national science organization	- Participants listed social and ethical priorities in nanotechnology R&D - Participants recommended community input into nanotechnology R&D - Concerns about purposes of nanotechnology e.g. weapons or warfare; surveillance and privacy. - Concerns over ownership and control - Tensions between research funded by private sector and 'public good' research. - Recommends modes of nanotechnology research governance that include social and ethical considerations - Public reports available at http://www.minerals.csiro.au/sd/index.html
Nanotechnology Awareness (Industry and Community) NanoVic July 2005	Australia	Telephone survey of 150 households to test community awareness of nanotechnology	- Survey found respondents had little knowledge but an increasing awareness of nanotechnology. - People are reserving judgment on possible risks of the technology until they learn more. - Respondents associated nanotechnology with medical devices, computing, very small scale technology, miniaturization and robots. - One risk mentioned was the fear that the

			technology 'would fall into the wrong hands'. http://www.nanovic.com.au/index.php?a=nanosociety.awareness&p=74
Imagining Nanotechnology: Cultural Support for Technological Innovation in Europe and the United States Gaskell, Ten Eyck, Jackson and Veltri Public Understanding of Science 14 (2005) 81-90.	Europe and USA	Multi-stage, random probability face-to-face sample survey (1000 interviews) in Europe Random probability telephone survey (850 sample size) in USA	- Comparison of public perceptions of technologies in USA and Europe - USA sample were more optimistic than the European sample about eight familiar technologies - Extrapolation from these findings to possible future reception of nanotechnology
Policy Through Dialogue: Informing Policies Based on Science and Technology Council for Science and Technology March 2005	UK	Report based on secondary sources of public dialogue processes in the UK, e.g. GM Nation	- Recommended that government at the highest level should adopt an explicit framework for the use of public dialogue to inform science and technology related policies. - Included Nanotechnology Issues Dialogue Group as one of the examples of current governance models.
STS Civic Forum on the Societal Implications of Nanotechnology University of Texas, Austin Moon, October 2005	USA	300 participants in a day-long interaction between general public, stakeholders and nanotechnology experts	- Some participants commented that they did not realize just how much developments in nanotechnology could affect daily life - They were surprised at how many nano products were already on the market or in development - There was a great deal of excitement regarding the potential medical applications on nanotechnology - Some apprehension, surprise, and wariness about the fact that the public at large is very unaware of nanotechnology
Informed Public Perceptions of Nanotechnology and Trust in Government Woodrow Wilson Centre J. Macoubrie 2005 Terry Davies 2006	USA	Macoubrie's study involved 59 participants using a scenario analysis approach	- In the absence of balanced information, people are left to speculate on the possible impacts of nanotechnology. - People often draw on analogies to past technologies, such as asbestos, dioxin, Agent Orange or nuclear power, and this can be misleading. - Consumers support more research and safety testing before products go to market - They think mandatory government controls are necessary
Public Participation in Nanotechnology Workshop: Initial Dialogue	USA	Public meeting of 175 citizens	- Meeting focused on approaches to engaging the public in nanotechnology related issues - Findings not yet publicly available - Speakers, abstracts of presentations and list of participants can be found at

NNI May 2006				https://nnco.nano.gov/p2/
EHS Research Needs for Engineered Nanoscale Materials NNI-NSF January 2007	USA	150 participants in public meeting. 15 speakers representing industry, academia, NGOs, and risk assessment consultancies	-	Public input from this meeting will be used to formulate the government's recommended priorities for safety-related research on nanomaterials, which, in turn, will guide agencies and program managers who fund research in the field.