REPORT OF PROCEEDINGS BEFORE

STANDING COMMITTEE ON STATE DEVELOPMENT

INQUIRY INTO NANOTECHNOLOGY IN NEW SOUTH WALES

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At Sydney on 10 June 2008

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The Committee met at 10.30 a.m.

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PRESENT

The Hon. A. Catanzariti (Chair)

The Hon. M. R. Mason-Cox
Reverend the Hon. F. J. Nile
The Hon. M. J. Pavey
The Hon. C. M. Robertson
The Hon. M. S. Veitch

NICOLA JANE ROGERS, Senior Research Scientist, CSIRO Land and Water, PMB7, Bangor, New South Wales, on former oath; and

SIMON CHARLES APTE, Research Director, CSIRO Land and Water, PMB7, Bangor, New South Wales, affirmed and examined:

CHAIR: Welcome to the fourth public hearing of the Standing Committee on State Development inquiry into Nanotechnology in New South Wales. In accordance with the Legislative Council's guidelines for the broadcast of proceedings, only committee members and witnesses may be filmed or recorded. People in the public gallery should not be the primary focus of any filming or photographs. In reporting the proceedings of this committee, the media must take responsibility for what they publish or what interpretation is placed on anything that is said before the committee. The guidelines for the broadcast of proceedings are available at the table at the door.

I remind everyone that any messages for committee members or witnesses must be delivered through the chamber or support staff or the committee clerks. I remind everyone to turn off mobile phones because they interfere with Hansard's recording of the proceedings. Should either of you consider at any stage that certain evidence you wish to give or documents you wish to tender should be heard and seen only by the committee, please indicate that fact and the committee will consider your request. If you take any questions on notice today, the committee would be appreciate if the response to those questions could be forwarded to the committee secretariat by Tuesday 1 July. Would either or both of you like to make an opening statement before we ask questions?

Dr APTE: We will launch straight into it. We will do a double act and take it in turn to answer the questions.

CHAIR: The CSIRO submission at pages 18 and 19 outlines the recent completed and ongoing work by the Centre for Environmental Contaminants Research on the environmental fate of nanoparticles. Can you provide some details on these projects?

Dr ROGERS: We are aquatic toxicologists at the Centre for Environmental Contaminants Research and our work so far has looked at the potential aquatic toxicity of zinc oxide particles, cerium oxide nanoparticles and silver nanoparticles. To do this we have used a freshwater algae as a model organism. We do not look at toxicity to a range of organisms; in these studies we have simply used one organism as a model.

I will start with our work on zinc oxide because at the moment that is where we have made most progress. The reason we chose these metal-containing particles was primarily that both zinc and silver are already known aquatic toxicants. The ionic forms of these metals are known to have high toxicity to aquatic organisms. That is quite different from their potential human toxicity. In aquatic systems they are quite toxic. The question we wanted to answer is whether the nano-size forms of these materials were potentially as toxic or more toxic than their traditional forms, such as the ionic forms of the metals or larger particles or micron-size particles. I provided quite a detailed summary of the zinc oxide work in response to questions on notice, so I will be brief about that today.

Our work has found that zinc oxide in both nanoparticulate form and bulk form is quite soluble in aquatic systems. So all of the toxicity that is manifest from particulate forms of zinc oxide is due to its dissolution to ionic zinc. So, the toxicity is no greater in that than we found for traditional zinc salts. Because of the known toxicity of zinc, it is already highly regulated in aquatic environments. So it is unlikely that nanoparticulate zinc would need additional regulation compared to ionic forms of zinc. I put one caveat on that: we have not tested formulated zinc oxide products as yet. The formulations—the coatings—may well change the amount of dissolution of the particle. There may be different toxicities for different formulations of zinc oxide particles. That is an illustration of how complex this area can become because there are many different formulations. We are thinking of things like sunscreens in terms of zinc oxide formulations.

That probably summarises where we are at with the zinc oxide work. Because the zinc oxide particles were so soluble it did not really enable us to study any potential mechanisms of toxicity of particulate materials, or nanoparticulate materials in particular. So the focus of our work—the metal oxides—has now changed to cerium oxide, which is a lot less soluble than zinc oxide. In themselves, cerium salts are probably not as toxic as zinc salts, on a weight-for-weight basis anyway, so we are less likely to see toxicity from cerium and it is the way we can study the potential toxicity of particles.

Preliminary evidence suggests that there is a difference between the toxicity of cerium oxide particles and cerium salt. The particles may be somewhat more toxic than cerium salt, but that is preliminary data. At moment we are trying to investigate what that mechanism might be. Finally, I will say a bit about our work on silver nanoparticles, which we have been studying for the past year at the Centre for Environmental Contaminants Research. Silver is highly toxic to aquatic organisms and it reached relatively high concentrations in the environment up to the 1970s, which was preliminary due to its use in the photographic industry. Most of the damaging environmental effects of silver have come from discharges around photographic plants, although that obviously is not the only source of silver in the environment.

With the advent of digital photography, silver concentrations have started to decline in the environment, so we see less toxicity due to the concentration of ionic silver in the environment. Another major use of silver, which historically has been true over centuries, is its use as a bactericide. It has been widely used as a bactericide. For example, it probably would have been the major anti-microbial use during the First World War. So its effects as a bacteriaside are widely known. I think that the silver industry and, in particular, the nanosilver industry, has picked up on this and we are starting to see many consumer products come on the market using nanosilver as a source of silver ion. The nanoparticles can be embedded in different matrixes, such as the plastics used in air-conditioners or washing machines, and you now see antibacterial washing machines on the market. Samsung has a washing machine called Silver Nano.

The nanoparticles have also been embedded into things such as underwear, because people want antimicrobial underwear, and into things such as plastic boxes for food storage and children's toys. For example, antimicrobial nanosilver is now embedded into dummies, teddy bears and those sorts of things, so many consumer products now contain nanosilver. I think it is industry picking up on the modern consumer obsession with hygiene. That is where the likely source of nanosilver will be in the future. Our work on the aquatic toxicity of nanosilver has really demonstrated that nanosilver particles, on a weight-for-weight basis, are less toxic than silver ions.

We used silver ions as well and the particles were about four times less toxic than the silver ions on a weight-for-weight basis. But micron-sized silver, which is the bulk material, is about 80 times less toxic than nanosilver particles. In rank order, silver ions would be more toxic than bulk silver. However, at the moment we do not understand the mechanism of toxicity of nanosilver particles, primarily due to the quite complex chemistry of the dissolution of the particles and their interactions with components of natural waters. Our future work will focus on mechanism of toxicity of the silver particles.

The Hon. MELINDA PAVEY: In your research so far into zinc and silver nanoparticles what consultations have you had with other bodies throughout the world about what you are doing?

Dr ROGERS: Much of the work of the CSIRO, in particular, on nanosafety, has come under the auspices of the niche-manufacturing flagship, which is one of the science focuses within CSIRO. We have had considerable consultation with people from the United States of America—people such as Dr Andrew Maynard from the Woodrow Wilson International Centre for Scholars, a visiting fellow of the CSIRO—who gave us some indication of the direction that nanosafety research should take within the CSIRO. We have also spoken to Professor Vicki Colvin at Rice University in the United States, who does a lot of work on the safety of nanomaterials. Specifically, within the Centre for Environmental Contaminants Research we have strong links with the European Nanonet—a group of researchers within Europe that are working on nanosafety. We collaborate with them quite strongly as well.

The Hon. MELINDA PAVEY: We understand that there is an OECD project on the testing of a representative sample of nanomaterials—a project in which Australia might participate. Are you able to provide details on what is involved in this project, including the timeframes, the list of nanomaterials, why they were selected, and the benefit to Australia of being involved in that project?

Dr APTE: A few months ago I attended the OECD meeting in Japan to discuss the technical aspects of the OECD program. Basically, the OECD recognised the need across the world to understand the toxicology and eco-toxicology of various nanomaterials. It is seen as a potential economic barrier to the development of the nanotechnology industry globally. The OECD devised a forward-looking program in which it selected about 12 nanomaterials. I will give you some examples but I will send you the complete list later on. The nanomaterials that it is interested in are things like silver, titanium dioxide, zinc oxide, cerium oxide, carbon nanotubes, dendrimers, carbon black nanoclays, polystyrene, and various other things. It is really based on known usages

across the world and also on the interests of industry. There are many industry representatives on the OECD committees and they would feed into the prioritisation.

The broad plan is for various OECD member countries to sponsor research activities into the investigation of these various nanoparticles, so it is a "sponsor a nanoparticle program". At the meeting I attended, various member countries were asked to step forward or volunteer to sponsor various nanomaterials. I estimated that the price tag for participating in this scheme essentially would be greater than $US10 million over the lifetime of the program, so it is a serious commitment. At the meeting a few countries were able to make that commitment. Japan, the United States, Canada and a few other countries stepped forward and volunteered to sponsor nanoparticles.

The Hon. MELINDA PAVEY: Australia did not?

Dr APTE: We were not in a position to undertake such a large financial commitment. What we did do was offer, in principle, to be a co-sponsor. We contributed to the program but not in such a primary way. We expressed an interest to co-sponsor work on silver nanoparticles and zinc oxide nanoparticles. You might ask: Why did we choose those two nanoparticles? Zinc oxide was seen as a potentially important nanoparticle for industrial usage within Australia—with the interest in cosmetics and sunscreen being one application—and silver is seen globally as one of the nanoparticles that is being used quite a lot as an antibacterial product, as Nicola mentioned. We envisage that there will be a lot of consumer usage of silver-based nanoproducts, so I think it is important for us to understand the potential dangers of these materials.

Referring to the timelines, primary sponsors were asked to develop a dossier plan of what they were going to test, how they were going to test it, and what methods they would use. That is due to go to the OECD in March 2009. Testing will start in about April 2009 and there will be a check-up to see how the program is proceeding in about March 2011. Material from this program will be published before then, but that is the official date to check progress on the whole thing. There is no determined end date of the whole program because we really do not know how difficult it will be. It is a bold undertaking that will involve the development of relevant test methods and their application. Referring to commitment dates, the OECD needs to get all its primary sponsors on board by December 2008. That is our deadline, if you like, to affirm our commitment to the OECD program.

Reverend the Hon. FRED NILE: Just going back to your comments about silver, I think you said it is being used in dummies?

Dr ROGERS: Yes.

Reverend the Hon. FRED NILE: Do you think there should be any restrictions on the use of it in such a thing as a dummy, which is being sucked, and so on?

Dr ROGERS: I think at the moment I really cannot comment on what the restrictions would be. The safety data are not in place. I am not a human health toxicologist so I could not really comment on the potential safety. All I could say is that silver is not particularly toxic to humans. We are interested in the aquatic toxicity. We are environmental toxicologists. Silver has known high aquatic and bacterial properties. It is not particularly toxic to humans but I really could not comment on whether it should be regulated in those kinds of products or not.

Reverend the Hon. FRED NILE: Do you think any advice should be given to commercial people to reserve those developments until the testing is complete, and so on?

Dr ROGERS: That is really a question for regulatory bodies as opposed to scientists. We can provide—human health toxicologists can provide—data on toxicity but it is a question for the regulatory bodies to answer as to whether products should be on the market or not.

Reverend the Hon. FRED NILE: The CSIRO submission also stated that one of the aims of the nanosafety theme is the development of generic environmental assessment protocols for nanomaterials by 2012. Could you provide further details on that?

Dr ROGERS: I will do that if you like. Simon has mentioned the OECD undertaking to test nanomaterials as a global commitment. One of the issues that the OECD and other environmental agencies are

working through at the moment is what are the best protocols to use to test nanomaterials. There are a number of protocols around that we use for testing other chemicals in the environment but because of the specific chemical and physical properties of nanoparticles we do not know whether those generic testing protocols that are currently available are appropriate for nanomaterials or whether some other controls would be appropriate to put into those testing materials or with different test methodologies would be useful. That is still really a research-based question. So, there is no way we can have a set of generic testing protocols without doing some research. Of course, to do the research we need some way to test the materials. So, this is very much an interim process. As we do the research we understand more about the sorts of things we need to include in generic testing protocols. I think 2012 is a reasonable time frame to rewrite or update some of the protocols required. So, that is one of the areas where the CSIRO would hope to contribute with its research-based program.

Reverend the Hon. FRED NILE: So, you are separating that environmental assessment from the effect on humans?

Dr ROGERS: Yes. The CSIRO has within its nanosafety research two programs. One is environmental effects and one is human health effects. Those effects are often very different, particularly when we are looking at aquatic organisms that are surrounded by the water that carries the nanoparticles. So, that would be the primary route of exposure. Whereas, to humans the primary route of exposure is through airborne exposure into the lungs or on the skin through du dermal absorption, and those are quite different routes. So, from that respect it is very useful scientifically to separate the two streams of research. Zinc and silver are quite good examples in that respect. They are quite highly toxic to aquatic organisms but less toxic to humans on a weight-for-weight basis.

Reverend the Hon. FRED NILE: I assume you compare notes?

Dr ROGERS: Absolutely, yes. They are two separate streams but we come under one group, one research group. But we operate as two separate streams.

The Hon. MICHAEL VEITCH: Could you let the Committee know what your views are on the current infrastructure you are using for your toxicology research on nanoparticles? Is it sufficient?

Dr APTE: I think the toxicology testing facilities we have are adequate. There are some challenges in developing human health testing. I am not qualified to comment on the human health testing. The biggest challenge in the nanotechnology area is the physical and chemical characterisation of particles. You often need large instruments like the Australian synchrotron or overseas synchrotrons, being techniques that we can get at Lucas Heights through the nuclear reactors. Not all techniques are available in Australia so one of the ways we are getting around this is to partner with overseas research organisations. So, we have very strong links with the University of Birmingham in the United Kingdom. We send a lot of our materials over there for characterisation. It is essential in this day and age to have international collaboration if you really want to get on top of research activities in general. That is the way we are going.

The Hon. MICHAEL VEITCH: So your involvement in the project you were talking about earlier with the co-partnering, what sort of investment would be required in your infrastructure to get you up to speed to be able to do that?

Dr APTE: The price tag—and this is just an estimate, I was asked the other day how much I thought this would be—I think you are talking about a minimum of a couple of million Australian dollars over two to four years to really deliver to that program something credible.

The Hon. MICHAEL VEITCH: My other question relates to staffing and being able to, firstly, attract and then maintain qualified staff to do the research. Are you encountering any issues in retaining people?

Dr APTE: We are lucky in that we have a world-class contaminants research group based primarily in Sydney and also in Adelaide. We really do not have any immediate issues of expertise. A lot of our researchers have moved on from other contaminants and have taken up the challenge of looking at nanoparticles. So, the generic area of research is contaminants. We have just slightly changed our focus to look at nanomaterials.

The Hon. CHRISTINE ROBERTSON: Recognising that you people are involved in environmental contaminants and recognising that they are very important, and that we have to work through human risk, the risk assessment processes that are covered in work safety type issues, and recognising that you are working in

the environment, do those risk assessment processes in any way affect the environment? Do you think they are appropriate in this very new field for workers to be utilising?

Dr ROGERS: I think that is a difficult question at the moment. I do not know whether those kinds of workplace regulations would impact much on the environment, because the disposal of nanoparticles is what would impact on the environment. That is, as I understand, different from workplace exposure. Whether or not they are appropriate, all I can speak of is the experience we have. We have to handle these particles in the laboratory so we are exposed in our workplace. So, that is something that is obviously close to my heart, and the people who work for us. We need to get information. As yet, we have found it difficult to get any information specifically on the risk of nanobased products in the workplace. From our point of view it is not as big an issue as it might be for manufacturing because we use very small quantities of these materials in order to run research-based experiments. That is quite different to the larger quantities that might be used in a manufacturing environment. All I can say from my own experience, there are no specific nanoregulations and so we use our scientific expertise to use the correct precautionary way of handling materials and the correct protective equipment. I cannot comment on the manufacturing environment, I just do not have the expertise.

The Hon. CHRISTINE ROBERTSON: Do the protections you use in your environment equate to another scientific field? Is there another area, other than nanotechnology, that would use the same protective processes?

Dr ROGERS: Yes. Generally we would use the same processes if we knew that a chemical would create fine powders or dusts. We may use a similar kind of protective process for handling nanoparticles if they were in a powder form if we knew something we would be handling would create fine powders or dusts. In the liquid form, for nanoparticles we would use similar protective equipment as we would use for handling liquids that may cause toxicity. That is how we would handle those materials in the laboratory but again there are no specific regulations in place in the laboratory. So we just use our scientific knowledge and background to protect ourselves as best we can.

The Hon. CHRISTINE ROBERTSON: Equating to other "dangerous" chemical issues?

Dr ROGERS: Absolutely, yes.

The Hon. CHRISTINE ROBERTSON: With respect to safety toxicity research, coordination and the avoidance of duplication are important issues. Can you suggest how research should best be coordinated nationally and internationally?

Dr APTE: To an extent, some duplication is good, especially in a frontier area like nanomaterials. So, we really are looking for some agreement between different laboratories to give us some comfort that the research is going in the right area. I make that point first. You would not really want to eliminate all duplication in the area. One of the really nice trends in this area is that everybody in the field recognises the need to partner because we simply do not have all the techniques under one roof to do all the work we need on nanomaterials: I mentioned earlier the challenge in physical characterisation. So, we are seeing the development of international networks. We are part of the European nanonet frame work. There is also a Nanosafe Australian network of researchers; there is a lot of sharing of data because it is such a new area. That is really what we have to pursue, the development and maintenance of these research networks. Certainly in Europe and the United States funds are available for these sort of knowledge networks. It is seen as a very important piece of research. So, I think the same applies in Australia.

CHAIR: What are the infrastructure requirements for toxicology research on nanoparticles in the environment? Is the current infrastructure adequate?

Dr ROGERS: Really, we need infrastructure on measurement techniques. When I say "measurement techniques", they are not the sort of measurement techniques that measure pristine samples and can provide us with the size of a nanoparticle. What we need is information on how the physical and chemical characteristics of what many matrix people describe as quite dirty environments, that is, real environmental samples. Often the case is that we cannot get access to put our data samples into nice, pristine, very expensive machines to come up with nice measurements. In Australia there is capability to measure nanoparticles, not all of those in environmental matrices, but the big problem with infrastructure is that we need the expertise to use those machines. So, we need people who are skilled in sample preparation so that we put the right samples in to

answer the questions in which we are interested, and researchers who are skilled in analysing the data that comes out of the measurement techniques that we choose to use. These techniques are quite expensive.

The way that we get around this is in a similar way to what Simon mentioned earlier in that we partner with people who have that kind of expertise, particularly in the universities. Again, our collaboration with the University of Birmingham is important. Dr Jamie Lead is a world expert in the understanding of aquatic colloids, which are basically natural nanoparticles in aquatic systems. So, we can tap into the expertise and the infrastructure they have available at the University of Birmingham to understand the physical and chemical characteristics of the nanoparticles. We can then use that information and apply that to what we are interested in studying in terms of toxicology.

The Hon. MELINDA PAVEY: I suppose this is the most important question: it has been suggested that the development of proven standardised testing protocols and capacity for nanomaterials could become a booming industry in its own right as an associated service industry to nanomanufacturing and technology development, and that there might be a potential opportunity for New South Wales, in particular, to set itself up as a centre for nanotechnology research. Do you agree with this view? If so, could you suggest what Government at both State and Federal level could be doing to foster New South Wales becoming a nanotechnology centre of testing area?

Dr APTE: The only word I think I would disagree with in that first sentence is "booming". I think there certainly is a need for a testing facility within Australia. I am not sure how I would define "booming".

The Hon. MELINDA PAVEY: World leading?

Dr APTE: World leading, fine. Yes. It is worth taking stock of where we are at. We can comment on eco-toxicity testing. The New South Wales Government actually has been very proactive in this area for many years. In New South Wales we have the Centre for Environmental Toxicology, which is part of the Department of Environment and Climate Change. That is an internationally renowned centre. So, we already have that sort of profile within New South Wales. There are several universities as well: the University of Technology Sydney has always had a very strong reputation and background in eco-toxicology. As a result we have a lot of trained graduates coming out of that university who have skills in the toxicity testing area. And, of course, there is our research group as well, which is also internationally renowned, which in the New South Wales. I think there is a strong knowledge platform there. Interestingly, there has been about one or two eco-toxicity testing companies that have been spin-offs in New South Wales from various people working in the New South Wales bank. There is that linkage there; we can see a trajectory there. Would I invest in my own spin-off company in nanotoxicity testing? At this stage, probably no, but I see down the track once the OECD has developed protocols that are internationally recognised that that may well be the window of opportunity. I think it is more the development phase at this stage that we are looking at.

The Hon. MELINDA PAVEY: So it is about the world getting its act together on how they want the toxicity tested in all dimensions and then seeing what advantages we have from that point?

Dr APTE: I think so. If I set up a company now and a client said to me, "I want these materials tested" it would be a matter of I say, "Well, we haven't got any standard protocols. We can do our best job and you just have to trust me that everything is okay." But I do not think many clients would be comfortable with that approach. We really need those defined protocols, accepted test methods, in place before we can really start to spin up an industry in this area.

The Hon. MELINDA PAVEY: So for research you would prefer Australia to follow the lead of the OECD and what the world bodies are saying rather than specialise in testing for industries that are doing their own commercialisation?

Dr APTE: I think it is a matter of doing both. I think the OECD framework provides us with a very pragmatic way of dealing with this nanomaterials issue. It also does not stifle research in Australia; it will synergise it. From the test methods that evolve from this very fruitful international collaboration I can see that with the seed for industries within New South Wales.

Dr ROGERS: Could I just comment. You mentioned Australia following the lead of the OECD. At the moment it is not so much following the lead. We have a significant opportunity to input the outcomes of our

research to the OECD process. So, the research we are doing, if we forward that to the OECD, we have an opportunity there for some of our leading research to be incorporated into the OECD-type protocols.

Reverend the Hon. FRED NILE: Would the OECD now be the approval body for the testing protocols you mentioned?

Dr APTE: The OECD does recommend testing methods for international usage. So, they tend to be the default-accepted standard in a lot of eco-toxicity testing.

Reverend the Hon. FRED NILE: Who has given the OECD the authority? Does that come from the United Nations?

Dr APTE: I am not quite sure. I do not think I am qualified to answer that question. All I can say is that within the area of eco-toxicity testing they are an internationally accepted authority.

The Hon. MICHAEL VEITCH: The Committee has heard evidence about the call for a moratorium on nanotechnology in New South Wales. Do you have a view about that, considering that nanotechnology is a very broad field?

Dr ROGERS: As you say, nanotechnology is a very broad field and it is important to realise that that encompasses so many different types of nanoparticles, applications of those particles, and all sorts of issues. I think a broader moratorium on nanotechnology without any clear framework of what that is based on, I do not understand what that really means. I do not see what the framework for basing that moratorium is. Certainly, if there is a complete moratorium announcement, we cannot do the safety research, and if we cannot do the safety research we potentially will miss some of the major benefits of nanotechnology. So, there is always a balance between those two things. There is potential for nanotechnology to be incredibly beneficial but, obviously, we need to understand any potential down sides of the technology at the same time. So, a moratorium would not allow us to either reap the benefits if they are there or to understand what those safety implications might be.

Dr APTE: I agree with what Nicola said.

The Hon. MICHAEL VEITCH: Just following on from that, as I see it, what happens are that the calls for a moratorium within the community feed off a lack of information. From your field, is eco-toxicity an issue? What should we do to better inform the community at large?

Dr ROGERS: The community at large are often more focused on human health effects, for very obvious reasons. People want primarily to make sure that nanoparticles are not doing them any harm but certainly now people are also quite concerned about environmental effects. People are concerned about both of those issues but I think human health is the primary focus. One of the difficult things for us as safety researchers is to try to understand exactly what information the public would like about nanoparticles and what kind of information would allow them to accept the technologies. We really do not know that much about public attitudes towards nanotechnology and what the public base their perceptions on. Often it is not science.

At the moment safety science is so new that it is likely to be changing because that is simply the nature of research; we find one thing out and then another piece of information comes along and we build a big picture. It is difficult at the moment to know what level to engage with the community because too much science can be confusing and send the wrong message and also if the picture changes, scientists are used to dealing with the body of evidence building up and our perception of safety changing, but that makes the community feel unsettled and that scientists do not have the answers, and at this stage of the game we just do not have some of the answers that the community might need. I think engagement with the community to find out exactly what bothers them about nanotechnology would be very useful.

The Hon. CHRISTINE ROBERTSON: This is a bit of a side issue but you mentioned polystyrenes. Are polystyrenes mostly nanoproduct?

Dr APTE: There are forms of polystyrene, very small beads, which are classified as nanomaterials, yes.

The Hon. CHRISTINE ROBERTSON: So the packing processes throughout our entire culture are now almost entirely based on polystyrenes, which are almost impossible to get rid of?

Dr APTE: The packing products would not be classified as nanomaterials.

The Hon. CHRISTINE ROBERTSON: They are different?

Dr APTE: They are different. This is a specific application.

Reverend the Hon. FRED NILE: You said earlier that there are no regulations in place for the workplace?

Dr ROGERS: We had trouble finding specific nanoregulations when we started laboratory research, yes, as far as I know. I do not know about the manufacturing environment at all.

Reverend the Hon. FRED NILE: Sometimes you find that people working in certain areas develop similar health problems. Has there been any research into the health of people like yourselves, who are working in this area, or any comparison about the blood diseases, increased cancer or anything like that?

Dr ROGERS: No, not that I am aware of. The area of nanotechnology is quite new and certainly as laboratory scientists, we use such tiny quantities but, as far as I am aware, there is no data or any studies into laboratory workers.

Reverend the Hon. FRED NILE: There have been no health checks as such or comparisons?

Dr ROGERS: Not that I am aware of. Are you aware of any?

Dr APTE: No.

Reverend the Hon. FRED NILE: Do you think there should be?

Dr ROGERS: Nanoparticles are chemicals in the same way that there is a broad range of chemicals that we work with in the laboratory and we take safety precautions with all of those. We have many, many safety procedures in place and we do not have routine health checks for other chemicals because we use them in a sense where we are as protected as we can be.

CHAIR: Do either of you wish to make any further comment?

Dr ROGERS: I have a final comment, and we have covered it to some extent around the public perception of nanotechnology. I reiterate the point that there is no nanotechnology. Nanotechnology is a very broad term that encompasses a huge range of different materials and their applications. Some of those products may turn out to have some toxicities that we as yet do not understand; many of them won't do and to a large extent it depends on not only the type of particle but also its application; say, for example, whether it was used as a free nanoparticle or whether it was embedded into some structure and also the life cycle of that product and whether that product would likely degrade into free nanoparticles and if so, what free nanoparticles and what form they would be released in.

All of those things need to be taken into account when we are talking about nanotechnology and in terms of consumer perception and public perception of nanotechnology, there seems to be nanotechnology as a single word—and there is no nanotechnology and some things will be quite beneficial and other things may not be, but we need to try to find a way to communicate with the public on that level as opposed to as a very broad brush stroke, which may have adverse impacts on the industry as a whole, which would be unnecessary.

CHAIR: I thank both of you for attending this morning, for your comments and answers to questions.

(The witnesses withdrew.)

ELAINE JILLIAN ATTWOOD, Consumer Advocate, Standards Australia Nanotechnology Committee, Consumers Federation of Australia, and

DAVID VAILE, Cyberspace, Law and Policy Centre, Law Faculty, University of New South Wales, affirmed and examined:

CHAIR: Thank you very much. Would either one of you, or both, like to make an opening statement before we begin to ask questions?

Ms ATTWOOD: Good morning to you all. I would like to begin by reading you the following quotation:

> What I generally saw on the pro biotech side was the attitude that the technology was good and that it was almost immoral to say that was not good because it was going to solve the problems of the human race, and feed the hungry, and clothe the naked. And there was a lot of money that had been invested in this, and if you are up against it, you are Luddites, you are stupid.
>
> That, frankly, was the side our government was on. Without thinking, we had basically taken this issue as a trade issue, and they, whoever "they" were, wanted to keep our product out of their market, and they were foolish or stupid and did not have an effective regulatory system.
>
> There was rhetoric like that even here in this department. You felt you were almost an alien, disloyal, by trying to present an open-minded view on some of the issues being raised. So I pretty much spouted the rhetoric that everybody else around here sprouted. It was written into my speeches.

That quote is by Dan Glickman, the United States Secretary of Agriculture under President Clinton, who was providing insight at the time into the pro-GM mindset of the government. However, this same type of attitude is almost always expounded to the public on the introduction of a new technology that government, and industry, is keen to embrace—and for the same reasons.

Governments are keen to be embracing the cutting edge of a technology to gain a market advantage over other governments in other countries—in other words, trade—and industry is desirous of getting their products to market before the competitors do—in other words, to gain a market advantage and to make money more quickly. I bring this to your attention simply because there are many similarities between the way GE products initially entered the marketplace and those of nanotechnology.

Never before has adoption of the precautionary principle been more necessary for governments to observe than it is now. Please keep in mind the circular logic that also was applied to GE products and which we do not want nanotechnology becoming a victim of.

The Hon. MELINDA PAVEY: Excuse me, is that GE, or GM?

Ms ATTWOOD: It amounts to the same thing—genetically engineered, genetically modified—and the terms can be used interchangeably. This logic follows the lines of "because no long-term epidemiological studies are in place, we have no evidence showing long-term harm, and since we don't have any evidence of long-term harm, we don't need studies to look for it." Nanotechnology is a new technology that is capable of being what we call a convergent technology; that is, it covers or can be used with a multitude of other technologies and, as such, promises many benefits. But along with the new advantages and benefits also come new dangers that we have never before had to think about.

People who raise the spectre of these dangers should not be ostracised for their caution or for their criticism in speaking out about them. These people are the canaries, if you like, of nanotechnology, and show where more research is obviously needed. But once satisfied and their concerns have been well and truly understood and addressed, they have the potential to become the most ardent supporters of the technology. There is an immense amount of work needed before we reach this stage, simply because there are so many areas to be covered. While the consumer movement is sure that the public will be told of the potential benefits of nanotechnology, what we are not sure of is whether we will be told about the dangers and disadvantages that are undoubtedly there and at present are unresolved.

We ensure, whether in the interests of global trade, that our country will blindly follow the parameters set down by countries that are further ahead in the commercialisation of nanotech products, but if previous experience is anything to go by, pressure will be applied by the World Trade Organisation to accept those

parameters and enforce them. So should we not in Australia be setting our own regulations, with our own citizens in mind, rather than just thinking about the trade opportunities? It is well known that industry does not welcome what it sees as "unnecessary regulation", which consumers may well think is necessary—labelling being one of them.

To date, the consumer's voice is not heard at the national level with regard to technology, and it should be; but I do commend the New South Wales Government for its foresight in making the first move to engage consumers as they are the end users of the technology in the marketplace and should surely have a voice, particularly in regard to regulation. On that note, I look forward to answering your questions to the best of my ability.

CHAIR: Mr Vaile, do you wish to add anything?

Mr VAILE: I would like to just generally support that. I will add a couple of other comments from my background, partly with the Australian Privacy Foundation and partly as someone who is interested in the evolution of technology, particularly the management of risks in relation to technology. One of the main features of very large technology projects is their relatively high failure rate which, in major information technology [IT] projects, is typically in the order of 75 per cent when judged against a range of project management criteria, including quality and scope.

In my view, one aspect of nanotechnology is, in a sense, a projection of some of the techniques and industrial and technical applications of information technology. I would be surprised if there is not a similar sort of profile at least for the first couple of generations when things go wildly off the mark and there are unintended consequences of a number of different sorts. With privacy in particular, it is difficult to project privacy harms out into the future because the benefits of a technology are obvious and heavily promoted by those who would financially benefit from them. These side effects on individual personal information security and individual privacy and those sorts of issues can take a long time to manifest and may never be known directly to the person who is affected by them, and they may occur in some other location. It is a classic problem that we have been trying to help people to balance the benefits and costs of participation in new technologies where there is no social or technical base of knowledge. I expect that nanotechnology will have that as an example.

I also add a comment in relation to international treaties and trade negotiations. I had an experience in relation to the United States-Australia Free Trade Agreement regarding the intellectual property aspect of that, which was a major part of it. Because you did not have in a sense an unbiased interest in, for instance, just introducing a sort of harmonised model of regulation across the board to Australia, particular in industrial interests, the copyright owners in that case were able to have Australian law adopt only, I suppose, the pro-owner, pro-distributor aspects of that regulation.

The problem was that pro-user protections and rights were left off, and many are now much inferior to what they are in the United States. That is an example which I invite the Committee to keep in mind when consideration is given to those international negotiations. I suppose the lesson there was that it is possible, through the exertion of a variety of influences, to have the outcome of that international negotiation and the introduction of a "harmonisation" of Australian law with other laws, but to nevertheless leave off some of the crucial features that will protect the broad mass of the population—the users, the consumers, the citizens.

I think I will leave my remarks there. I have provided a very brief and unfortunately late submission touching on two examples of privacy threats, one in relation to genetic information and diagnostics generally, and the other of an example of the current proposal in the United States to use nanotechnology as a very wide-scale instrumentation and surveillance technology.

CHAIR: Before we begin questions, I should point out that, if you should consider at any stage that certain evidence you wish to give or documents you may wish to tender should be heard or seen only by the Committee, please indicate that fact and the Committee will consider that request. As well, if you take any questions on notice, the Committee would appreciate the responses to those questions being forwarded to the Committee's secretariat by 1 July.

Ms ATTWOOD: Certainly.

CHAIR: How does the CFA assess what the consumer perspective concerns are with respect to new areas such as nanotechnology? Are the issues you champion on behalf of consumers essentially the same, or are there specific issues relevant to nanotechnology?

Ms ATTWOOD: I will deal with the first part of your question first. The CFA is the peak consumer organisation in Australia, and it has over 100 organisation members. How many of those are individual memberships, I could not say, but there would be quite a few so it is quite representative. Its representation comes from lots of different types of consumer organisations, from church groups to women's groups, to financial counselling; it is a very broad brush that they undertake.

They also have very strong ties with Consumers International, which has 220 members across 115 countries. Consumers International at this point does not have a set policy, but what it has come up with is that it is speaking with the transatlantic consumer dialogue, and they are working on such a policy at the moment and it is quite likely that when that is finalised Consumer International's members, including the CFA, will adopt that as their policy.

There is also a group called Which? in the United Kingdom, which does virtually the same thing as Choice does here in Australia. They have come up with a 10-point plan which does broadly cover what consumers want, and for the moment the CFA is willing to put its support behind that. Having said that, I have just become aware of a report by Elizabeth Nielsen for the Canadian Consumers Association. Her conclusions to me sum up better than anything else what consumers really are looking for out of this technology, and I would be quite pleased to give you that summary later on for your records. They also work very closely with the eight consumer tenets that were handed down by the United Nations back in the 1980s, and they have a set of objectives within their constitution that they work with.

On the issue of specific things, there are several of them. Certain materials have been used in the marketplace now for quite some time, with no apparent concern for either the manufacturers, the end users or the environment. But with the advent of nanotechnology, and taking those same macro materials down to the nano level, there are different properties that these nanomaterials have. So that, in itself, is specific and we are going to have to address them.

Dr Andrew Maynard from the Woodrow Wilson Centre found that nanotubes, which are one of the nanomaterials, when injected in the study into the lungs of mice, produced the same sort of disease in the lungs as asbestosis does; it was because the nanotubes were a certain length. So it may be that it is just that specificity; we do not know. But this is the second study in 12 months that has indicated that nanomaterials can cause human health problems—although, it has not been extrapolated to humans because obviously it is not one of the things we do on humans. Nevertheless, it is in the pipeline.

Again, the concern there is that other countries that are further advanced than we are in nanotechnology are bringing nano products into the marketplace; they are being commercialised before there is any real regulation set in place. Again, using GE as an example, it is very difficult, if you find anything wrong after these products are in the marketplace, to remove them. We do not want this happening with nanotechnology. As I said, I am not against it by any means, because there are some good things to be had from it, but we have to be careful about making sure that the benefits outweigh the risks.

The second issue is that nanotechnology is a convergent type of technology and is used over a whole lot of other technologies. So we are going to have things like nanomedicine, nanoelectronics, nanobiology and nanotechnology. I was interested to hear the previous witness remark on that, because it is not a single entity; it is over of lot of them. And since it can be applied over a multitude of other disciplines, there is the capacity for it to change the way those disciplines work for ever. So there is a need to ensure that the risks of the new technology are known, characterised and counteracted, so that the perceived benefits are real and outweigh those risks.

The third area is regulation itself. Regulation must be specific for nanotechnology. We are unable to use the existing regulations, since the risk assessment and risk management strategies that are in use for those materials at the macro level do not apply at the nano level. Nanotoxicity tests relate to size, shape, surface area and surface activity, whereas at the macro level they result from mass and compositional studies, so they are different. They are the three things that I would say are specific to nanotechnology.

The Hon. MELINDA PAVEY: You are the CFA representative on the Standards Australia Nanotechnology Committee. Can you advise us on the work of that committee, including what issues you have raised and how they have been received within that forum?

Ms ATTWOOD: Standards Australia's nanotechnology committee started back in 2006, and I joined about three months after they had their first meeting. They have very strong ties to the International Standards Organisation [ISO] and also the International Electrochemical Committee, and they meet very regularly. The ISO works with the main committee and three subcommittees. The first of those three subcommittees deals with nomenclature, the second deals with characterisation and metrology, and the third deals with occupational health and safety. Because those committees are mirrored at Standards Australia level, I joined the occupational health and safety subcommittee, since I do not have the technical expertise to be able to contribute to metrology and nomenclature.

I am happy to tell you that Australia's standing with the ISO is very well accepted. Our chairman, John Miles, is on the main committee and also on the measurement side of things, and Mr Howard Morris, who chairs the subcommittee for occupational health and safety, has worked remarkably hard, and we now have the first technical report from this committee on occupational health and safety, which will detail some of the measures that need to be taken in the workplace. At present this is going out for the international grouping to vote on, and if it is accepted—as it should be, because an awful lot of consultation has gone on to get to that stage—it will be the first technical report that has come out of the International Standards Organisation. I think that is really a feather in their cap if that comes off; it will be a major breakthrough.

As a committee member, I can have input into anything on that committee; nobody stops me from having a say on anything. As I said, I am not an expert in some of those areas, so I rely on my fellow committee members, who come from a vast array of different areas that are interested in nanotechnology, from the CSIRO to some of the private industry people, and what I do not understand I will ask their advice on.

My interest stemmed from the fact that when I was on the board of Food Standards I recognised that nanotechnology was going to be a big issue in packaging. At that stage it had not occurred to me that it might also be in food. While I was still on the board, I started reading what I could about it. By the time the CFA was looking for a representative for the standards committee, I shook my hand very unsteadily and said I would like to apply for it. I was able to learn a lot more through there.

At the very first meeting I attended I told them that from a consumer's perspective, apart from the safety, it was a labelling issue that I was interested in pursuing. As a comparator, I reminded that committee that the biggest mistake that was made when introducing genetic engineering into the food supply was that consumers had it foisted upon them without any real public debate about what many considered to be inadequate legislation. We do have a standard for that but it was not triggered unless the particular foods contained any residual foreign DNA or the substance was so different from its normal comparator that you would have to label it. We do not want that happening with nanotechnology. So I used that as a means of impressing upon them that you have got to take the public along with this. Even if they do not know anything about it at this stage, they are going to in the future. There are no two ways about that.

Since then, there have been many questions with nanotechnology regarding environmental aspects, and social and ethical issues that still require answers. So if history is not to repeat itself the Government will have to do a lot to educate the public in this matter. From a consumer's point of view, information can be gleaned from many different sources, and all have a part to play. But there is no doubt that the single, most effective means of getting information to the consumer is by the use of labelling. While my colleagues are in many cases quite sympathetic to my call for labelling, they do not think it is the remit of Standards Australia to provide that. Nevertheless, during their upcoming overseas visits they have offered to canvass other members to see what their views would be about that. The other issue coming through Standards Australia is that its standards are not mandatory, but voluntary.

Reverend the Hon. FRED NILE: You said that Standards Australia should not do the labelling.

Ms ATTWOOD: That is the only avenue we have as a consumer through which to pursue that at the moment because there are no standards other than what we are developing here.

Reverend the Hon. FRED NILE: But if Standards Australia does not do it, who will?

Ms ATTWOOD: Because it is a broad remit, it would need to be through Food Standards Australia New Zealand if it was in food and packaging, and it would need to be through the pesticide authority if it was going to be in pesticides. I am not sure who regulates clothing—it might be the ACCC; I am not sure. There will not be one particular regulator at this point anyway. My view is that there probably should be an oversighting regulatory authority, but we will talk about that later.

Reverend the Hon. FRED NILE: What would the label have on it?

Ms ATTWOOD: If you allow me to return to the GE comparator, when the standard was developed for that Food Standards said that they were not labelling for health and safety. In their opinion, they had checked all that and the only reason they would consider labelling was from an information point of view for consumers. They do not label for process. That was the argument. But that is not quite correct because we do label for things such as organics, ultra-high treated milk and for—

The Hon. CHRISTINE ROBERTSON: Homogenised.

Ms ATTWOOD: Yes. So that is not strictly the case; we do actually label for processes. So there will need to be some authority to label for the process—the fact that this process has been used when manufacturing this particular product.

Reverend the Hon. FRED NILE: What will the labels read? Will they say, "This is nanotechnology"?

Ms ATTWOOD: It will say that the product is produced through nanotechnology or something like that. I do not know exactly what it will say, but that would indicate that it has been produced through nanotechnology techniques.

Reverend the Hon. FRED NILE: What would be the purpose of the labelling?

Ms ATTWOOD: To inform the consumer so that they have a choice.

Reverend the Hon. FRED NILE: So they do not buy it.

Ms ATTWOOD: Some will and some will not—it depends on the way the marketers advertise it. At the moment nano-silver is being used in refrigerators and nano-silver is being used in clothing—socks and that sort of thing—and footwear. It is a very strong antibacterial so they are making an issue of the fact that it is a good thing. Not everybody will not buy it, but those who have some doubts will have the choice.

Reverend the Hon. FRED NILE: Could you label it as nanotechnology with no health risk? You may imply by labelling it that there is a health risk.

Ms ATTWOOD: Not necessarily, no. It would depend on how people view things. I saw a demonstration with a shirt that had tomato sauce poured all over it. It was then hosed down and all the sauce came off. I am a housewife too so I can see that a lot of people would want to buy something like that. They would not consider it a health risk. But at this point we do not know what happens to the nano-silver particles when they come out of the shirt. Where do they end up?

Mr VAILE: I want to make a couple of points in relation to the process that labelling would feed into. In many different areas the concept of consent or informed choice is used as a good way of enabling people to decide to cross into some sort of activity or use some sort of product. That is particularly so in relation to privacy and also in relation to medical treatment. It is the justification for labelling on lots of products. I would like to make a general comment on the nature of consent and choice. Mainly, I suppose on one side there is proposing the gold standard for such a process, which would include people being properly and adequately informed before the fact, with prior consent that is revocable and is not coerced. So you can go back in future if you find out later that something has changed or was misrepresented. You are not losing anything in particular if you do not avail yourself of that choice.

I suppose the weak, bad version of choice, if you like, which is often slipped in in some environments, is where it is not properly informed. That goes to the question of labelling. It is not prior; it happens later. You discover something later and you are asked to put up with it or not, and it is not revocable. There is nothing you can go back on and there is some sort of coercion involved. You do not have much choice and you are obliged

to go into that. My view in relation to the nanotechnology area is because it is a convergent technology, the nature of its future applications are not known and the nature of the potential complications or interactions—I am not necessarily suggesting just health effects—are not known at the moment, I would suggest that the higher standard of choice is appropriate, and that would support a high standard of labelling. If we say, "We don't want to discourage people, because some people will look at the word 'nanotechnology' and respond badly to it", I suspect that is really a question of education rather than an argument for leaving that sort of information off labelling if it is otherwise appropriate.

The Hon. MICHAEL VEITCH: This question is for both of you. It goes to the heart of this inquiry, which is about regulation. Elaine, in your opening address you spoke about the fact that the occupational health and safety laws as they currently stand are insufficient and would need amending to accommodate nanotechnologies. Can you highlight where they are inadequate? There is a follow-on question for David. In your written submission you talk about privacy issues. What sorts of regulatory reforms would you require to accommodate your privacy concerns?

Ms ATTWOOD: To start, we acknowledge that there are already nanoparticles in the atmosphere and that we exist with. We are talking here about manufactured particles. We are also more likely to be talking about things that are not set in a matrix of some sort—they are free, as I heard an earlier speaker say. I am of the opinion that if the particles are safely in a matrix you do not have the same problems as you would have with free particles.

Some of the things that have been looked at in the technical report are other sorts of filters, for example, that might be used. I have not got that report in front of me so I cannot tell you all the things that have been discussed but I am sure you would be able to get hold of that once it has gone through and Standards Australia has it back with them. They went to all the manufacturers and asked them what they were using and whether they had made any specific effort to try and make the workplace safer because they were using nano technology materials. The consensus seemed to be that they do not use a lot of it—only a very small amount is used—but because they can become airborne they do have to make sure that the filters used in the workplace are extremely fine. I know we have dealt with ultra fine particles before but these are smaller again. That is the sort of thing that we are looking at in the marketplace with the occupational health and safety issues. There are a lot of others that I cannot remember offhand. I would encourage you to get in touch with Standards Australia and ask for their technical report. I am sure they would be happy to let you have it.

CHAIR: Mr Vaile, would you like to add to that?

Mr VAILE: I want to emphasise repeatedly that it is a convergent technology, and it is a very new technology, so it is unlikely at this stage we can be confident that the full range of potential effects, whether they are biological or from some other area, are properly known. That, I suppose, is an argument for application of the precautionary principle rather than an argument to say do not use it. What it means, for instance, is that the particular standards of an effective filter may be unknown at the moment. The other potential interactions with possibly drugs or medicines or foods or other sorts of environmental contaminants in certain situations are probably unknown at the moment. I am not aware of the level of research that is being undertaken into that at the moment. I am aware of the comparison with the biological effect of very small particle size asbestos particles. My assumption is that there is nowhere near as much research going into those potential side effects at the moment as there is into new applications. Unlike the pharmaceutical industry, it is not regulated as a relatively well-understood mature industry with clearly appreciated potential harms for human health, I suspect there is not the same burden of obligation to do that sort of research.

I sympathise with the resources that are required to do that, but it is global consensus in that area that the potential harms of a drug that does not work are so wide that that level of research is appropriate. My understanding at the moment is that it is very much at the beginning of the research into those sorts of effects with nanotechnology. I am not trying to raise any sort of bogeyman but I am trying to emphasise the potential difficulty at this very early stage of the very immature point in technology evolution and also the potential for interactions and compound effects that we do not necessarily see in one situation to come about through the application of these things. The literature I have been reading suggests that it is at the start of a new industrial revolution and, as Elaine suggested, the range of applications is only now becoming understood. The range of potential complications of things that you would need to consider regulating on I think is also probably at this stage unknown.

The Hon. MICHAEL VEITCH: In your submission that we received this morning you said:

> If Nano-enabled diagnostics devices are developed people may feel as though they need to choose between privacy and medical care.

Can you explain what the privacy issues are that you refer to there?

Mr VAILE: This is a more general issue with the privacy of medical records. If people have illnesses or predispositions which are either discriminated against by employers, or through lack of sympathy by the public or whatever, such that they feel they may lose their job or they may not be able to travel, or those sorts of things, there is a choice that confronts those people which is, "Do I trust the privacy of the health record system to keep this just within the realm of treatment?" You cannot have awareness and control of diagnostic things that are occurring, particularly in the treatment of the information that is generated out that. The more sort of rational person, wanting to balance up their own risk of either discrimination or adverse treatment on the basis of their condition as opposed to what they might lose out on by not getting treatment, would err on the side of caution.

Again one of the problems in looking at this in relation to health and diagnostic treatment is that it is relatively early days. The scale of the devices that are possible, if not necessarily operational yet, is such that you can do all sorts of things that at the moment the immune system would do, or that various diagnostic tests would do, and have that attached to live instrumentation. Instead of having to rely on several steps and go through an extensive and complicated physical process, where it is clear that blood has been taken or a DNA sample and things like that, it may well be that there are ways of having external bodily detectors for some nanotechnology devices that can give feedback from the body without the person having to submit to a medical examination. I am not sure of the proximity or the details of those sorts of technologies, but if that is in place and if there is no trust that the practitioner, the company around the technology, the entire institutional infrastructure, and the records created by that sort of diagnosis are completely safe, then the person would be well advised to ask questions. If they cannot tell that they are being tested, or information about their health status is being collected, is it safe for them to proceed into that sort of arena?

The Hon. MICHAEL VEITCH: What you are saying is that our current privacy regulatory framework would not cover that?

Mr VAILE: I do not think so. I have an interest in the attempt to create, for instance, privacy guidelines for an electronic health record and my understanding is that there is no widely accepted well-consulted national consensus that particularly satisfies the concerns of privacy advocates and patient groups across the field. I suppose an historical example is that that is not stopping a range of incompatible but very energetic projects being put up to create a variety of electronic medical record systems which are linked together.

The two issues that come out of it that for me are, firstly, we are quite capable of introducing a very serious and obvious technology—electronic health records—with potentially massive privacy implications without getting the privacy principle right, without, on a policy basis, seeing that we have the regulation working. Secondly, if this goes ahead, there is the infrastructure already for the rapid transmission of information that may be collected through nanotechnology. Those two things together suggest to me that while there is work going on at the moment, there is no particular reason to have confidence that either the policy framework puts privacy at a high-enough level to get it right before it is in place, or that the information coming out of a nanotechnology process will not immediately be sucked up into what now looks like a relatively un-satisfactorily controlled electronic medical records system.

The Hon. CHRISTINE ROBERTSON: Ms Attwood, I apologise for picking up your words. I have a habit of doing that.

Ms ATTWOOD: I am glad you did. It fills in those mental blanks.

The Hon. CHRISTINE ROBERTSON: You talked about the precautionary principle. What do you perceive as the precautionary principle in relation to nanotechnology?

Ms ATTWOOD: Where we do not know then we take the view that we do not do it until we do know, until the testing has been done. So that if there is any doubt then we will not commercialise it until we have had further testing done to make sure that it is safe.

The Hon. MICHAEL VEITCH: That includes longitudinal studies?

Ms ATTWOOD: I guess it would depend on which area it was in. I do not have any strong views about that. I am not a researcher myself so I really could not be specific about that.

The Hon. MICHAEL COSTA: So let us just ban it?

Ms ATTWOOD: No, I would not ban it.

The Hon. CHRISTINE ROBERTSON: No, she was not saying that from her speech. I was interested to know what a consumers' group thought of that word.

Mr VAILE: My understanding of the applications of the precautionary principle is that it is focused on where there is a sort of one way gate that you are going through, where it is not possible to, at relatively low cost and inconvenience, reverse something that you are going into.

The Hon. CHRISTINE ROBERTSON: Yes, I understand that. I just wanted to know what the consumers' group was calling that. The committee has received a lot of evidence of ideas of what that meant.

Ms ATTWOOD: Earlier, there was talk about whether there ought to be a moratorium. I know one particular group—I think it is Friends of the Earth—have called for a moratorium. But I do sympathise with the fact that if you did that then you cannot really find out what is wrong, but what I would say is, hold off on actually commercialising that. There are already things in the marketplace now—from memory some of the figures about 550 to 650 different things in the marketplace—that you can buy that may be using nanotechnology. As I said, some of those probably will not cause any problems at all—tennis racquets and things like that where it is all in the matrix probably would not be a worry—but when you come to food and packaging, and medical things it might be a different matter.

The Hon. CHRISTINE ROBERTSON: The committee has heard a lot about nano and IT, those sorts of issues. I am interested in your paper and how it actually compares with the current practise of hooking together things like "award cards" as they are capable of assessing individual consumer issues, and certainly social science studies are done off the sorts of information they collect. Does that hook in with the privacy issues you have addressed here?

Mr VAILE: I am sorry I do not understand what you mean by hooking in?

The Hon. CHRISTINE ROBERTSON: The current practise with some of the award cards is to hook that information together—you get specific ads that relate to your consumer practise, et cetera.

Mr VAILE: The framework of privacy protection and personal information security protection is restricting collection, use and distribution of personal information, that is, information that you can potentially ascertain an individual's identity from for just the purposes that they are used. I mentioned before that the principle of informed and ideally revocable choice, that is usually the gateway that enables the authorisation of people to go into programs or situation where their information is being used for other purposes. I suppose one of my concerns is that the controls around some of those existing practises are relatively weak. I deal with some of the major data aggregators and with some of the privacy regulators around the country and internationally and there is a concern that there is a continual, I suppose, intention between the commercial desire to exploit information and the desire of the individual only to have it used for the purposes provided, and the individual has no particular reason in many cases to value or even permit the sort of reuse of it for other purposes. In those projects there are very stringent controls, for instance, in relation to social science research. Having been through some of the ethics committees at universities, they go to great lengths to control and limit and sort of supervise what those, I suppose, transfers of information are. I suspect, where you have that sort of a research framework around it for certain purposes, then in most cases that protection is enough.

In relation to the commercial loyalty cards, and those sorts of things, some of them are well protected but the majority are not. I suppose my general concern there is that the potential for reuse and distribution of that information both to other companies and outside the country is not obvious to the consumer. It is not necessarily disclosed to them and there is no contract between them and the third party that gets that sort of information. There is a massive market in data aggregation, particularly in the US. We had the Secretary of the House of Congress Commerce Committee talk to us out at the university and describe a very disjointed and fragmentary range of privacy controls in the US, to the extent that they are often ineffective and they often only apply to very

small sort of pockets of data. In the US the relative balance between the claims of industry and government to reuse that information at their discretion, compared to that of the individual, is very much in favour of the former. In the EU, and probably in Australia and many other countries, it is much more towards the centre where there is a reasonable debate between the two claims.

The Hon. CHRISTINE ROBERTSON: In relation to the health record issue that you brought to this inquiry, which really is not about nano, what do you think the privacy protection is? Is it about the health practitioner or the health consumer?

Mr VAILE: I am mostly interested in the perspective of health consumer.

The Hon. CHRISTINE ROBERTSON: You are, yes.

Mr VAILE: In terms of the information, I think it is clearly the consumer. There may be some other issues for the practitioner.

The Hon. CHRISTINE ROBERTSON: The health practitioners are the ones making the fuss, are they not?

Mr VAILE: There is a potential conflict, and there is a real conflict between patients and practitioners over their ownership and rights to information in their medical records, which is effectively unresolved. They won some legal battles giving them more control than consumers would like, but they do not have complete control.

Ms ATTWOOD: I want to clarify the precautionary principle that is most widely accepted in this regard that has been put out by a worldwide group of about 40 different civil societies, public interest and environmental organisations. They have set out eight principles. One is the Precautionary Foundation which states?

> The Precautionary Principle, already integrated into many international conventions, has been described as follows: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically." Such an approach requires preventative action in the face of uncertainty, assigns the burden of protection to those responsible for the potentially harmful activities, considers all alternatives to new activities and processes, and insists on public participation in decision-making.

With regard to nanotechnology, it continues:

> This would include prohibiting the marketing of untested or unsafe uses of nanomaterials and requiring product manufacturers and distributors to bear the burden of proof. Simply, put "no health and safety data, no market."

CHAIR: Do you want to make short comments on anything the committee did not address?

Ms ATTWOOD: I would like to leave with you for your perusal afterwards a copy of the items that are laid down by the Canadian study that I feel would sum up most adequately what the consumer really feels about nanotechnology. If you allow me to do that I will not waste any further time.

CHAIR: Thank you for travelling so far and for appearing before the committee. Your answers to questions are very useful.

Ms ATTWOOD: Thank you very much for your invitation.

(The witnesses withdrew.)

(Short Adjournment)

HOWARD MORRIS, Program Manager, Nanotechnology Occupational Health and Safety Research and Development Program, Office of the Australian Safety and Compensation Council, Department of Education, Employment and Workplace Relations, Australian Government, GPO Box 9880, affirmed and examined:

CHAIR: Thank you for attending this hearing and for your support of the inquiry. If you should consider at any stage that certain evidence you may wish to give or documents you may wish to tender should be heard or seen only by the Committee, please indicate that fact and the Committee will consider your request. If you take any questions on notice today the Committee would appreciate it if your response to those questions could be forwarded to the Committee secretariat by Tuesday 1 July 2008. Would you like to start with an opening statement?

Dr MORRIS: Certainly, I have a brief opening statement. Good afternoon, everybody. As I mentioned earlier I represent the Department of Education, Employment and Workplace Relations. I would like to point out that, as such, the views I express are not provided with the intention of representing the views of the Australian Safety and Compensation Council [ASSC], which is made up of government employer and employee relations representatives, including WorkCover New South Wales. However, we do work very closely with ASSC members. We work in close liaison with them. The Office of the Australian Safety and Compensation Council supports the activities of the ASSC and provides advice on occupational health and safety and workers compensation matters and also undertakes standards reviews, development and implementation.

The Office of the Australian Safety and Compensation Council also coordinates the department's intergovernmental role in occupational health and safety and workers compensation through intergovernmental agencies, such as, the OECD and the ILO [International Labour Organization]. In support of the national nanotechnology strategy, the Office of the Australian Safety and Compensation Council has implemented a nanotechnology occupational health and safety research and development program. This program has Australian government funding up to the end of the 2008-09 financial year to examine and address nanotechnology occupational health and safety issues. I have provided a copy of this program to the Committee this morning. I am the manager of this program and I submit a copy for examination.

The control of emissions containing nanoparticles in occupational settings is not a new subject. For example, there are well-established methods to prevent exposure to welding fume, which contains some nanoparticles as part of the fume. But the objective of our research and development program is to help ensure the effective control of exposures to the expanding range of engineered nanomaterials that are now getting produced and made available and also the increasing number of research laboratories in workplaces where the nanomaterials are being used. Finally, to finish my introductory statement, I would like to thank the Committee for the invitation to appear today and to be able to help and assist with the inquiry.

CHAIR: I will ask the first question. The Committee understands that you have recently attended an International Standards Organization [ISO] meeting on nanotechnology. Can you advise the Committee on the outcomes and implications arising from this meeting?

Dr MORRIS: Yes. I attended the meeting recently on 26 to 30 May with Dr John Miles, a colleague from the National Measurement Institute. John has previously been a witness for the Committee. On the International Standards Organisation [ISO] nanotechnology committee there are now four working groups covering nomenclature and terminology, characterisation of measurement, and health, safety and the environment. There is now a new group, which covers materials specifications. These working groups will develop a range of standards, technical specifications and technical reports. There are now documents being developed across all working groups. A number of new items were proposed at the meeting. There are currently now five projects focused on health, safety and the environment, which is my focus area.

A major outcome of the meeting, which Ms Attwood referred to earlier, was the completion of the technical report on health and safety practices in occupational settings relevant to nanotechnologies. The ISO bodies have now voted to approve publication of the report. I expect it will be published in around two to three months' time. It has been a significant international collaboration, led by Dr Valdimir Murashov from the Nationalist Institute for Occupational Safety and Health in the United States. Through the Standards Australia nanotechnology committee Australia has contributed significantly. My role has been to coordinate the Australian input and help draft a report. In that I got very strong support and input from the Standards Australia nanotechnology health, safety and the environment working group, with members from the Australian Council of Trade Unions, the Consumers Federation of Australia—Ms Attwood, the Plastics and Chemicals Industry

Association [PACIA], the National Industrial Chemicals Notification and Assessment Scheme [NICNAS], Flinders University and the Council of Textile and Fashion Industries of Australia. Our work has also been supported by my colleagues in the Office of the Australian Safety and Compensation Council and all the stakeholders in Australia. The report will assist nanotechnology organisations—by that, I mean both businesses and research laboratories here and overseas—to control occupational health and safety. Also, importantly, the process of development has helped us to become participants in the work in this area and to promote our involvement in other activities.

In terms of other implications or other opportunities for Australia, they lie in the opportunity for us to propose new work items and to lead developments and standards. Therefore, I encourage New South Wales nanotechnology stakeholders who might wish to get involved in the standards development process to do so. Our involvement in the process is voluntary, but it would enable international development and support in areas of interest to Australia, New South Wales, individual stakeholders and organisations. Further important initiatives currently underway lie in the development of a standard list of parameters that should be measured before we look at testing the toxicology of nanomaterials. Thus, we can fully understand the nature of the material before we go ahead and test it. Some of the parameters, for example, are length, width, chemical composition, solubility and surface area.

A further initiative is that the British Standards Institute in Great Britain, BSI, has proposed that its guide for safe handling and disposal of nanomaterials, which is currently publicly available, might be converted into an ISO document and basically made an international document. This would certainly benefit the Australian development process. It would therefore examine and address any issues in the document effectively by becoming an ISO document. It will go through an international peer review in the process. The Office of the Australian Safety and Compensation Council [ASCC] will support Standards Australia and provide input to the proposed document if ISO agrees to the project. Finally, I mention that ISO members present at the meeting also discussed important topical issues such as the recent findings into the possible health effects from multirolled carbon nanotubes.

The Hon. MELINDA PAVEY: The Committee has been advised that the ASCC is working on developing a national position paper on regulating nanomaterials in Australian workplaces and that New South Wales WorkCover has been working with you on that. The position paper is being finalised sometime this month. Can you advise the Committee on the development of this paper and what will occur following that?

Dr MORRIS: The department's office has been critically examining in great detail the issues relating to the regulation of engineered nanomaterials but I think as yet we have not been involved in developing a national position paper on this topic. We have been working with other government agencies on a paper outlining the Government's nanotechnology objectives and approach to the responsible management of nanotechnology which will soon be finalised and released. I anticipate that the Australian office of nanotechnology will coordinate publication, media release and other information about this paper when it is published.

We very much intend working closely with the nanotechnology occupational health and safety reference working group, which includes WorkCover New South Wales, to develop a national position paper relating to regulation of nanomaterials. The office of the ASCC and myself have been in regular contact with officers from WorkCover New South Wales on a number of topics. We are certainly fully aware of the interest and focus WorkCover has in this area, and we look forward to working with WorkCover on the projects on the nanotechnology occupational health and safety research and development program. We most certainly welcome WorkCover's input into the work.

The Hon. CHRISTINE ROBERTSON: WorkCover New South Wales advised in evidence that it joined the newly established ASCC nanotechnology working group. This is much the same line of questioning, but have you gone through the objectives of the working group?

Dr MORRIS: Yes, I can certainly go through that. I have provided the Committee with the draft terms of reference for the group, and I ask that they not be made publicly available because at the moment they are just drafts. WorkCover New South Wales has joined the newly established group and in fact it is a Department of Education, Employment and Workplace Relations reference group, not an ASCC group. Its membership includes representatives from ASCC members, for example, occupational health and safety regulators, the Australian Council of Trade Unions and the Australian Chamber of Commerce and Industry but with relevant occupational health and safety experience and expertise. It also includes representatives from NICNAS and from

the Australian Office of Nanotechnology. I recently set up the group and will be looking to hold the first meeting of the group by mid July.

The Hon. MELINDA PAVEY: Are there any other workplace authority representatives from the other States?

Dr MORRIS: Yes. New South Wales, Queensland, Victoria, Western Australia and South Australia are represented.

The Hon. MELINDA PAVEY: Keep going—I am sorry I interrupted you.

Dr MORRIS: There is a good range of States represented on the group. Broadly speaking, the group will support the implementation of the national nanotechnology occupational health and safety research and development program and provide support for a coordinated national approach to the management of occupational health and safety in nanotechnology. It will provide a forum to develop national positions, which may be proposed to the ASCC for endorsement. It will certainly promote engagement and input from nanotechnology stakeholders. It will be looking to facilitate a coherent, consistent approach across Australian stakeholders, for example, across the States and Territories.

The group will look to support the work of member organisations in managing nanotechnology occupational health and safety, for example, New South Wales WorkCover. It will aim to prevent duplication of, for example, the research and other programs that are underway in Australia. It will certainly examine key issues such as the regulatory framework and manage occupational health and safety regulations. It will promote effective sharing of information. Finally, it will provide advice on privatisation for projects and research focus on the research and development program, and identify new projects for consideration.

With regard to the group, certainly, members are invited to participate or lead projects on the program. I can inform the Committee that Workplace Health and Safety in Queensland will chair the nanotechnology occupational health and safety measurement reference group which has been established to bring together experts to develop Australian capability in measuring exposures of nano particles in the workplace. I have also submitted draft terms of reference for the measurement group. Again, I ask that they not be made publicly available yet as they are drafts.

The Hon. CHRISTINE ROBERTSON: The kind of products that you are interested in and looking at, how are you actually working to define those areas? There seem to be a lot of "nano" products around for decades that have not brought the questions forward.

Dr MORRIS: Yes. Specifically, we will be looking to help manage engineered nanomaterials in the workplace. You are quite right that there have been a lot of nanoparticles around in the air, combustion products produced as incidental nanoparticles and processes for a long time, but specifically the work that I will be focusing on is looking to assist with the management of new engineered nanomaterials. The information on, for example, controlled methodologies, which is known, can be applied to the control of engineered nanomaterials. Conversely, what we find out from looking at engineered nanomaterials should also then be applicable to processes which produce nanoparticles incidentally. So the specific focus is on protecting the health and safety of people from exposure to engineered nanomaterials.

The Hon. CHRISTINE ROBERTSON: So the risk of assessment processes that have to be utilised now because of the lack of a scientific-based knowledge of effect, what do you think of the usefulness of that at the moment when nanomaterials are currently being used in product?

Dr MORRIS: The big issue is that we have currently limited but not zero information about how hazardous nanomaterials might be. It is an issue but our information in this area is growing reasonably quickly. New research results are being published quite frequently across the world so our knowledge is growing. Probably to answer your question, risk assessments cannot be made with absolute certainty because we do not have in-depth knowledge of the hazardous nature of all the particles but we certainly have some information which can be applied to understanding how hazardous the particles are. For example, there is significant more concern about nanoparticles that are insoluble than particles that are soluble. So there are some parameters which we know about that are of greater concern. Similarly when particles are fibre like they raise the concern as well as opposed to ground particles—

The Hon. CHRISTINE ROBERTSON: Because of history?

Dr MORRIS: Because of what is known about the possible health effects from fibres in the past. There are certain properties that we know about that can be applied to understanding the hazards but we need more research to basically grow our knowledge of how hazardous these specific particles are. Indeed, there is quite a range of different types of particles so we would certainly expect them to have a range of different hazardous properties and I do not think it has been found.

The Hon. MELINDA PAVEY: In terms of the position paper that is being developed, will you be specifically getting information from, for example, the CSIRO, which gave evidence to us today in terms of its work on the effect on the environment of zinc and silver? They have done substantial nanoresearch into the particles and the impact they have on our ecosystems. Is that the sort of information you will be putting into your research paper and is that communication happening now?

Dr MORRIS: Certainly. I have fairly regular contact with Dr Maxine McCall, who is the leader of the nanosafety program at the CSIRO. We certainly know about the work that the CSIRO is doing. The CSIRO also accepted the invitation to be a member of our nanotechnology measurement reference group because it is undertaking measurements of nanoparticles in CSIRO laboratories. So yes, the work that CSIRO is doing will certainly be part of the information that we use.

The Hon. MICHAEL VEITCH: Will the research include investigation of the effectiveness of personal protective equipment such as respirators and things like that? Is that the sort of thing you will also be looking at?

Dr MORRIS: Certainly, we are. In fact, we have commissioned a review of the evidence that is currently known for the effectiveness of workplace controls, including respirators. That project is underway at the moment and the contract is due to be completed at the end of June. We expect to be able to publish a report probably six to eight weeks after that on specifically what evidence is available for how effective workplace controls are. Recent work has in fact shown that conventional methods for control of aerosols in various situations are likely to be quite effective for controlling exposure to nanoparticles.

There is work by the National Institute for Occupational Safety and Health and a very, very recent community paper that was published last week—and I have provided copies of these scientific papers—have shown that local exhaust ventilation and process encapsulation, if applied properly, can be certainly quite effective. So, to answer your question, yes, we are certainly working on this topic and we will be publishing a review of the evidence in probably July or August this year.

The Hon. MICHAEL VEITCH: One of our written questions talks about the fact that you have been involved in a number of community forums around nanotechnology. Can you give your feedback to the Committee on the level of awareness of nanotechnologies in the broader community that you have experienced through these forums?

The Hon. CHRISTINE ROBERTSON: And can you add to that how that community forum was put together and who they were?

Dr MORRIS: I have been involved certainly as a speaker in one Australian Office of Nanotechnology public forum; I have been in the audience for a couple of others; and I also participated in the ICON conference in February. So I maybe have got limited experience in this area to draw on but my experience is that public forums are a valuable exercise in community engagement. Part of the reason is that the audience is actually presented with a number of views, like at the Aon public forum there were three speakers: the first speaker covering nanotechnology, applications of nanotechnology and how they are used; then I was talking about occupational health and safety but also about the positive benefits for environmental health and safety from use of nanomaterials; and the third speaker spoke about ethical issues.

I think providing a broad range of views in the forums is certainly very useful. I found the information exchange to be two-way, which was good. For example, at the ICON conference one person raised quite strongly the issue of material safety data sheets and the fact that there are concerns in that area; the fact that they were using carbon nanotubes, but in fact the material safety data sheet had been provided but it was for graphite. Certainly, I think information exchange is very good; it is two ways: we are able to provide information for the audience but also to pick up on issues that are raised. All up, I think the forums do help in raising awareness and

understanding, but I think they need to be supplemented by other work as well to reach a wider audience; for example, to reach the university researchers.

The Hon. MATTHEW MASON-COX: I noted in your introduction you said you are not here on behalf of the ASCC, is that right?

Dr MORRIS: Yes.

The Hon. MATTHEW MASON-COX: So you are here as a Commonwealth employee of the department?

Dr MORRIS: Yes.

The Hon. MATTHEW MASON-COX: And you provide secretariat services to the ASCC, do you, or you provide scientific support?

Dr MORRIS: Probably both. The role is supporting the ASCC in both cases, but it is also a role in working with the Federal Government agencies in the area as well and with other nanotechnology stakeholders.

The Hon. MATTHEW MASON-COX: So do you have much interaction with industry and what is happening at employer-employee workplaces?

Dr MORRIS: In the nanotechnology area at the moment limited interaction. Certainly, on the Standards Australia Nanotechnology Committee there are a number of representatives from industry associations and generally, for example, there are representatives, as I mentioned earlier, from the textile federation; there is a number of representatives that we work with indirectly. We do have input via industry associations. On the ASCC and on reference groups, the Australian Chamber of Commerce and Industry are represented from the nanotechnology occupational health and safety reference group. So we certainly have interaction through the industry associations.

What I see is that in fact one of the focuses over the next 12 months will be to increase our interaction and engagement within industry and research laboratories in this matter, and I think the reference groups we have established will help to promote that liaison, engagement and interaction.

The Hon. MATTHEW MASON-COX: I was wondering what your views were on the regulatory gap, if there is one, for nanotechnologies being used in the workplace?

Dr MORRIS: On that, engineered nanomaterials in the workplace are, in fact, already regulated as a subset of workplace chemicals and, as such, any obligations on workplaces for workplace chemicals generally also applied to engineered nanomaterials, and that covers properties such as hazardous substances, dangerous goods and explosives. So, all three apply. However, saying that, I would also like to point out that the regulatory framework is pretty flexible and can be adapted to cover engineered nanomaterials, but there are regulatory issues associated with engineered nanomaterials. If I could just mention them?

Overall the framework is sound, but there are issues. A number of issues certainly can be derived and come back to our limited knowledge in respect to the hazardous nature of engineered nanomaterials, but knowledge is improving. The first issue is that we need to be able to classify materials accurately, and this requires detailed knowledge of the hazardous nature of the particles. Why is the classification important? Because then it informs the information that we provide for the users of the materials on material safety data sheets and on labels.

Further than that, the knowledge of the chemicals present and the hazards that they pose also determines the need, in certain cases, for organisations to notify authorities, such as occupational health and safety authorities, that these materials are being used, stored or handled. Further, in certain cases, there is also the need for routine health surveillance of workers. So, understanding the hazardous nature of the properties has distinct implications through classification for labelling material safety data sheets and other regulatory requirements.

A second major issue relating to the regulation is that at the moment we only have limited capability of undertaking reproducible workplace exposure measurements. This is a global issue; not just for Australia.

Measurement capability is also needed to measure exposures against workplace exposure standards, and there we have a further issue of the area of establishing meaningful exposure standards for nanomaterials. Another issue, and we mentioned it earlier, is about our understanding of how effective conventional controls are in managing exposures. A further issue we have got is looking at the relationship between reasonably practicable and the precautionary approach in the context of occupational health and safety legislation and nanotechnology, and this certainly needs to be examined. That certainly needs to be examined. That is a summary of the key issues we see in relation to nanotechnology and regulation. Maybe I could go on later to describe the work we are doing to help address these issues.

Where do we go from here with the examination of the regulatory framework? In the Office of the Australian Safety and Compensation Council [ASCC] we have had a look at the overall national framework and will be presenting a paper to the nanotechnology occupational health and safety reference group at its first meeting on this matter. We would suggest that the next step in the examination of the subject might be for the regulators to go away and examine where there may be implications for the specific regulations and codes of practice for nanotechnology.

The Hon. CHRISTINE ROBERTSON: Is the aim that the work you are doing now will actually advise the regulatory process?

Dr MORRIS: Very much.

The Hon. CHRISTINE ROBERTSON: Using the issues that you just delivered.

Dr MORRIS: Yes. This is looking at the overall framework but then we need to look specifically at the regulations.

Reverend the Hon. FRED NILE: Dr Morris, thank you for the research package you have given us as background material. I notice one deals with research in Japan into multi-walled carbon nanotubes. It says that to maintain sound activity on industrialisation of nanomaterials it would be prudent to implement strategies to keep good control of exposure to fibrous or rod-shaped carbon materials both in the workplace and the future market until the biological carcinogenic properties, especially the long-term biodurability, are fully assessed. You mentioned earlier about the tests on the mice showing some similarities between the effect of nanotubes and asbestos. What impact is this research having on the issue of regulating nanomaterials?

Dr MORRIS: The two recent scientific publications that are provided are certainly valuable contributions to our understanding in this area. They basically reported that one type of carbon nanotubes, which is long multi-walled carbon nanotubes with dimensions that are similar to asbestos fibres, can produce reactions that might subsequently progress to mesothelioma in a similar way to asbestos when they are injected into the peritoneal or abdominal cavity of mice. That is the work that has been done with mice and the papers have been submitted. The toxicity and potential implications of long multi-walled carbon nanotubes is an issue of priority for the Office of the ASCC. We have already briefed ASCC members and the nanotechnology occupational health and safety reference group on this matter. I took the opportunity when I was at the International Organization for Standardization [ISO] meeting to discuss this issue with international experts in the area. In that way we will be able to ensure that our response in Australia can adequately protect Australian workers and is also consistent with the international direction. In Australia at the present time I understand that multi-walled carbon nanotubes are handled in a significant number of university laboratories.

I guess the first point to note and stress is that the findings are applicable only to long multi-walled carbon nanotubes. These specific findings cannot be considered applicable to the diverse range of engineered nanomaterials that are being developed or are in use today. Regarding the validity of these studies—and again I asked people about this—it is considered in the Japanese study by Takagi and co-workers that a high dose of fibres was utilised but no issues have been raised in regard to the validity of the work by Poland and his co-workers in the UK and the US.

The Hon. MATTHEW MASON-COX: Has it been peer reviewed?

The Hon. CHRISTINE ROBERTSON: That is what he is saying.

Dr MORRIS: Yes. I think the papers will have been peer reviewed before publication. Certainly in discussions about the British and US paper by Poland and his co-workers no issues in terms of the methodologies or techniques were raised at all.

While the studies do not address whether humans might be exposed to the nanotubes in a way that causes disease, taken together and with consideration of other publications on the toxicity of carbon nanotubes the papers certainly suggest great care should be taken in the handling specifically of long multi-walled carbon nanotubes. The findings also emphasise the need for manufacturers and suppliers to undertake appropriate testing of the new engineered nanomaterials consistent with their duties under existing occupational health and safety legislation. We are in the process of gathering evidence in relation to these multi-walled carbon nanotubes regarding specifically the steps that might lead to mesothelioma formation in a similar way to the steps that occur that might lead to mesothelioma formation from asbestos exposure. Considering those distinct steps, we have some information and I will briefly mention to the Committee what we have found so far. Certainly that information will be added to when the review we have commissioned into toxicology of nanomaterials is available in a couple of months' time.

The first issue is whether processes that use these multi-walled carbon nanotubes can actually produce airborne concentrations of the materials that can then be breathed in by workers. A United States health hazard evaluation by the National Institute for Occupational Safety and Health [NIOSH] from 2006 and the recent Korean study, the papers for which I have provided, have identified airborne concentrations of nanotubes or nanofibres in nanotechnology facilities. These have been identified for some of the processes that have been undertaken but not for others, so it is process dependent. Importantly, in the US study a photo of a fibre above 5 microns in length is shown, whereas in the Korean study the fibres were less than 2 microns long. I mention that because asbestos fibres of above 5 microns in length are reported to be of the greatest concern. That relates to whether the processes can produce airborne concentrations. The second issue is whether the particles will actually be breathed in by workers. United States and Korean reports encouragingly suggest that if conventional control methodologies such as local exhaust ventilation and process encapsulation are used they can be effective at capturing carbon nanotubes. The Korean work, for example, showed that by the application of encapsulation the number of nanotubes in the air was reduced from approximately 190 fibres per millilitre to 0.018 fibres per millilitre. A significant reduction was achieved by the application of encapsulation.

The next question is whether, after they have been breathed in, the multi-walled carbon nanotubes can end up in the lungs. This has been shown to happen in experiments with mice when exposed by whole-body inhalation. The third question—a critical question—is whether the fibres can then translocate from the lungs into the mesothelium, the mesothelial layer, as asbestos fibres do. To my knowledge the answer is not known in respected of long multi-walled nanotubes, and we need evidence on it. There is clearly a need for immediate research on rodents to examine this point.

The final point on this issue is biopersistence, the length of time that the fibres may be in the lungs and the mesothelium. In one rodent study that I have seen the nanotubes were shown to be persistent for up to 60 days in lungs after intra-tracheal administration. Another report that we have has indicated that carbon nanotubes may tend to fracture across the fibres rather than along the fibre, which is the case with asbestos. This might lead to fibre shortening in practice and subsequently to reduced toxicity. Carbon nanotubes also have a tendency to agglomerate and tangle, which also might serve to reduce the likelihood of discrete long fibres or ropes being present.

So will long multi-walled nanotubes get to the mesothelium and be there in sufficient quantity for a sufficient time to lead to possible mesothelioma? This will depend on a heap of factors and we certainly need more information on this process and what can happen to inform us on this matter. We certainly have enough information to suggest that users and manufacturers of the material should use the best possible controls to prevent exposure to long multi-walled carbon nanotubes.

The Hon. MICHAEL VEITCH: So would the recommendation be that those manufacturers using long multi-walled nanotubes should use the same processes as for asbestos?

Dr MORRIS: At the moment we recommend that users of these materials should apply the best possible practicable methods to control exposure until we know more about the extent of the health hazards. We have some information, but by no means a complete picture. We will certainly be working to gather evidence on this matter.

The Hon. CHRISTINE ROBERTSON: Is that quite different from the process of introduction of asbestos all those years ago?

Dr MORRIS: I do not have great knowledge about the introduction of asbestos a long time ago.

The Hon. CHRISTINE ROBERTSON: My husband was a chippy; I do.

Reverend the Hon. FRED NILE: The Korean report mentions what you said a moment ago; that is, the necessity to have very good ventilation. I think there is even a comment about replacing the sticky mats at the entrance to the laboratory or workplace. It would require more expense on the part of the manufacturer to provide that A-grade ventilation system and so to protect the workers. Do you have any comment?

Dr MORRIS: I agree that there will be expense in involved in establishing these controls. However, at the moment we would suggest that organisations use the best practicable means to control. By "practicable" we mean in terms of current understanding of how effective controls are and what they cost, and taking them into consideration.

The Hon. MELINDA PAVEY: For clarification, are we manufacturing carbon nanotubes in Australia or are we just importing them?

Dr MORRIS: I understand that mainly we import the carbon nanotubes into Australia. I have not seen the processes, but I understand that a couple of universities are synthesising some carbon nanotubes as part of their research. I do not know which universities are doing that.

The Hon. MELINDA PAVEY: So we are not into the manufacturing stage yet?

Dr MORRIS: No. I specifically stress that the concerns expressed in recent reports are about the long multi-walled carbon nanotubes, not nanotubes in general and not nanoparticles in general. They are about one specific nanotube.

CHAIR: Would you mind for the record giving the titles of the articles that you have provided?

Dr MORRIS: Yes.

The Hon. CHRISTINE ROBERTSON: So that we can include them in the evidence.

Dr MORRIS: I provided four articles. The first article is a National Institute for Occupational Safety and Health evaluation report dated October 2006. The reference is "HETA #2005-0291-3025. The second paper is entitled "Inhalation Toxicology: Monitoring Multiwalled Carbon Nanotube Exposure in Carbon Nanotube Research Facility". The authors are J. H. Han and co-workers. The third article was published in the *Journal of Toxicological Science*, volume 33, No. 1, page 105 to 116 of 2008. It is entitled "Induction of mesothelioma in p53+/- mouse by intraperitoneal application of multi-wall carbon nanotube". The authors are A. Takagi and co-workers. The final paper is "Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study". The authors are Craig A. Poland and co-workers.

CHAIR: Thank you. Would you like to make any further comments? Would you like your notes to be part of our evidence?

Dr MORRIS: I will review them, because they have only recently been prepared.

CHAIR: We will take that on notice.

Dr MORRIS: I will certainly be able to provide some notes. It is worth mentioning that there is likely to be a large number of instances in which the application and use of engineered nano materials will not present any particular hazards to people. For example, if they were embedded in this glass, that piece of wood or that book, they would be unlikely to present any hazards to people. However, if someone were to sand that wood, the particles could be released and there could be hazards. In many cases there may not be any hazards associated with the use of these materials. Certainly, we expect a range of hazards associated with the materials depending upon their nature—whether they are soluble or long fibres. There is likely to be a range of hazards associated with the materials. As I mentioned, our work in the area of occupational health and safety will be looking

specifically at helping to protect the health and safety of workers from these new, engineered nano materials that are used. Thank you for the opportunity to assist the inquiry.

CHAIR: Thank very much. Thank you for your time.

(The witnesses withdrew.)

(Luncheon adjournment)

JAMIE WALLACE NICHOLLS, Regulatory Strategy Project Officer, Australian Pesticides and Veterinary Medicines Authority, and

PHILIP THOMAS REEVES, Principal Scientist, Australian Pesticides and Veterinary Medicines Authority, sworn, and

JAMES PATRICK SUTER, Acting Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority, affirmed and examined:

CHAIR: If you should consider at any stage that certain evidence you wish to give or documents you may wish to tender should be heard or seen only by the Committee, please indicate that fact and the Committee will consider your request. If you take any questions on notice today the Committee would appreciate it if the responses to those questions were forwarded to the Committee secretariat by Tuesday 1 July. Would anyone like to make a short opening statement?

Mr SUTER: Yes. Thank you for the opportunity to present to the inquiry. From the perspective of Australian Pesticides and Veterinary Medicines Authority, we are encouraged that the New South Wales Parliament's inquiry into nanotechnology allows government agencies such as us to demonstrate the efforts that we are putting into this area. Our interest relates primarily to the regulation of nano forms of agricultural and veterinary chemicals in Australia. We do that under the National Registration Scheme that was established in 1995 by an intergovernmental agreement. Under that agreement the Commonwealth, State and Territory parliaments agreed to establish a framework to regulate the manufacture, supply and use of what we call agricultural veterinary chemicals, or AgVet, in this country.

Our role is to regulate the manufacture and supply of these chemicals up to and including the point of retail sale, and each state and territory is then responsible for the use of those chemicals in their jurisdictions. The main piece of legislation under which we operate is the AgVet code. It is the law of the Commonwealth that applies concurrently to each State and Territory throughout the country and it makes provision for the evaluation, registration and control of AgVet chemicals. In establishing that arrangement the respective parliaments acknowledged: that the protection and the health and safety of human beings and animals are enhanced by putting in place a regulatory system for these chemicals; that the principle of ecologically sustainable development requires a regulatory system so that the use of chemicals today will not impair future generations; and that, as a country, we need to further trade in commerce between Australia and places outside Australia. To do that we need a viable, primary industry sector and a good domestic manufacturing sector for chemicals

The parliaments also acknowledged that we should establish a regulatory system and that, so far as practical, it should be uniform, provide certainty, and be predictable, adaptive and responsive as technology changes. The four areas on which we would like to concentrate are: firstly, our regulation of AgVet chemicals; secondly, our regulatory environment, which can be quite complex; thirdly, our participation in a whole-of-government approach to nanotechnology; and, finally, our key initiatives at the Australian Pesticides and Veterinary Medicines Authority. As I said earlier, we regulate the manufacture and supply of what we call AgVet chemicals, which fall into two classes: agricultural chemical products and veterinary chemical products. These are statutory definitions.

The definition of agricultural chemical product is extremely wide and includes herbicides, insecticides, fungicides, dairy cleansers used on farms, crop markers, urban pest control products, termiticides, effects of insect repellents on humans, swimming pool disinfectants, algaecides and household and home garden products used in pest and weed control. It does not include fertilisers. Veterinary chemical products have a similarly wide statutory definition and include any substance that is administered to an animal to prevent, diagnose, cure, or alleviate a disease, condition or infestation, or to modify its physiology. Typical examples are: vaccines antibiotics, anaesthetics, endoparasiticides, ectoparasiticides, and some vitamins and minerals.

Currently, there are 5,657 registered agricultural products and 3,281 registered veterinary products, which gives you some indication of the size of the market. We operate in a fairly complex regulatory environment. We are one of the Commonwealth-State cooperative bodies and we have a diverse range of stakeholders relating to the chemical industry, farmers, farm workers, the general community, consumers, State and Territory governments, and our international regulatory counterparts such as the United States Environment

Protection Authority, or the United Kingdom Veterinary Drugs Directory. We have a wide consultation regime with our stakeholders.

We have a number of formal committees—a community consultative committee, an industry liaison committee to liaise on matters of policy, an industry technical committee that settles on technical matters such as guidelines, and the manufacturers licensing committee for manufacturers of veterinary chemical products. We also have a registration liaison committee—a committee between us and our State and Territory counterparts—to make improvements to the National Registration Scheme. Our input into the national nanotechnology strategy includes a number of initiatives. We see ourselves as an active participant in the whole-of-government initiative. The way we see it, the national strategy provides an approach that will assist in the development of a nanotechnology industry and address safety implications. It brings research bodies, the community and governments together.

From a regulatory perspective, as one of Commonwealth's regulators, a key priority of the strategy is to review the impact of nanotechnology on current regulatory frameworks, including our own. We have developed our own roadmap of activities to progress the regulation with nano forms of technology for AgVet. We realise that this technology is moving at a pretty fast pace and there is a pressing need for us to ensure that we have our regulatory processes in place to receive applications for nanomaterials. It is a bit challenging in that, as I understand it, there is not yet an internationally agreed and accepted definition of nanomaterial. Given that it is an emerging technology, there are some knowledge gaps around it.

We have created a dedicated staff position to review our current procedures for making applications to us, to review our existing regulatory framework and data requirements, to undertake a stocktake of existing registered products with the AgVet industries, and also staff training. That position is filled by Dr Jamie Nicholls. We are an active participant on the national Nanotechnology Interdepartmental Committee, the Health and Safety Environment Working Group, and we have an input into the Commonwealth's position papers through our host department, the Department of Agriculture, Fisheries and Forestry. We also see a need to raise public awareness through the national Nanotechnology Communications and Public Awareness Network and we will be assisting in that with the provision of information about nanotechnology and AgVet chemicals. I realise that that is quite a mouthful, but I thank you for giving me a chance to make an opening statement.

The Hon. MELINDA PAVEY: The Committee understands that Australian Pesticides and Veterinary Medicines Authority, along with other relevant agencies, is reviewing existing regulatory frameworks to ensure that they appropriately address the impacts of nanotechnology. Can you advise the Committee on the progress of your review and any indicative outcomes to date?

Dr REEVES: The Australian Pesticides and Veterinary Medicines Authority recently commenced a review of the existing regulatory framework to determine whether it is suitable for the regulation of nano forms of AgVet chemicals. Without wishing to pre-empt the findings of that review, the Australian Pesticides and Veterinary Medicines Authority believes that the existing regulatory framework, albeit with relatively minor amendments, will be suitable for nanomaterials. Based on our preliminary work, and in consultation with other Australian Government regulatory agencies, it appears that at least two aspects of the existing regulatory framework will be worthy of special consideration. These are the risk assessment protocols and the regulatory triggers.

The existing legislation has provisions for assessing the compositional form of both the active constituents and AgVet chemical products. In practical terms, this means that the conventional form and the nanoform of an active constituent or of an AgVet chemical product may be assessed as distinct chemical entities or chemical products. Different risk assessment protocols may then be applied to the conventional form and the nanoform, if that is necessary. We expect that this scenario will arise quite often, especially in situations where product formulations are altered by replacing a conventional form with the nanoform of the chemical in order to achieve an improved efficacy profile. From a workflow perspective, the conduct of the differential risk assessments depends on the nanoapplications being identified early, and in this respect we are revising our application requirements in order to identify those nanoapplications at the time the application is lodged.

The second important consideration that I mentioned was to ensure that the risk assessments in the existing regulatory framework are triggered by the nanoforms of AgVet chemicals. It would appear that refinement of the existing regulatory framework to ensure the regulatory triggers are suitable for nanomaterials may require one amendment to the regulations. Under the intergovernmental agreement, the amendment process cannot be undertaken by APVMA in isolation but will involve participation of State, Territory and Australian

governments. What I am referring to, currently there is a situation where the regulations allow trial work without regulatory approval for quantities of veterinary chemicals of up to three kilograms or agricultural chemicals up to six kilograms. Clearly, if we were dealing with nanoforms of those materials, we would want to revisit those trigger points.

Finally, refinement of the existing regulatory framework to accommodate nanoforms of AgVet chemicals will rely heavily on the exchange of information at both the national and international levels. At present, agencies of the Australian Government, including us, actively participate in the work of the OECD, which contributes to the hazard and the risk assessment practices by developing and harmonising assessment methods. Of particular interest to the APVMA is the work of the working party for manufactured nanomaterials, which is testing a representative set of industrial chemicals. Much valuable information on the safety of nanomaterials will be generated by using predictive modelling by that project and similar projects.

The Hon. CHRISTINE ROBERTSON: So this issue relies a lot on accurate or honest labelling and issues of commercial in confidence—the issue of knowing whether it is a nanoproduct?

Dr REEVES: Yes, that is correct. Basically what we have done very recently is revise our application forms, both the paper version and the electronic version, so that the applicants are asked a simple question about whether their product contains a nanomaterial or not. That is going to flag to us whether there is a need for a special sort of evaluation simply because we are aware that nanomaterials will require different risk assessments to the conventional chemicals.

The Hon. CHRISTINE ROBERTSON: So, does the lack of definition of nano cause disruption to this issue for you?

Dr REEVES: It does. There are many definitions of nanomaterials. For example, we have adopted the OECD definition of a nanomaterial, which essentially has three criteria. One is that it must be engineered as opposed to naturally occurring. Secondly, the size of it should be less than 100 nanometres and, thirdly, it should have novel toxic properties which are attributable to the size. So, by the time you bring those together we have that definition, and that is the one we are working to. The United States has a definition which is just less than 100 nanometres. The United Kingdom has less than 200 nanometres. Friends of the Earth propose that it should be less than 600 nanometres. So, clearly from those answers and those definitions it depends entirely on what definition you are using as to what the current status is of nanomaterials in the country, for example.

Reverend the Hon. FRED NILE: We understand the national industrial chemical notification assessment scheme is responsible for assessing industrial chemicals, which could include agricultural and veterinary products. What reference or use does your authority make of its assessments and, if the National Industrial Chemicals Authority reassessed such a chemical, what implication does is have for the Therapeutic Goods Administration?

Dr REEVES: A major objective of the risk assessment of industrial chemicals conducted by the national industrial chemical notification assessment scheme [NICNAS] is the protection of Australian people and the environment. Industrial chemicals for this purpose do not include chemical substances that are used solely as pesticides or veterinary medicines. However, some industrial chemicals are used as active constituents in pesticides or veterinary medicines as well as for industrial chemicals. Biocides are a good example. Biocides are chemical products such as sterilisers and disinfectants designed to kill unwanted organisms. A more common occurrence of that cross-over use is seen with the excipients or the non-active ingredients. Many of these have been assessed by NICNAS and/or they are listed on the Australian inventory of chemical substances by NICNAS as industrial chemicals. They are also used as excipients in AgVet chemicals. So, for both active constituents and non-active constituents that demonstrate the cross-over use, use is made of the NICNAS risk assessment reports pertaining to toxicology and environmental studies if they are available.

A good example is surfactants, which are the surface-active agents. Many surfactants have a very wide range of applications. For example, we would use them in washing clothes. We also use them as wetting agents in pesticides formulations such that a leaf surface is wetted to increase penetration of pesticides through the wax or hairy-leaf cuticle and into the leaf. The environmental risk assessment reports prepared on these chemicals for NICNAS are considered by APVMA when the surfactants are subsequently used in pesticides. It is important to recognise, however, that when reports are sourced from NICNAS, or from the Therapeutic Goods Administration for that matter, to reduce the duplication of assessment and to arrive at a concordant decision across regulatory agencies, even though the APVMA may use the hazard assessment, it will invariably be

necessary for us to undertake a risk assessment. This is because the risk outcome is dependent on the use as well as the exposure to the chemical.

These parameters are often poorly defined at the time when an industrial chemical is assessed, but very well-defined for agricultural or veterinary chemical products. Therefore, even if the chemical has been assessed by another regulatory agency, a separate consideration of risk will invariably be required by the APVMA. If in reassessing an existing product NICNAS reports a change to the hazard status as you suggested, or for that matter a change to the level of risk to human health and safety or to the environment, this information is taken into consideration by the APVMA, who may review and possibly reconsider the registration status of that product.

The Hon. MATTHEW MASON-COX: What is the scientific capacity of your organisation to assess nanomaterials and products?

Dr REEVES: Currently the capacity is quite low. To better understand the situation you need to appreciate that we are primarily concerned with public health and safety issues to the environment. We actually outsource our assessments to the Department of Health and Ageing for public health assessments and to the Department of the Environment, Water, Heritage and the Arts for environmental assessment. Even though our capacity in-house is relatively low, particularly at the present time, we rely quite heavily on outsourcing.

The Hon. MATTHEW MASON-COX: How many chemicals registered with you are actually using nanoparticles—perhaps as a percentage of what you would normally have registered? You have 3,000-odd registered chemicals, so how many would be using nanoparticles?

Dr REEVES: It really comes back to the issues of definitions that we discussed earlier.

The Hon. MATTHEW MASON-COX: Assuming the OECD definition?

Dr REEVES: If we use the OECD inflation, which we do, the answer is zero.

The Hon. MATTHEW MASON-COX: If you use the "I have a small particle type definition" what sort of percentage would you end up with?

Dr REEVES: We are well aware of one report that says that we have registered one pesticide, which is said to be a nanoemulsion. If you use the definition of a nanomaterial with a dimension in one or more dimensions of, say, 600 nanometres, I think that would probably be correct.

The Hon. MELINDA PAVEY: From whom was that report?

Dr REEVES: Friends of the Earth.

The Hon. MICHAEL VEITCH: What sort of occupational health and safety [OH&S] protocols do you have in your workplace when you conduct the assessment of a chemical?

Dr REEVES: The application for all new active constituents and new products requires data across 10 areas, one of which is OH&S. Again, we do not do the assessments in-house; they actually go to the Office of Chemical Safety in the Department of Health and Ageing, which does both the public health, the toxicology, as well as the OH&S assessment.

The Hon. MICHAEL VEITCH: You are talking about the current chemicals you have on your register. Do you keep an eye on what is coming in, any new chemicals from overseas for instance, having been researched or used in the field?

Dr REEVES: Yes, we do. That is a very important aspect. The first thing we did in 2007 was ask the question of our industry liaison committee have they any knowledge of any nanomaterials being manufactured or being imported or being in the pipeline, and the answer was none at all. We intend doing a call for information to the industry within the next couple of months actually. I should make a point on that. We can ask the question of industry are they manufacturing nanomaterials. The answer is zero, however, I think we need to be very well aware that they might actually buy in that information from universities or other small research institutions. So, what I am saying is that we can go from a base of zero with a sort of exponential swing very

quickly. So, we have to be prepared. That is a possibility. So, now, instead of just asking industry, we need to widen our question and ask some of the research organisations as well.

Mr SUTER: I would add also that for new compounds we do what is called international work share. So, if one of the major multinationals wants to release a new compound, whereas they require a separate assessment in, say, Canada, the European Union, the United States and then here, we do various components of it. I suppose in this country the history is that we usually see these compounds come in much later when they are registered in the United States and the European Union because that is where the markets are. But these international work shares give us exposure, I suppose, to the technology that has been introduced into the bigger markets. That is an avenue where, if there is a new active that is going to have nanomaterials in it, we will probably be alerted to it earlier.

Dr REEVES: Perhaps I should add that the OECD is also surveying other countries on that very point and we are actively participating in that. So, we hope to get additional information from overseas.

The Hon. CHRISTINE ROBERTSON: In your work can you define for us hazard assessment and risk assessment as differences?

Dr REEVES: Sure. I can provide a very simple example. Obviously, we normally define risk as the product of hazard and exposure. Of course, you have to understand the hazard, which is the inherent danger or properties of a chemical. Once we have decided that, it depends on whether you can actually regulate the exposure, whether it is through the skin, inhalation or ingestion, as to whether that hazard is realised and becomes a risk. That was my point earlier about the hazard assessment that is conducted by the National Industrial Chemicals Notification and Assessment Scheme [NICNAS], for example, up to that point. However, the Australian Pesticide and Veterinary Medicines Authority [APVMA] knows exactly the specified use for a product when it comes in for registration. So, we have these risk-based labels, whereas some organisations have hazard-based labels simply because at the time they do the assessment they are very well aware of the hazard but they have no idea exactly where the chemical may be used. It may have many industrial uses. So, they cannot do the risk assessment part.

The Hon. CHRISTINE ROBERTSON: A topical chemical ingested changes it from hazard to risk—the risks are after ingestion? It could possibly be poisonous if ingested, is that an example?

Dr REEVES: Yes.

The Hon. CHRISTINE ROBERTSON: "Must not be swallowed"?

Dr REEVES: Yes. So, what you are doing by not swallowing is reducing exposure to the oral route. Likewise, if you wear personal protective equipment, you would reduce exposure to the topical route.

The Hon. CHRISTINE ROBERTSON: If research was to show health or environmental concern regarding a nanoversion of a chemical included in currently registered products, what actions are open to the APVMA for reassessment or product recall? Also, was your organisation responsible for the decision regarding Dieldrin? That is the process that this inquiry is all about, is it not?

Mr SUTER: The short answer to that question is yes. We have a range of actions open to us. We can suspend a product, cancel a product, recall a product, or have a product declared as a prohibited import if need be. For products that are registered, the question for us is the trigger. So, we can issue a recall right across the supply chain down to end-user level, and that can take a range of forms. It can just simply be a notification to users or it can be a full product market recall that leads to the product being returned and destroyed. The triggers really are that we have to be satisfied that there is either some undue hazardous safety of people—there is going to be an affected sample to environment or humans, it might be an unintended effect on the environment or there might be some risk to trade. Once we are satisfied of those things, then we have a range of powers. Our experience has been that we really have to balance the exercise of the power with the circumstances that are before us.

The tests for suspension, cancellation and recall are pretty much the same. It is pretty much an evidence-based test for us, so we would need something before us to show that it can happen. These powers that we have, they are in addition to the recall powers that exist under the Trade Practices Act. I suppose the question is: Do we think that our framework of powers is adequate? We would say yes, they are. Where we have some

frustration is that each time we exercise them, they are reviewable in the Administrative Appeals Tribunal. We might have health and safety risk and usually the person against whom we are taking the regulatory action invariably ends up with a stay of proceedings and our regulatory action is thwarted somewhat.

When you talk about whether the tools are adequate, you also have to look at who can review your use of those tools. We can reconsider the registration of something. We can reconsider the registration of existing product, we can reconsider the approval of a label and we can also reconsider the approval of an active constituent, so we can target either or any combination of those things. We do have an ongoing, existing chemical review program and the outcomes of that are: if it is shown to be really bad, then registration ends.

If it needs to be removed from the market, then we remove it. It might be sufficient, just for example, to change the way the chemical is used, which results in a label change or it might be that we can say it is okay if further protective equipment is worn. If the question is: Could we get a nanoversion product off the market where there was the demonstrated health and safety concern? Yes, we would have the tools to do it, though I add the caveat that each time we exercise these tools the Administrative Appeals Tribunal has a right of review.

The Hon. CHRISTINE ROBERTSON: And you are not going to tell me about Dieldrin?

Mr SUTER: I was not there then, but it would have been us.

The Hon. CHRISTINE ROBERTSON: That was my question because that is the process. It was registered and withdrawn.

Mr SUTER: With existing chemicals like that—and this might sound a bit strange—sometimes the safest way to dispose of them is to actually use them.

The Hon. CHRISTINE ROBERTSON: Just like the farmers did.

Mr SUTER: Because in Australia we do not have the high temperature destruction facilities that other countries have.

The Hon. MATTHEW MASON-COX: In relation to your comments about the existing regulatory framework, I think you said that they were okay, although there were some assessment protocols and regulatory triggers that you would like to have perhaps reviewed or refocused to deal with nanosized products. Could you take on notice and provide the Committee with more specific detail on the triggers and that whole area so that we can be sure we are across the regulatory side and where you consider there to be potential problems? The other question was in relation to how you define nanomaterials on your registration form. I presume there is a registration form that is sent in to you that someone fills in, electronically or on hard copy. Could you provide us with a copy of that and, specifically, do you provide any guidance in that form as to what constitutes a nanomaterial in your definition? You mentioned the OECD definition but is size enough in relation to that form in the sense, is it a nanosized material? Is that sufficient to warrant that form to note it is nanomaterial or do you actually say to them, "The OECD definition of a materially is 'bang, bang, bang'. If you are in that area, then fill in this part of the form." I just want to understand that process in a bit more detail. Please take those questions on notice. You mentioned about the Administrative Appeals Tribunal, the stay of proceedings and some frustration in that regard. Can you elucidate that a little bit more? Are there valid grounds here or is it just because your legislation is drafted too widely? What is the nature of your concerns?

Mr SUTER: We can take regulatory action against a product for a range of reasons. One reason might just be that it is not registered. It is perfectly safe but it is not registered, and in order to establish the level regulatory playing field for those who do abide by the rules, we should stop supply of that product. It is part of our regulatory function. That product is not dangerous but in terms of the credibility of the regulatory system, there is an unfair market advantage. In circumstances where we have done that, our track record in the Administrative Appeals Tribunal has not been strong. Usually the applicant gets a stay of proceedings, a right to continue to sell their product. Where no public harm has been demonstrated, it is almost impossible for us to stand on our digs and say that a stay should not be granted.

In some ways that might be fair enough. However, where there is a product that does cause harm, we do not take recall decisions lightly because usually you are affecting someone's business; you might be putting their employees out of work through no fault of their own. Where harm is demonstrated, such as the thing is carcinogenic or, in one example, completely ineffective and leads to crop damage or personal damage, we think

the commercial balance of the right to continue to sell that product that might have existed is outweighed by the public health component. Sometimes we have trouble persuading the Administrative Appeals Tribunal to err on the side of public health caution.

The Hon. MATTHEW MASON-COX: Do you then take those sorts of cases to the Federal Court by appeal?

Mr SUTER: We are actually in the Federal Court today in Perth on a similar matter, yes.

CHAIR: Do you have any further comments you would like to make before we close?

Mr SUTER: No.

Dr REEVES: No.

Dr NICHOLLS: No.

CHAIR: On behalf of the Committee I thank you for your time and evidence here today. Please provide any answers to the questions taken on notice by 1 July 2008. That would be much appreciated.

Mr SUTER: We will.

(The witnesses withdrew.)

MICHAEL ROBERTS, Director, Research Unit, University of Queensland, sworn and examined:

CHAIR: If you consider at any stage that certain evidence you wish to give or documents you may wish to tender should be heard or seen only by the Committee, please indicate that fact to the Committee and we will consider your request. If you take any questions on notice today, the Committee would appreciate if the response to those questions could be forwarded to the Committee secretariat by Tuesday 1 July 2008. Would you like to make an opening statement before beginning questions?

Professor ROBERTS: My only statement is that I do not regard myself as a nanotoxicologist. I am actually what I would call a routine pharmacologist and toxicologist. I was asked and I did speak at the United States Food and Drug Administration [FDA] session on nanotoxicology last year basically to try to present the scientific overview. There is a lot of information out there which I think is misleading and actually sometimes creates anxiety, which it should not, and we need to have a balanced and objective overview in terms of what we do which should be scientifically based.

CHAIR: During the inquiry, the Committee has been advised that you have undertaken a considerable body of work that is internationally regarded on the penetration of nanoparticles through the skin. Has your recent research indicated any concerns or issues regarding the application of nanoparticles to the skin?

Professor ROBERTS: Can I ask the question: What is the possibility of doing that in camera, in the sense that we have not published some of the findings that we just have now recently got? If they are released, then basically it will affect publication per se. In other words, we have only found these in the last two to three or four months.

CHAIR: Okay.

The Hon. CHRISTINE ROBERTSON: I move:

That the Committee resolve to undertake an in camera segment of the inquiry forthwith.

Motion agreed to.

The Hon. CHRISTINE ROBERTSON: Professor, do you have any idea how long your in camera evidence would take?

Professor ROBERTS: Probably two minutes.

CHAIR: All right. We will clear the room.

(Evidence continued in camera—see separate transcript.)

(Conclusion of evidence in camera.)

(Public hearing resumed.)

The Hon. CHRISTINE ROBERTSON: Are there standards in place for toxicity assessment that can be applied to nanomaterials and is there a range of methodologies for tracking nanomaterials or nanoparticles when assessing their toxicity, and if so does this pose any problems?

Professor ROBERTS: All research poses problems—I would not be game to suggest there were no problems with any research—and nanoparticles are no different. I think there are standards in place. I think the big thing to be recognised with nanoparticles is that they have what is called soluble and insoluble nanoparticles and they need to be thought about differently; they are not exactly the same. In that area, probably the most important thing we have to get sorted is quantification of the measurement or characterisation of the properties of nanoparticles—that is, the size, the charge, the surface area, and the intrinsic toxicity.

The Hon. MICHAEL VEITCH: Some of the submissions have put forward the view that toxicology research with regard to nanoparticles should focus on things that are close to commercialisation or have a view towards commercialisation. Is that a view you would hold?

Professor ROBERTS: No, it is not, because I am a researcher. Let me explain. We are working on things like vaccines. With regard to vaccines, you probably will not find too many people actively on it, but we would probably want to deliver those. They are nanotechnologies. They should not be missed out on in this process. You will find that other researchers are working on other types of nanotechnologies which are probably not in what I would call the commercial or mainstream research phase. You should not limit yourself. It is a bit like Fleming with penicillin—sometimes the serendipity products are the ones that take over. You cannot necessarily judge what the products will be.

The Hon. MICHAEL VEITCH: What sort of national coordination is there of toxicology research to ensure duplication is not taking place within the research sector?

Professor ROBERTS: The major organisation for all pharmacologists and toxicologists is called the Australasian Society of Clinical and Experimental Pharmacology and Toxicology [ASCEPT], which I think was founded in about 1978. It has a number of sections, including toxicology, clinical toxicology, and a range of others. It also has this occur in every State. As a professional organisation, it is probably the organisation that looks after all the members in that area.

The other key organisation is probably the National Health and Medical Research Council, which has key roles. I sit on its task force or advisory committee in nanotechnology. It has a clear role in terms of safety standards, as it does with other things, and it is the major supporter of research in this area, that I know of.

The Hon. MICHAEL VEITCH: Obviously that research has to take place utilising infrastructure?

Professor ROBERTS: Yes.

The Hon. MICHAEL VEITCH: Does the infrastructure in Australia meet the requirements of the current levels of toxicological research?

Professor ROBERTS: I think in all areas you would find some area where it does not quite meet the levels. For instance, we built a flexing machine. One of the questions asked is: If you flex your skin, does it penetrate? There is no equipment in Australia. I spoke to Sally Tinkle, at NIA, the one who did the flexing work. So we built this machine from scratch. It allows us to take excised skin and move it backwards and forwards. It is basically a matter of, you have to do with what you have and then try to make it fit.

The Hon. MICHAEL VEITCH: Is that machine available anywhere in the world?

Professor ROBERTS: We made it. I know that one of my colleagues in the United States has made a very similar one, a person called Nancy Montario, who I do collaboration with. She has made a similar machine, but she is doing work on pig skin whereas I am working on human skin.

Reverend the Hon. FRED NILE: Are you creating human skin?

Professor ROBERTS: We have two lots of human skin. One is in vivo, which is from patients, so we are looking at various conditions. We often use what is called breast reduction skin, from someone who has surgery, or abdominoplasty, when they remove skin. We take that from elective surgery with ethical approval and we study what happens to material on that human skin.

Reverend the Hon. FRED NILE: It is possible to make skin, though, is it not?

Professor ROBERTS: Yes. We do make cultured skin, but in my view that is not a good representation of human skin, in the sense that the stratum corneum is not usually properly formed and not as well formed as you see in the skin in vivo. It is getting close, and some of my colleagues are actually doing it, but it is not as good yet.

The Hon. CHRISTINE ROBERTSON: The New South Wales Government has suggested that perhaps different toxicology or nano research groups should be set up. Do you think it is a good idea for State-based groups to come into existence, or do you think it would be better to have Australia-wide—?

Professor ROBERTS: I think the way ASCEPT works, it has individual State chapters. I cannot see why we do not use those chapters. For instance, I am working with people in Perth, Adelaide, Melbourne, and

with some people in Sydney because we have a complimentary and alternative medicine centre grant. We work across all those States. I do not think we should be seen as a State-based thing but, rather, a national thing. There are people in other States who have better expertise in areas than I do, which is why we work together. We are a small country in population terms, and we have to maximise our resources by working together, not trying to work in silos.

The Hon. CHRISTINE ROBERTSON: How much sharing is occurring in this area?

Professor ROBERTS: I know that we put in an NH&MRC grant, which certainly went across the area. The NH&MRC grant which I currently have regarding nanotechnology involves people from the TGA, people in my university, it has some input from people in San Francisco, some input from people in Germany—

The Hon. CHRISTINE ROBERTSON: Is there more chance of your winning that grant if it is a joint program?

Professor ROBERTS: I cannot say. If you are going to judge a project, you want to judge whether it is going to have an impact. One of the key questions is: Is there a wow to the grant? So it is not just a track record and the idea, but: Is it going to make a difference? I think for funding bodies you have to look at that. Some things we are addressing—I think that is why we got funded—are important issues. We are addressing wider sunscreen penetration into skin in vivo. We did not know that previously. So that is actually important. I think that is one of the reasons why we got funded, because these grants are very hard to get.

CHAIR: Do you have any further comments to make?

Professor ROBERTS: In relation to question No. 3?

CHAIR: Is there anything further that you would like to tell the Committee?

Professor ROBERTS: The only other comment I would make is that one of our grants is from the US air force, which came to us with funding. I think one of the other things we should be doing is encouraging funding internationally back to Australia in the areas where we have some competence and skills. I think that is really important.

Reverend the Hon. FRED NILE: What does the US air force want you to find out?

Professor ROBERTS: You asked about silver. They are interested in all the air force materials, including silver and a range of other things, that are toxic that air force people might be exposed to, and their reactivity. There is a problem of funding within Australia. We have not actually applied anywhere in Australia for that sort of funding. But they came to us and we applied through their system and got one of their grants. I think the only other comment I would make is that you asked about how best to coordinate toxicology research nationally. I think that is where the NHMRC once again has a key role, because then it is peer reviewed and basically is not dictated by any particular interest group.

CHAIR: Do you have any thoughts on whether there should be a moratorium on nanotechnology, or do you think that would be a backward step?

Professor ROBERTS: Why do you want to have a moratorium?

CHAIR: We have heard evidence to that effect.

The Hon. MELINDA PAVEY: It is one of the recommendations of Friends of the Earth and the Australian Manufacturing Workers Union.

Professor ROBERTS: I had this experience when I was in the US. I do not know whether this is relevant, but Friends of the Earth spoke before me and I spoke after. They had based all their data on studies done with pigskin. I presented all the human skin data to show that there was no penetration through human skin but there was through pigskin. Then they said to me that they did not realise that human skin and pigskin were any different. So that was the basis for their whole argument. Once again, it is a question of: What are the objections? If the issue is hazard reduction—you have not got proper exhausts or whatever—then you need to

look at the workplace situation. But I am not sure what the basis is for having a moratorium, and you have not given me a good reason to support it.

CHAIR: Two groups of previous witnesses suggested that that should happen. I want to see what you think about the issue.

Reverend the Hon. FRED NILE: We are not promoting a moratorium.

CHAIR: We are not suggesting we do that; we are just asking for your thoughts.

Professor ROBERTS: As I said, I cannot see any reason why, for instance, zinc oxide creams should be withdrawn from the market. I am in the skin cancer capital of the world in Brisbane. We have the highest incidence of skin cancer anywhere in the world. The last thing I want to do is try to discourage someone from using a sunscreen that is aesthetically appropriate. That would be crazy. The hazards from the cancer are much worse than using the product.

CHAIR: Thank you very much for your time.

Professor ROBERTS: I hope it has been of some value.

The Hon. MELINDA PAVEY: But if the properties of the zinc, the blockout, involved another chemical—

Professor ROBERTS: My biggest worry is quantum dots, which people are using all the time because they are very highly fluorescent. In its inner core it has cadmium. That is why I am saying look at the intrinsic toxicity. If you are using materials that are intrinsically toxic that is what you have to be careful of.

CHAIR: Thank you very much for travelling so far to give evidence before the Committee.

Professor ROBERTS: I hope it has been helpful.

CHAIR: I am sure that it has.

(The witness withdrew.)

MARION JOY HEALY, Director, National Industrial Chemicals Notification and Assessment Scheme, GPO Box 58, Sydney 2001, and

MATTHEW GREDLEY, Team Leader, Reform, National Industrial Chemicals Notification and Assessment Scheme, GPO Box 58, Sydney 2001, affirmed and examined:

CHAIR: Welcome to the inquiry and thank you for your presence here today. Before we begin, if you should consider at any stage that certain evidence you wish to give or documents you may wish to tender should be heard or seen only by the Committee, please indicate that fact and the Committee will consider your request. Also, if you take any questions on notice today the Committee would appreciate it if the responses to those questions could be forwarded to the Committee secretariat by Tuesday 1 July.

Dr HEALY: Sure.

CHAIR: Would either of you like to make a short opening statement?

Dr HEALY: What we would like to do by way of an opening statement is run through about half a dozen or so slides. You have a paper copy of them in the information pack. The purpose is to set out in a structured way where the National Industrial Chemicals Notification and Assessment Scheme [NICNAS] sits in the overall scheme for the assessment and management of industrial chemicals in Australia.

From the questions that you have provided to us, and from the discussions I heard you have with my APVMA colleagues, the Committee is aware that in Australia chemicals are essentially dealt with within four categories. Chemicals in foods, such as additives and residues, are largely dealt with by Food Standards Australia New Zealand; agricultural and veterinary chemicals are largely managed by APVMA; medicines and medical devices are largely dealt with by TGA; and anything that does not fit into those three categories is regarded as an industrial chemical and comes to NICNAS and the agencies that we work with. I note that the definition of "industrial chemical" was one of the questions raised by the Committee. By definition in our legislation "industrial chemical" is any chemical that does not fall into those three categories.

This slide summarises the roles and responsibilities of the agencies we saw on the previous slide: NICNAS, TGA, FSANZ and APVMA. You can see that three of the agencies: NICNAS, TGA and FSANZ are in the health portfolio and APVMA is in the agricultural portfolio. For those agencies within the health portfolio the regulatory policy or the policy, if you like, that guides our regulatory framework comes from that health portfolio and from APVMA for the agricultural portfolio.

The next line, on scope of the activities, is one I wish to place some emphasis on. NICNAS was set up as largely what we would call an assessment organisation. Our main function is undertaking assessment and providing national advice on assessments around the various aspects of the safety of industrial chemicals. You will see that the agencies for medicine, food and agricultural and veterinary medicines have both an assessment and a registration function. That is an important distinction that I want to draw to your attention and I will talk a little bit more about that as we go on. NICNAS also has responsibilities across occupational, health and safety, environmental and broader public health sectors. Again that is different to the responsibilities of TGA and FSANZ for medicines and food but similar to the responsibilities for APVMA.

Focusing on the industrial chemicals sector—part of the chemicals management framework from now on really—you can see on that slide there are a number of different groups that are involved in the whole system and you need all of those groups to be working together to make the system work. So NICNAS has this largely assessment-related function. As to the control measures that might be put in place to manage an industrial chemical, NICNAS has some regulatory powers but the majority of the regulatory powers are exercised at State and Territory level. For occupational, health and safety, worker safety and public health, there are national coordinating bodies but the powers actually sit with the States and Territories. There are a number of co-regulatory measures that are developed by the industry itself. For the system as a whole there is a process of continuous improvement, if you like, which is operating partly through NICNAS and partly through other elements of the system. So NICNAS is sitting within a large framework that involves a number of agencies both at the Commonwealth level and at the State and Territory level and there are coordination and liaison mechanisms that are established to facilitate the operation of the system as a whole.

Under our legislation we have a number of objectives. The one that is probably most relevant to our discussion today is around determining the risk to workers, the public and the environment associated with the introduction of industrial chemicals. The term "introduction" is also very important in the discussion that we are having and in what NICNAS' role and responsibilities are. Some of the downstream use, or the regulatory powers for that particular part of the system, again sits with the States and Territories. NICNAS also has the objective of providing information and making recommendations largely around actions that should be taken in relation to particular industrial chemicals, both to the Commonwealth and the State and Territory regulatory authorities. We give effect to some of Australia's obligations under various international agreements. We are able to collect statistics on chemicals and most recently—this is a new object introduced last year—we are able to make national standards for cosmetics imported into Australia.

NICNAS' functions are around chemical entities. This is an important difference compared to the other regulatory bodies that the Committee has been speaking to. The other bodies are largely looking at products. In the case of NICNAS we are talking about chemical entities. The exception—and a reasonably narrow exception to that general position—is in relation to cosmetics and the introduction of the standard last year. It is important to note that for chemicals that have not been used in Australia we operate a pre-market assessment and notification scheme. If chemicals are to be introduced into Australia and they are not on the national inventory then they need to be notified to NICNAS, we will undertake an assessment and then we will subsequently issue an assessment certificate.

The scope of industrial chemicals, as I have already touched on, is very broad because of the definition whereby if the chemical does not fall within one of the three categories, it is defined as an industrial chemical. Our scope covers so-called new and existing chemicals and, as I have already touched on, the national inventory, called the Australian Inventory of Chemical Substances, is the dividing line between new and existing chemicals. So our activities and our legislative functions are derived from the objects of our Act. A large proportion of our activities is around assessments for new and existing chemicals and then we have a fairly active engagement internationally through the OECD. IPCS is a program from the World Health Organisation and then the various conventions.

We have an ongoing regulatory reform program, which is around dealing with emerging issues and improving the efficiency and effectiveness of the repository system. We have a compliance program under our own legislation. We run a company registration program for companies, as they are obliged to register with us if they are introducing chemicals. Of course, we have a client support and education type function. When we talk about clients, we have industry clients, government clients, and the general community. We would see the provision of information for the safe use of chemicals to the general community as falling within our general scope.

Moving to the last slide. These are the principles by which we operate. We aim to use sound incredible science and take the approach of having the minimum level of regulation that is required to achieve the health, safety and environmental outcomes that we are looking for and to avoid duplication. To ensure that our decisions are risk-based we operate fairly inclusive practices and try to have transparent and consistent approaches and certainly to have chemical safety information available. Thank you.

The Hon. MELINDA PAVEY: Looking at the example of zinc-oxide nanoparticles that can be used in surface coatings, cosmetics and sunscreens, which I am sure you are aware of, it would appear that NICNAS would be responsible for assessing that chemical while the Therapeutic Goods Association is responsible for sunscreens. What is the relationship between the assessments that would be conducted by both organisations?

Dr GREDLEY: The scope of the assessment does vary so the TGA is going to be largely looking at health and NICNAS is going to be looking at public health, workers' safety and the environment. The first point is that the scope of the assessments are going to vary. The area of overlap, if you like, would be on the health assessment, and the extent to which TGA might use an assessment done by NICNAS, or NICNAS use an assessment done by TGA, will, in part, depend upon when the assessments are done and how the chemical is going to be used, which may or may not be the same.

The Hon. MELINDA PAVEY: In the example of zinc oxide—the committee knows from evidence it has received that the CSIRO has come up with a revolutionary way to use zinc nanoparticles to create a sunscreen that is aesthetically more pleasing—will you run through that particular process? I am sure it would have been a ground-breaking process for NICNAS and TGA in terms of approvals?

Dr GREDLEY: The zinc oxide has been looked at by TGA for its use in sunscreens. So the responsibility for sunscreens sits with the TGA and so a chemical for use in a sunscreen, especially with a SBS factor greater than 15 will lie with the TGA.

The Hon. MATTHEW MASON-COX: What if it is in cosmetics, in a foundation or something?

Dr GREDLEY: If it is in a secondary sunscreen under the cosmetic standard that was introduced last year—that is the first time when NICNAS would have a responsibility really for a sunscreen in a cosmetic. Prior to that they all sat with TGA—we would have some responsibility for those kinds of products. The position that exists at the moment is essentially that we are picking up for those filters that have been approved by the TGA. At the point that the cosmetics standard came into existence, we are adopting, if you like, the TGA position if a new one comes into existence, and obviously there will be a cooperative and collaborative approach to the assessment.

The Hon. MATTHEW MASON-COX: Cooperatively and collaboratively with the TGA?

Dr GREDLEY: Yes, with the TGA. One of the issues that always comes to mind when we are talking about utilising the assessments from across agencies is the exposure side of the product that we are talking about, and that would be an issue that would come into play here. So if we are talking about a chemical in a sunscreen then the TGA will be making some assumptions about whether that is used every day or for two weeks while everyone is at the beach and will also be making judgments for a cosmetic and moisturiser, for example, which might be a product that is used everyday. So there will be some different judgments made on the exposure side.

On the hazard characterisation—I heard my APVMA colleague talking about the difference between a hazard and a risk assessment, so this is what we are coming to now—which is the intrinsic properties of the chemical we should be coming to and we will be coming to a common view. The exposure side might be a little bit different. Of course, NICNAS will do the workers' safety and the environmental assessment as well.

The Hon. MATTHEW MASON-COX: I may have a wrong impression but the impression I have received is that the assessment at NICNAS is a lesser assessment in regard to, perhaps, the science that is done on the assessment itself in relation to all the implications that result from the use of a chemical, whatever that might be, compared to a similar assessment done by the TGA. The example that the Hon. Melinda Pavey mentioned in relation to the cosmetics and sun lotions is a case in point. Is that a wrong assumption I have made? Is it a very similar assessment?

Dr GREDLEY: The overall approach is the same basically. We are all using, if you like, a risk assessment approach that has been agreed internationally. So the overall approach that applies to all chemical areas is the same. The regulatory scheme for industrial chemicals in Australia, as well as in most countries around the world, is a lighter touch than for therapeutics, agriculture and veterinary chemicals. So as a general principle that is the case. There would be specific examples, and sun filters is one of them, where the system has been set up so that, as I have said earlier, at the time that the cosmetic standard was introduced it was introduced with only those filters that had been approved by the TGA being approved also for cosmetics. The question then arises of how new filters will get approved, and we are envisaging, because of the role those filters play in skin cancer, that there will be a close working relationship with TGA on any new filters.

The Hon. MATTHEW MASON-COX: In relation to existing chemicals that are, if you like, reproduced at the nano level, nanoparticles, do you see any problems in that regard? How do you handle that situation?

Dr GREDLEY: There are a number of steps obviously NICNAS has been taking. It has been involved in work on nanomaterials for some number of years. Certainly it is one of the emerging issues that it sees as important. There are a number of steps that have been taken, and have been taken over some period of time now, to develop the equipment for addressing nanomaterials. Those steps range from—I guess the OECD work is what we see as particularly important. And I guess we see that there are a number of questions that need to be answered as we go forward on nanomaterials. Certainly one of those questions is around the data on the toxicity of nanomaterials and on the assessment approaches. The OECD is doing the work internationally that we believe will lead us to the answers in the long term for nanomaterials.

The Hon. MATTHEW MASON-COX: At a practical level like if someone wants to use a chemical which is registered for use in Australia, but it happens to have a nanoparticles involved in its manufacture, is that just simply okay for them to use that chemical in Australia?

Dr GREDLEY: There is always an obligation to ensure safe use, but there is no regulatory requirement that prevents the use of those nanomaterials at the moment.

The Hon. MATTHEW MASON-COX: They do not have to come back to you to seek any sort of confirmation that that is okay, regardless of the toxicology?

The Hon. CHRISTINE ROBERTSON: If they have changed it, do you mean?

The Hon. MATTHEW MASON-COX: No, it is the same chemical except it now uses nanoparticles rather than the particles that were in there previously. They are just smaller sizes but it might have some other impact that noone is aware of because the science has not been done.

Dr GREDLEY: Existing chemicals that are on the Australian Inventory of Chemical Substances can be used within any restrictions that might be noted on the inventory. There is a general requirement under the legislation that if there are issues that change around the chemical, so if there is information about the toxicity, if the use changes dramatically then there is a general obligation on the introducers to come back to use.

Reverend the Hon. FRED NILE: How do all the different cosmetic products physically get to you or to the TGA when somebody makes a new cosmetic range?

Dr GREDLEY: Under the NICNAS legislation if the chemical is on the national inventory within any restrictions that are noted on the inventory then those chemicals can be used in cosmetic products. NICNAS does not run a product-based scheme, it runs a chemical entity scheme. The second part of what I was going to comment on, and maybe this is more pertinent to your question, is around the communications side. Is their information available for people so that they understand their obligations?

Reverend the Hon. FRED NILE: Do you tell the companies that are producing this material that they have a responsibility to report to you?

Dr HEALY: Yes, we run an active training and communication program and we have face-to-face training material on our website and the usual array of communication material to try to ensure to the best of our ability that people are aware of their obligations.

The Hon. CHRISTINE ROBERTSON: Is it a legal obligation or "We want you to do this"? Are you reliant on the product labelling? Are you reliant on the manufacturers letting you know what chemicals are in their products?

Dr HEALY: NICNAS has two roles: to look at new chemicals that will be introduced and then there is a very explicit obligation on what we call introducers, that is, companies who might want to introduce that chemical, to come to NICNAS to tell us about the chemical and for it to be assessed. So any nano forms, any new chemicals, chemicals that are not already in use in Australia that are in a nano form, will come to us through that route pretty automatically.

The Hon. CHRISTINE ROBERTSON: How is that policed?

Dr HEALY: We have a compliance group and we do a certain amount of desk-based auditing, as well as visiting sites and there are various information sources we are able to utilise. For example, we have a close relationship with Customs so that we have access to information about what chemicals are being imported. I am worried that I did not quite answer the question that you wanted me to.

Reverend the Hon. FRED NILE: In relation to the compliance aspect, you said you have people who do that.

Dr HEALY: Yes, we have a small compliance group. Our group is looking at compliance with our own legislation, the NICNAS legislation. NICNAS is one part of a fairly complex system. So there will be compliance activities being undertaken in each of the States and Territories and in each of the different

sectors—the occupational health and safety, public health and environmental sectors. So for NICNAS we are looking at the introduction of chemicals. Our compliance group is looking at: Are companies registered with us? Are they introducing chemicals that are not on the national inventory? They are the two main compliance functions that we would be undertaking.

Reverend the Hon. FRED NILE: Do you work through a State department or do you do it directly at the Federal level?

Dr HEALY: Under our own legislation we are working directly, but we also have cooperation and collaboration with our State-based colleagues, particularly in the occupational health and safety sector, the workers safety sector, which is partly historical. Some of the actual regulatory controls are exercised through, for example, poisons legislation. So the State and Territory health departments would be exercising a level of control as well.

The Hon. MICHAEL VEITCH: I believe that NICNAS is conducting a review of the current regulatory framework as it applies to your agency. Are you able to advise the Committee of any gaps that you have identified to date in the current regulatory framework as it relates to nanotechnologies?

Dr HEALY: In our own work we are looking at a number of different questions to work out whether we think there is a gap or not. The type of questions that we are actively exploring is: What is manufactured nanomaterial? I understand you have already had some discussion around that point. How do we assess the risks or potential risks that might be associated with nanomaterials? Then there is the management of those risks and the stakeholder engagement. They are the questions we see that we need to address and they are the ones that we are actively working on. We have a number of strategies to try to address those questions. The OECD work, which I started to talk about a little earlier, we see as one of the very important mechanisms to address those questions, particularly around the risks that might be associated with nanomaterials and the predictability of those risks, as well as with the assessment protocols. We see it as particularly important because it is drawing together work at an international level. Of course, the capacity of an organisation like the OECD is much greater than any individual group within Australia.

At the national level you would be well aware of the activities that are happening. There is a strong level of coordination between the technical people in the regulatory agencies. That is part of capacity building. We have been building our own technical capacity, partly through our OECD work, now for a number of years. We have stepped it up over the last little while. The engagement of the National Health and Medical Research Council [NHMRC] or the interface and the work of the NHMRC expert advisory group, which is a mechanism for also providing advice at a national level, we see as being important. Then, of course, there is the communications side.

Reverend the Hon. FRED NILE: In your review you emphasise that there is no registration aspect of your area, whereas there is for medicine, food and pesticide. Do you consider as part of the recommendations that you should have that power? Would that help you in carrying out your role?

Dr HEALY: There is actually a whole other process underway at the moment through the Council of Australian Governments [COAG] looking at the regulatory frameworks for chemicals, particularly for industrial chemicals and agricultural and veterinary chemicals. A question you have raised about where should the regulatory powers sit is being considered through this other process. There is a Productivity Commission study on chemicals and plastics regulation, and it is feeding into COAG considerations.

Reverend the Hon. FRED NILE: Would you make a recommendation that registration powers be given to you?

Dr HEALY: There is a draft report from the Productivity Commission study, which at the moment is recommending that NICNAS have less regulatory power and primarily does risk assessment or is an assessment agency, with the development of the regulatory requirements being coordinated through national bodies but implemented through the States and Territories.

Reverend the Hon. FRED NILE: Do you think that is adequate? Are you allowed to have an opinion on that?

Dr HEALY: I think the main thing is the cohesiveness of the system.

Reverend the Hon. FRED NILE: It sounds complicated.

Dr HEALY: We live in a federation and there are many cases where the Commonwealth, State and Territory powers need to work in a cohesive way. This is one of them. In all the frameworks for chemicals you need State and Territory and Commonwealth powers to be working together to give you a whole system, and there are just different points in the system where there is the division of the powers.

The Hon. CHRISTINE ROBERTSON: Do you have any issues with consistency across the States?

Dr HEALY: In nanomaterials or more generally?

The Hon. CHRISTINE ROBERTSON: It would affect nanomaterials if different States shoot off in a direction other than according to the regulations that your work has recommended.

Dr HEALY: Yes, and this again is where the cohesiveness of the system and the issues being considered through the Productivity Commission study come into play. That study is looking at consistency and how what we call the national coordinating bodies are operating. Those national coordinating bodies have, obviously, representatives from the Commonwealth, States and Territories on them.

The Hon. MICHAEL VEITCH: What definition of nanoscale material do you use?

Dr HEALY: It is a vexed issue.

Dr GREDLEY: Currently there is no internationally agreed definition, but there is a working definition out of the OECD which we are tending to use, that is, material that is engineered with specific new functions in mind at a range of between 1 and 100 nanometres. However, we are particularly aware of the concept that a company can engineer a nanoparticle at 105 nanometres and therefore be outside the definition. For us, not only is the definition important but it is the functionality and the use of the chemical that is important. Does that particle size change the risk characteristic compared to a conventional form? Therefore, we would be interested in a particle of 105 nanometres as well as a particle of less than 100 nanometres. So we are not particularly tied to a definition.

The Hon. CHRISTINE ROBERTSON: Would a definition help?

Dr GREDLEY: A definition will help, but a definition has limitations. We want to be flexible enough to draw out information on materials that are still going to have a changed risk because of change to the particle size but are potentially outside that immediate definition.

CHAIR: Do you have any further comments that you would like to leave with the Committee?

Dr GREDLEY: I would just like to add to Dr Healy's comments around our OECD and nationally coordinated work. We also have formed a nanotechnology advisory group involving industry and community. We are liaising and consulting with these two sectors because, first, the industry ultimately is providing data, particularly for new chemicals and bottom end materials; and, secondly, because the community is empowered to nominate chemicals of concern which we should be assessing. Therefore, both groups need to be aware of the implications and characteristics of nanomaterials.

CHAIR: How is the message getting through to the wider community about nanotechnology?

Dr GREDLEY: In terms of NICNAS's remit, we have provided two publications which are in your information packs, the results of a survey on what nanomaterials are currently available in Australia, and an information sheet on what is a nanomaterial. Following various coordination meetings with regulatory agencies and discussions with our nanotechnology advisory group, we are looking to go the next step, which is potentially to do another call for information, updating on the previous call in 2006, but also asking for more detailed information on the nanomaterials that are available in Australia. Secondly, to start informing the community—and this is a concept idea at the moment because we have not finalised any thoughts yet—around case studies of what are nanomaterials in the community, what are the facts associated with them, and to inform the community on what they might do, as well as businesses what they might do, should they be utilising nanomaterial, how they can assist NICNAS in doing its job.

The Hon. CHRISTINE ROBERTSON: Information from whom? Calls for information from?

Dr GREDLEY: The 2006 was a call for information from NICNAS to industry requesting information on what nanomaterials were in the marketplace.

The Hon. CHRISTINE ROBERTSON: So you just send that out to all the registered industries, is it?

Dr GREDLEY: Not just registered industries but through other businesses which are not registered with NICNAS. It is a general call.

The Hon. CHRISTINE ROBERTSON: Like through the chamber?

Dr HEALY: We publish a chemical gazette which is widely read throughout the industry, and I guess it becomes the source of notices and information in an official capacity. We would always put a notice in the gazette calling for that kind of information as well as the general information on our website and the like, but the chemical gazette is the very formal mechanism by which we would call for that information.

The Hon. MICHAEL VEITCH: Do the State bodies have a role to play in that information dissemination to the community?

Dr HEALY: Yes, they do. Again, we have a formal relationship with the States and Territories through a memorandum of understanding that was signed pretty early in the days of NICNAS. This, I alluded to earlier, means that most of the State representatives are coming from the occupation health and safety side of the equation. That provides a ready mechanism for us to be developing materials with the States and Territories. As well, we have less formalised networks with the States and Territories. In fact, one recommendation that arise from a review of our own processes a couple of years ago was closer coordination with the States and Territories, so over recent months we have been exploring how we might have that closer relationship and probably formalised as well. Certainly, one of the areas where we are interested in and from the conversations I have had with my State and Territory colleagues there is also interest in the dissemination of information. NICNAS is quite happy to prepare hopefully what is authoritative information, factual information that we will disseminate through our own networks, and our State and Territory colleagues have indicated that they are very interested in taking that information and disseminating it further through the State and Territory networks. That would be a good thing because often our State and Territory colleagues are closer to the on-the-ground action.

Reverend the Hon. FRED NILE: Just looking at these pamphlets, NICNAS is covering all these industrial chemicals. I cannot see any reference to "nanotechnology" on the three pamphlets. Is nanotechnology one-tenth of what you do or one-fifth of what you do?

Dr HEALY: Yes. The call for information sheet, which is the results of the call for information from industry, which is in the information pack, is quite interesting to look at because it shows what a small number of nano forms are actually being reported and in what small volumes they are being imported into the country. There is something of the order of 38,000 chemicals on the national inventory, so even if this call is out by 50 per cent we are still talking about a very small number that are being used. That is not a reason to say that we do not need to be careful and vigilent, but it is an area that is emerging rather than having emerged, I think it is fair to say.

(The witnesses withdrew.)

(Short adjournment)

SUZANNE VIRGINIA SMITH, Research Programme Leader, Nuclear Solutions, Institute of Materials Engineering Science, Australian Nuclear Science and Technology Organisation, P.O. Box 1, Menai, NSW, sworn and examined:

CHAIR: Welcome, Dr Smith. Thank you very much for being here this afternoon and coming here to give evidence. If you should consider at any stage that certain evidence you wish to give or documents you may wish to tender should be heard or seen only by the Committee, please indicate that fact and the Committee will consider your request. If you take any questions on notice today the Committee would appreciate it if the response to those questions could be forwarded to the Committee secretariat by Tuesday 1 July. Would you like to make an opening statement?

Dr SMITH: Yes, I would. First, I would like to thank the inquiry for the opportunity to address this forum. Before I address you questions I would like to take this opportunity to explain a bit of my background: I think it would be useful for everybody. Although I run a program in materials engineering science my history has been in radiopharmaceutical development and I have a number of patent technologies in that area. I have been at ANSTO for about 13 years working in that field. I have intellectual property in both patent technology and in developing products for clinical trials and for good manufacturing practices. The reason I say that is because a lot of the background is very relevant to one of the things I am about to speak about.

I moved into materials science because the rapid advance is unusual and the often unpredictable properties, materials and nanoscience created a strong interest to apply much of the radiopharmaceutical technology to that field. The reason it is interesting is the fact that when you look at these materials they have unusual properties that are very hard to measure, and this is where radioisotopes can be exceptional in that process. So, they actually provide very high sensitivity, and because they can be tailored for application they are very useful for that process. The investment in the national reactor and also the national medical cyclotron means that we have a lot of flexibility and design in those probes to look at these properties. Why it is useful for the nanotoxicology area is that you are able to label these particles and then track them, and one of the questions that has arisen with respect to nanotechnology is understanding how to monitor these processes, understanding where they go and being able to get viable information that is useful for the process.

Before I go into that and the more specifics in how it can contribute to the materials, I think it is worthy of discussing a little bit of the lessons learned in drug development. Much of the problem with the field has been in trying to get a product to market and it has been limited by the length of time it takes to market and also the risk assessment of materials. Those lessons are also very valuable in the nanotechnology field as well. There are four main areas that I think are probably key to developing these sorts of processes and to applying them into the materials area and the nanotechnology area. The first is identifying lead compounds, and much of that, if you look at the pharmaceutical industry you will look at one in 8,000 to 10,000 products make it to market. What you see there is that there is a lot of money invested and a lot of money invested in products that may not work as well and therefore the cost involved.

At ANSTO we are looking at developing technology to screen these materials much earlier, and we are applying those processes to materials applications. This is important in the process when you are talking about developing a product from concept to market place because you want to look at things that are actually going to be good but also identify the ones that are going to fail. The earlier you identify them in the drug development process the more money you save. Scaling up in the production process is another issue that is a real problem, and if you look at the history with respect to pharmaceuticals, they will identify a product back in 1975 for targeting, but it took almost 20 years later before they could actually make a product to market.

Sometimes it is about developing technology and other times it is really developing a better understanding of scale-up processes. If you look at the nanotechnology field, one of the biggest issues here is understanding how to scale up and how you can use this sort of technology to help in the scale up of materials, but also how you can use that technology for keeping a safe environment. If you look at labelling these processes and monitoring their work environments you can actually get information well before it becomes an issue.

Toxicity of compounds is one of the areas we have been looking at more closely. We had collaboration with Queensland University and AIBN as well as looking with CSIRO. One of the issues here is being able to label the particle so you can track it. A lot of toxicity studies, if you remember, are generated because people want to understand if a compound is toxic. The chemotherapeutic is really where the drivers come from. So the principles of designing products that allow you to determine toxicity of a material are developed with that in

mind. If you are talking about developing toxicology processes for particles, it is very difficult to quantify or develop assays that are relevant for the process. The reason this is difficult to do is that many of the conventional detection systems that are in place now are well below what we need to be able to achieve.

We need much higher sensitivity, so what we have been looking at doing is incorporating radioisotopes into the particles, making sure that the chemical structure is the same so that we can monitor them. We look at two aspects: we look at any cell assays and we look at the exposure, and then we also look at them in biopathways. You can simulate environmental conditions where you can monitor the process of transporting these particles through water, soils, and algae and through various species through the ecosystem.

One of the biggest issues here, I believe, is that many products can fail the marketplace because their toxicity is found out later. There is a classical example in the antibody technology where they actually brought a product to market, found allergic reaction and basically had to go back to the drawing board. The key lesson from this was that all additional products that were in the marketplace were also wiped out. They could not get into the marketplace because of a single technology. With nanoscience technology, because we pool the concepts and we have not defined the particles, we have not defined the applications well, because communicating the type of science that happens if there is a failure in one area can have a significant impact across the field. So the toxicology statements understanding these transport properties are critical for the whole of the community and the whole of the nanotechnology community.

The regulatory process is probably one of the most significant aspects that are beginning to change in the pharmaceutical industry. If you look at the amount of products that make it to trial, only one in five passes when they are in clinical trials. One would hope that we would have a better success rate earlier in the process, but it is only one in five. They actually fall down in phase two of the studies. If the success rate for the phase two studies could be improved to two in five, the cost of bringing a product to market would be reduced by anywhere up to 50 per cent. That is what has been quoted. The cost to take a product to market can vary between $800 million and $1 billion. If you understand when you should screen earlier on and when the issues are most critical to deciding whether a product is good or safe to use—if you make those decisions early when not a lot of investment has been put in you can save yourself a lot of money.

That is the strategy people are taking. One of the strategies they are building into drug development scenarios is they are actually producing imaging agents. They are using them in phase one studies because those studies will allow them to determine what we call the therapeutic index, the dose—what goes to the target site and what goes to the rest of the body—and hopefully be able to decide the products that are least likely to succeed. If you have more confidence in that process you will get better performance in phase two.

The principles are very much the same in the nanotechnology area. Because the nanotechnology area is dependent on shape, chemical composition and size and little is understood about the interactions, it is essential that companies implement the review process very early on. This is for the benefit of staff who manufacture the product, the environment and the customer. Applications are quite diverse, so the risk assessments will be expected to be quite diverse. The expectation will be quite different from one product to another. You do not necessarily need to generate a whole regulatory body but you do need to align those regulations, or the tests, to the regulatory bodies that you are looking at. There are opportunities to look at that in a more sensible manner.

There is always no doubt that if you apply these screening assays very early in the process, you can actually reduce costs to market. There is no doubt about that process. One of the problems with the pharmaceutical industry that we pay for now is that we allow them to protect the information—to leave the information until later. It costs too much money to make it in the open market because they have put the risk assessment too late in the process, so a lot of money is lost. One of the strategies that would be very useful is to make that information readily available for the community, both for industry and research, so that these lessons can be learnt very early on. If there is a product that has already been developed in the marketplace, by learning about another technology that could actually be hindered by risk or hazard you can re-engineer material very early in the process, and that information is very valuable.

I believe that overall the commercialisation of nanotechnology would benefit from developing internationally acceptable standards for the characterisation of nanomaterials, modifying the relevant existing toxicity assays, because a lot of them are not relevant in the way they are done, and then implementing these processes very early in the piece. If you develop a research program that understands the footprint—that is, depending on the product and where it is used, understanding its impact on the environment—you will address

some of the community concerns and that would also be quite powerful. That information should also be widely disseminated.

How do you do that? Probably the most likely and useful scenario would be a national facility that collectively brought together groups of people who were experts in certain areas to contribute to various aspects of the process. In that process, that information should be made available to industry and researchers. If you think about those sorts of strategies, you can then transfer the technology and also validate techniques. One of the areas in which we are suffering in this field is that there is a perception of how an assay should be done in one field and not in another, and we cannot translate the data. That is a real weakness in the field.

CHAIR: Are there standards in place for toxicity assessment that can be applied to nanomaterials? Is there a range of methodologies for tracking nanomaterials or nanoparticles when assessing their toxicity? If so, does this pose any problems?

Dr SMITH: Assays are available, but one of the problems is how you determine how an assay should be designed. I will provide a classic example. If we want to look at toxicity in algae we have to determine what is a reliable or realistic number of particles that will be exposed to a group of algae. If you have a collection of algae or a cell assay, how do you determine what is a reasonable exposure of nanoparticles in terms of environmental toxicity? In those scenarios there is still not a lot of information available. Information about the detection-level systems to determine how you use them and where those particles go—whether they aggregate in solution and whether they stick to surfaces or internalise—is not readily available. It is very hard to determine and to quantify the effects of these processes as well.

With respect to how you can do this and whether they are safe to use, if we use radiotracers—which is one of the techniques we want to use—you can simulate highly sensitive scenarios and look at tracking processes. However, you simulate the scenarios in laboratory conditions. You then start to understand these processes and their impact, and then you can model them and try to develop scenarios that are relevant to the outside.

The Hon. CHRISTINE ROBERTSON: Do you have any ideas about how you regulate or legislate for modifications of processes relating to individual chemicals? Do you have any ideas on that?

Dr SMITH: I do not understand.

The Hon. CHRISTINE ROBERTSON: I have the impression that you are proposing modification of certain risk assessments and so on so that there are standards of assessing chemical hazards and risks.

Dr SMITH: Yes.

The Hon. CHRISTINE ROBERTSON: How do you word a requirement for modification of a certain thing? How do you give firm advice on what should happen in the future for test anything in this area? Your idea is okay, but how is it implemented?

Dr SMITH: You would say to someone, "in realistic dose levels". You would have to speculate a scenario of what the exposure rate would be or the quantity of exposure to the product. When you do a toxicity assay, it must be set at a meaningful level. You do not tell someone to swallow 10 grams of a product when you know that they will never be exposed to that amount. Many of the assays are developed at that level. They do not relate to a practical scenario. One thing you can suggest is that the levels or doses used to measure the toxicity of a particle is at a meaningful level. In this case, if I said I was exposing them to milligrams of a nanoparticle, I would question whether someone would actually be exposed to that quantity of product. You can talk about "realistic" levels of exposure. Does that answer the question adequately?

The Hon. CHRISTINE ROBERTSON: Yes.

The Hon. MELINDA PAVEY: Can you elaborate on the cost to business of safety and toxicity testing? Can you advise the committee on the potential for reducing these costs without compromising safety and how the ANSTO facility could put New South Wales in a leading position on that front?

Dr SMITH: In that situation, one of the things I would recommend is that you look at developing screening assays for particles. Research groups are all out there producing products, but no-one questions

whether the product is safe or if it breaks down. Simply introducing that at the early development stage—and there are simple assays of stability and basic cell assays—could reduce costs. You would not progress them to scale-up processes because you would have made a sensible decision about whether it is safe to implement to the next level. You would also get information about re-engineering. One of the weaknesses in any development program is that the toxicity studies are introduced far too late. Bring them up early and you start to make a decision about where you going with the product. It is not only about success or performance; it should also be about the hazards of the product.

The Hon. MELINDA PAVEY: But you are hoping to revolutionise the whole research sector with your proposal.

Dr SMITH: Yes, you could do that. In this case, we have a fair bit of engagement with people who want to understand how their products perform. It is really about encouraging an industry group to engage and realise the benefit to them as well as to the research community. If you wanted to look at getting them to engage in this, you simply have to illustrate scenarios where people have left it too late or had adverse effects and not been able to get it through. Genetically modified foods are a typical example of where people left it too late to engage the community and the industry.

You can develop scenarios to explain it. We are looking at commercially developed products at the moment that are already in the marketplace because we believe they are going to be very good benchmarks. When we look at toxicity assays and we want to develop them at a meaningful level, we give industry some level of confidence that their stuff is going to be assessed in a fair and non-conflicting manner. They should be engaged in any process you develop and they should have some influence over it and how it is done. It must be useful. One of the problems is that these assays are never developed by engaging all interested parties: the public, industry and researchers. Does that answer the question?

The Hon. MELINDA PAVEY: Yes.

The Hon. MICHAEL VEITCH: You have been talking about three different sectors. Where does the funding for toxicology research come from?

Dr SMITH: At the moment ANSTO does not get direct funds for that. I have collaborations with a number of people who get Australian Research Council funds. We develop technology for a number of applications that are also suitable for nanotoxicology. ANSTO provides some funds—although it is a small amount—and we have ANSTI funds for students to work on developing the assays. In most cases there are no large bodies from which to get funds. If it were to change, I propose that when people get research and development funds in the science and development programs they put up suggestions about how they will assess their product's performance in a safety sense. That is one way of generating a community that takes this on board very early in the grants system. With a national hub, we can pool that information and share the costs of maintaining something to do that sort of work.

The Hon. MICHAEL VEITCH: So you are advocating national coordination of toxicology research.

Dr SMITH: Yes, I am. I would definitely advocate that. I would also look at how people examined all processes—that is, the engineering and scale-up processes. We can get information extremely quickly. We can look at monitoring within seconds of how a process is moving around the room. That is online monitoring. That allows you to get feedback mechanisms very quickly in the process and you get information from high-throughput systems, which you cannot do readily with other technology.

The Hon. MICHAEL VEITCH: Are you advocating that the infrastructure required for toxicology research in New South Wales and also throughout Australia should be a part of that national coordination?

Dr SMITH: It would be very useful. There are aspects about places within Australia that are very good and certain parts of toxicology. No one institute is good at all aspects of it. That is one of the things we need to realise. There are lots of experts to do it, but applying those experts to address the issues and the gamut of issues that needs to be addressed for nanotoxicology and the gamut of issues that are so important for this industry to do well would definitely need national coordination.

Reverend the Hon. FRED NILE: You said that you are looking at the significant cost to businesses wishing to take a product to commercialisation. That is expensive. What would it cost? We hear that when a new drug is released it costs $400 million.

Dr SMITH: For a pharmaceutical industry they quote anything from $800 million to $1 billion in the United States market. I do not know how realistic that number is, but it is really about the whole program.

Reverend the Hon. FRED NILE: Is that for nanotechnology?

Dr SMITH: No, this is for the pharmaceutical industry. I do not know the bottom line number. When they do the costings of a research and development program they include all the failures as well as the successes of the program because that is what it takes to get it to the marketplace. Because the applications of nanotechnology are so diverse it would be very difficult to cost. The pharmaceutical industry put a lot of effort into doing that. Some of the arguments and the criticisms that it has faced is the cost that it needs to charge for its products. Industries and the health care insurance community have forced it to demonstrate why it is charging these prices. It is to sustain its business. It is not unreasonable to assume that, if someone were producing nanotechnology for human use, the scenarios would be similar. However, for other areas of industry you would have to make the costings for that. I am not familiar with that, or with whether people have looked at that process.

Reverend the Hon. FRED NILE: In a sense, because of the testing that you are doing, you are saving commercial companies money?

Dr SMITH: We are hoping that we contribute by developing technology earlier on that helps them with the yes and no decision. We can contribute to cutting down the costs and the phases of studies on which they need to move further.

Reverend the Hon. FRED NILE: Should those commercial companies not contribute to what you are doing?

Dr SMITH: There are two ways of doing it. One of the problems with that is that it could be seen as a conflict of interest if you are doing this for a company. If you do it directly in relationship with a company you might have to keep that information secret because it has asked you for a materials transfer agreement. That is why it is in the interests of the community. That means everybody and also the public forum. We must provide a national hub where people know that this process is transparent. If industry people came to that site, put their processes in place and knew that it would be transparent, you could then set up processes so that the governing is done well and so that information is readily available for people to share.

If it is a single relationship you can get tied up in that process. That is not unlike what happened with the pharmaceutical industry. It leaves the regulation until late, but it has already invested $400 million. It will not shout from the trees when things go wrong; it will try to engineer it quietly and get through the process. It is not that I think industry is deceptive; it is just that money has been invested, so how does it do this? If a body or group governed a national facility, industry people, researchers, and regulatory bodies could contribute to that process and they could be sure that the information they provided could be validated and stand up to scrutiny, which is what you want in the end.

The Hon. MELINDA PAVEY: What are the infrastructure requirements for toxicology on nanoparticles, and is current infrastructure around Australia adequate? It is a big question.

Dr SMITH: It is a very big question. Some aspects would be fine. I would have to say that where I have been dealing with issues we do not have the right infrastructure. We do very small-scale studies. I am looking at engineering and developing assays that have a fast throughput, that are meaningful and that validate the process. That means testing a larger area and putting enough effort behind the process. However, you would have to look at monitoring and quantifying where the particles go when you were setting up those sorts of systems. With radiotracers you would need different infrastructure to do it. You could do it in some parts of ANSTO but you would need to develop more sophisticated scenarios to handle that process.

The Hon. CHRISTINE ROBERTSON: The wisdom of introducing toxicology studies during the research and development stage of any product is obvious. It is just that the implementation issues are quite difficult, and it is difficult for us to make recommendations. Perhaps the research funding body should be asked

what component of the research programs relates to toxicology studies. Perhaps commercialisation should not occur until that has happened, or only if it is proven that it happened during that process. I am not sure where that fits into the legislative regulatory role.

Dr SMITH: Sure.

The Hon. CHRISTINE ROBERTSON: And that is our role.

Dr SMITH: In a regulatory role you can influence funding bodies to a certain degree. I think you can have some influence on that process.

The Hon. CHRISTINE ROBERTSON: Not many State funding bodies have research programs.

Dr SMITH: No, there are not. In that case, the only place you could influence this process from a research and development point of view would be from the industry side of things. One of the problems about which industry is concerned is that it does not have a clear path for these processes. One of the arguments that people come up with is that there are no relevant assays and they ask what kind of assays can be developed for the process. I am still waiting for the information to come before I embark on that process, so it is kind of a circular thing. In that scenario there would have to be some influence for industries to look at those processes early in their research and development programs. If there is funding for industries or for regulating industries that is where their place would be. Overall, I think the most significant thing we could do is to set up a facility that allowed people to engage actively in that process. I do not know how you would force the process earlier on, unless it really needs to be done.

CHAIR: Do members have further questions?

The Hon. CHRISTINE ROBERTSON: Your briefing was excellent.

CHAIR: Would you like to make any further comment on issues that we should know about but that we have not asked you?

Reverend the Hon. FRED NILE: You mentioned a new reactor?

Dr SMITH: Yes.

The Hon. CHRISTINE ROBERTSON: Is it up and running?

Dr SMITH: Yes.

Reverend the Hon. FRED NILE: What benefit has it given to you?

Dr SMITH: From my point of view a number of areas in this program would be very useful. In the research and development program in which we are involved we are looking at all stages of the development of material. We are looking at the whole-of-life cycle—whether we look at scale-up processes or the impact on the environment. To do that, the radiotracers allow us very high sensitivity. We want to develop online processing systems where we can look at the engineering and scale-up of the process, look at reducing the synthesis time, and also look at reducing the amount of quantitative product. Understanding where that footprint is can be done with radiotracers. We can then feed that back into corrective action and, basically, risk management of the material.

The isotopes afford us a whole gamut of technology. A technique called neutron activation is extremely useful. You can activate a particle but keep the structure and the activity intact. You change something like 0.0002 per cent of the molecules in one particle, which is extremely high sensitivity. Having that ability means that you can get information in all sorts of areas that you would not get it anywhere else. You can also get information of solid interfaces, which is incredibly valuable for the technology development process. I believe that the reactor will enable a lot in the field of nanotechnology. Certainly the engagement that I am getting from people at the moment is that there is a genuine interest in how they can capitalise on that tool to advance their technology.

Reverend the Hon. FRED NILE: Do you have ready access to it? Do many people want to use it?

Dr SMITH: Yes. There are two aspects to it. Because of the design of the reactor there are lots of opportunities to do that, and they are certainly interested in getting engagement. The neutron scattering capabilities will underpin a lot of the structural work that we need to do, and the iteration facility will provide information at another level in design. You referred to access to the reactor. I have worked hands-on with the cyclotron and the reactor and I enjoyed both those experiences because they are extremely powerful tools.

The Hon. CHRISTINE ROBERTSON: It is worth going back to look at the new one.

Dr SMITH: The competitive edge it gives to this country is huge. You cannot get that capability or the relationship that we have anywhere else in the world. It is quite extraordinary. I did fellowships in Harvard Medical School and in other places. You do not get the same level of interaction that you can get here. It is lovely.

CHAIR: Is there anything further that you wish to add?

Dr SMITH: No, thank you.

CHAIR: Thank you for being here and for your answers and presentation today.

(**The witness withdrew.**)

Committee adjourned at 4.49 p.m.