The Responsible Nano Forum

A beacon or just a landmark?

Reflections on the 2004 Royal Society/ Royal Academy of Engineering Report:

Nanoscience and nanotechnologies: opportunities and uncertainties

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Introduction from Hilary Sutcliffe

A lot has happened in 5 years….or has it?

It's hard to believe it is 5 years since the publication of the Royal Society and Royal Academy of Engineering Report into nanotechnologies, hasn't it gone fast? To mark that milestone, we thought it may be interesting to invite opinion formers to reflect on the legacy of the report and its impact, not just in the UK but internationally. We are delighted that 28 people chose to share their views with us, that Dr Andrew Maynard agreed to write the Foreword and that two of those who sat on the original RS/RAEng working group were able to give us their perspectives.

I won't attempt to highlight or summarise the reflections here, because they are expressed so much better by the contributors. However we thought it might be a useful point in time to consider briefly what lessons may be learned from the last 5 years which may be appropriate for the development of other emerging technologies - perhaps synthetic biology, geoengineering or the converging or hybrid technologies of nano, bio and information technologies, cognitive science and robotics.

Reflections on the future

Inadequate toxicology distorts the debate

The repercussions of not understanding the toxicology and ecotoxicology early enough can distort the debate about a technology. As Professor Richard Jones outlines on page 14, if there is no clarity about toxicology, inflexibility on funding and poor communication about safety research and testing, this need dominates the debate. There is a great deal of talk about 'learning the lessons of GM', this was a fundamental lesson which appears we have been very slow to learn and apply, though things appear to be gathering pace in this area recently.

The focus on risk can prevent the wider concerns, particularly the social and ethical repercussions of a technology and its various applications, being discussed early enough, as Dr Santillo from Greenpeace outlines on page 10.

The inability to stand up and talk confidently about the technology provokes a vicious circle of concern and loss of trust which may conceivably have repercussions beyond immediate applications. However, if the data on risk improves quickly and perhaps because of the significant public engagement and government action to involve other stakeholders, it may be possible to avoid this with nanotechnology, but the next year or so is critical. Future technologies will need to look at this aspect of their development particularly carefully.

Transparency and honesty can't be sidestepped

But where important information is lacking - there will inevitably be uncertainties and risks, or, as Professor Seaton describes on page 7, other issues may be of higher priority - then transparency and openness is essential. This is another GM mistake which, unfortunately, it appears that industry in particular could be making again. Long gone are the days when business and governments automatically engender trust with the public. It now has to be earned. Openness and communication are central to building that trust.

Disclosure of testing for safety and efficacy of products before they are brought to the market looks set to become a new area of corporate responsibility, not just because of the development of new technologies, but also disillusionment about claims and hype over ordinary products.

Focus stakeholder involvement earlier

On a positive note, a significant effort has been made, particularly by the UK government, to engage the public in nanotechnologies, in fact the UK is seen to lead the world in this regard. With hindsight, we may feel that the engagement could be more focused a little sooner, considering applications or specific aspects of the technology instead of 'What do you think about Nano' type projects. In nano and with future technologies, it will be important that a range of stakeholders, notably scientists and businesses, should do more of their own public and stakeholder engagement programmes.

International coordination is essential

What does appear to have been unusual and effective in nanotechnologies is the international cooperation through individual countries working together and through the EC, the OECD and the ISO process (though for how long the UK can keep its lead in this area is debatable according to Dr Peter Hatto on page 28). These new technologies do not happen in isolation, international cooperation is essential and nano is working out as an interesting case study for the future on how that may happen.

Support real benefits and real innovation

As Tim Harper reminds us on page 23, all this needs to be underpinned by innovation and appropriate funding to bring the much-vaunted new applications to market and make good use of the UK's expertise in research and development. Part of the whole trust 'deal' with society will be to ensure that these new technologies also deliver the goods in solving some of the most pressing problems of the day - whether it be climate change, nutrition, human health or poverty and, as Dr Grimshaw reminds us on page 34; we also need to consider the wider social and ethical issues, consider who is going to be left out of this whole process and what repercussions that may bring.

So back to nano. Thank you very much to everyone who you took the time to share your reflections with us. We have found this exercise most interesting and hope you do too.

We will contact you again on the 10 year anniversary and see what's happened by then!

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Foreword from Dr Andrew Maynard

On July 29th 2004, the Royal Society and Royal Academy of Engineering published "Nanoscience and nanotechnologies: opportunities and uncertainties." It was a milestone moment for the emerging field of nanotechnology. Authored by a panel representing a wide range of expertise and perspectives, the document highlighted the promise of nanoscale-based technologies, delved into the potential hurdles to safe and sustainable development, and, eschewing "singular" wisdom, introduced the world to the term "nanotechnologies." It also set out a clear path toward realising the great potential of a significant emerging technology, while avoiding harm.

Five years on, how are we doing?

Back in 2004, I was co-chair of the U.S. government working group addressing the potential implications of nanotechnology[1], and leading nanotech health and safety-related research at NIOSH – the National Institute for Occupational Safety and Health. I had previously provided comments to the RS/RAEng panel, and was looking forward to the final report with anticipation. I even cut a trip to Singapore short to be present at the report's U.S. launch, which was hosted by the Woodrow Wilson Center—foreshadowing my move to the organization some months later.

At the time, concerns were mounting over possible new risks associated with creating materials and devices at the nanoscale, and how these would affect the technology's development. The previous year, Michael Crichton's book Prey had sent the nanotech community into a tizzy over a speculative public backlash against the emerging science and technology. And researchers were beginning to reveal hints that novel nanoscale materials could also affect humans and the environment in unconventional ways—getting to places and causing harm on a scale that belied their small size.

Into this growing tension and hype between the great promise and potential for harm that emerging nanotechnologies seemed to represent, the RS/RAEng report came as a clear voice of reason. The document was authoritative, clear, grounded in science, yet responsive to the broader social, economic and political environment within which nanotechnology was emerging. It also placed a clear emphasis on the need to engage publics, address safety concerns and regulate emerging technologies successfully if the potential benefits from nanoscale science, engineering and technology were to be fully realized.

The RS/RAEng report wasn't the first to tackle these issues. But it was the first to provide a clear and overarching perspective on what the opportunities and challenges were, and how to grasp the former while overcoming the latter. In doing so, it helped to focus the thinking of the time, and illuminated a path forward toward the responsible and effective development of nanotechnology.

[1] The Nanotechnology Environmental and Health Implications (NEHI) working group within the US National Nanotechnology Initiative

If the report had not been written, I cannot imagine we would have seen as much activity as we have over the past five years on developing safe, acceptable and successful nanotechnologies. Since its publication in 2004, research, publications and discussions on the potential impacts of nanotechnologies have increased dramatically. Various European committees have reviewed the state of the science and recommended actions to underpin safe use and effective regulation. New pan-European research programmes have been funded to tackle specific health, safety and societal issues. In the U.S. the National Nanotechnology Initiative has consolidated federal approaches to addressing environmental health and safety concerns, and research into human health and environmental impacts of nanotechnologies has increased.

National and international initiatives have brought stakeholders together to explore the development of responsible nanotechnologies. Standards organizations have been galvanized into writing whole rafts of nanotech reports, guidelines and technical standards. Awareness has grown over the need to engage the developers and users of nanotechnology-enabled products on the development of emerging technologies. And moves have been made toward tighter regulation of new nanomaterials in Europe and the U.S.

And, most importantly, no one to our knowledge has been harmed from being exposed to new engineered nanomaterials.

Yet despite all this activity, it's harder to pin down how much concrete progress has been made. If the RS/RAEng report was published in its current form today, its assessment and recommendations would be as relevant as they were five years ago. A few things have changed over the past five years—the original report didn't predict the widespread use of nanoscale silver in consumer products for instance, and it shied away from describing increasingly complex developments in nanoscience that are now beginning to translate into viable technologies.

But many of the top-line recommendations in the 2004 report would not be out of place in a 2009 assessment of nanotechnology opportunities and challenges.

Some of the recommendations made by the RS/RAEng tackled issues that would never be resolved overnight. In these cases, it's not surprising that more still needs to be done. For instance, life cycle assessments, workplace exposure, developing appropriate measurement methods and engaging the public on emerging technologies, are all areas that will most likely remain important for decades.

In other areas, it's harder to understand why progress has dragged so. The U.K. is still lacking a dedicated interdisciplinary centre for nanomaterial risk research, for example, leaving industry and government decision-makers without a strategically important resource for filling key knowledge gaps. And research into the potential impacts of carbon nanotubes—highlighted as a critically important issue in the report—has been hampered by a disregard for the RS/RAEng recommendations by research funders.

In some cases, actions have been taken that fly in the face of the RS/RAEng recommendations. A recent paper in Environmental Health Perspectives highlighted 45 sites around the world where unbound nanoparticles are being released into the environment for groundwater and soil remediation (a map of the locations is available at **http://www.nanotechproject.org/inventories/remediation_map/**)—in spite the RS/RAEng panel recommending that until more is known about their environmental impact, "the use of free nanoparticles in environmental applications such as remediation of groundwater be prohibited."

But reading through the original report, what strikes me more than anything is how the clarity that the RS/RAEng brought to thinking about the responsible development of emerging technologies has been lost.

Over the past five years there have been endless discussions, workshops, reviews and reports on the responsible development of nanotechnology. In many cases, they demonstrate a disturbingly pre-2004 understanding of the issues. It's as if the RS/RAEng report is viewed as a landmark, but not a beacon—everyone knows about it, but no one takes the time to read (or re-read) it.

A few weeks ago, the Department for Business Innovation and Skills in the U.K. – BIS – launched a public consultation to inform the Government's strategy for nanotechnology. It's a good idea, and should help the U.K. develop a clear roadmap for developing responsible and successful nanotechnologies. But it's ironic that five years after the RS/RAEng provided the government with clear advice on what was needed to develop safe nanotechnologies, the occasion is being marked by yet another review.

It's moves like this that make me wonder whether, despite all the action following publication of the RS/RAEng report, there hasn't been that much progress.

But there is a more serious issue here. Engineered nanomaterials—which were the primary focus of the RS/RAEng report—represent one technology innovation out of many that are likely to emerge over the coming decades. Scientific knowledge, and the technologies it spawns, are increasing at a geometric rate. The opportunities and challenges these emerging technologies will present are likely to bear scant resemblance to those experienced in the twentieth century—we are already seeing this in areas like nanotechnology, synthetic biology and information technology. Yet we seem stuck in a rut, attempting to manage 21st century technologies with a 20th century mindset.

The RS/RAEng report pointed the way towards changing this mindset and grappling with new challenges in new ways—ways that brought people together in partnerships to proactively grasp new opportunities while preempting and managing emerging risks. It provided a template for how to develop emerging technologies responsibly.

Nanotechnologies have had a fairly easy ride so far. Public awareness remains low. Progress has been incremental and often below the radar. And no one has died—yet. We may not be so lucky with the next new technology to come along. Unless we learn from and build on the broader lessons of the 2004 Royal Society and Royal Academy of Engineering report, we could find ourselves facing opportunities and challenges we are ill-equipped to deal with.

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A personal view from Professor Anthony Seaton

I think it is helpful to imagine what might have happened had such a report not been published. At the time, Prince Charles had put the royal seal of approval on fears of the planet turning to grey goo and some environmental pressure groups were raising fears across a range of possible hazards to humans and the environment. There were signs that battle lines were being drawn up for a fight that could seriously hinder the development of these nanotechnologies similar to that waged over genetic modification; calls were made for a moratorium on their further development. But the report was published, "welcomed" by Government and generally accepted by society, and committees were set up to consider the many recommendations made. The main anxieties of both public and researchers/technologists were reduced and the technological and commercial development proceeded apace. Interestingly, although almost no new money was set aside by the UK Government for research into health, environmental and societal hazards, as recommended by the report, a substantial research effort has in fact started. And, so far at least, nobody appears to have been harmed by nanotechnologies.

Those of us on the working group had to rack our brains as to possible hazards. The physicists were able to deal with the grey goo story from first principles, but the possible medical and environmental hazards were not amenable to such an approach, since there was limited understanding of the mechanisms of interaction of small particles with human or other cells and tissues. We proceeded by analogy with known risks from other small scale materials to which populations have been exposed, and came up with two important and well-researched ones: asbestos as an analogy for carbon nanotubes and air pollution particles for roughly spherical nanoparticles.

Being a group largely composed of scientists, we naturally called for more research and appropriate funding.

I have to say that I was somewhat less enthusiastic, as a medical scientist, than was the majority of the working group about the amount of money and the research structures called for. A body convened to examine a specific issue will always call for more research and money specifically for that issue, taking account of the scientific uncertainties and the need for a multi-disciplinary approach to investigate them. However, what it does not take into account is the degree of priority that the issues raise with the funders. In this case, it was only necessary to consider where a medical research funder would rank theoretical risk from nanoparticles (for it was in manufacture and use of nanoparticles that we foresaw hazard) against other current priorities such as those associated with pandemic infectious diseases, climate change, the ageing population and brain diseases, the development of vaccines, tackling alcohol and air pollution and so on, to realise that in terms of public health the issue was small. In my view, this remains the case, but this is not to say that it will remain so nor that it is unworthy of scientific investigation. So what was to be done while the committees set up by the Government were deliberating?

I think the most important immediate effect of the report arose from our recognition that hazards were possible and identifying areas requiring investigation. There is a natural suspicion that working groups such as this one, though independent and representing august bodies such as the two Academies, tend to take a conservative and establishment view, no matter how resolutely they make their independence clear. In this case, the very mention of asbestos was sufficient to allay such doubts. It also had the very useful effect of making scientists and technologists producing and using nanotubes aware of possible risk and has allowed regulators to produce advice intended to reduce this risk.

The report also helped stimulate the European Union to fund several programmes of research into nano hazards. And from a personal point of view, a number of those of us who already had a background of research in the areas of air pollution and asbestos and held current grants in the field got together without any specific funding as a multi-disciplinary consortium to try to answer some of the questions raised by the report. This is the loose association called SnIRC, the Safety of Nanoparticles Interdisciplinary Research Collaboration, based on the Institute of Occupational Medicine in Edinburgh, an independent self-funding research charity. Within these five years, SnIRC has proved able to develop a wide-ranging programme of research across the fields of occupational hygiene and human and eco toxicology and through its partner in the University of Edinburgh has answered one of the most pressing questions, with respect to asbestos-like properties of some carbon nanotubes. There is now sufficient understanding on which to base sensible, pragmatic measures to protect researchers and workers against most foreseeable hazards, even though there is insufficient yet known to enable us to predict which nanoparticles might entail real rather than theoretical risk. But it is not necessary to know for sure that something is dangerous before taking action to reduce risk.

Complex problems are not solved overnight. Nanotechnology raises many complex issues relating to possible adverse consequences and at first sight these appeared overwhelming. The report narrowed them down to toxicological, regulatory and societal/ethical. Never before has the introduction of a new technology been attended by an effort to understand and forestall hazard before any adverse consequences have been demonstrated, so to that extent any such effort would have been ground-breaking. On the toxicological side, the necessary research has already made important advances in understanding and a body of work aiming at finding generic properties of nanoparticles and their surfaces is underway. Methods of protection of workers and consumers from airborne nanoparticles are understood, allowing regulators information on which to base guidance, though appropriate methods of measurement of particles in this size range and of measuring the relevant toxic component or physical characteristic are still awaited. There is very much interesting research to be done at the interfaces of toxicology, measurement, occupational hygiene and surface chemistry. I am not clear as to whether the report's recommendations to Research Councils and others on societal and ethical issues surrounding the introduction of new technologies have been taken up generally. They are worth re-reading and universities need to take account of the desirability of ensuring that scientists take account of possible societal impacts of their endeavours.

Although I am generally positive about the introduction of nanotechnologies, I am not complacent and should end with a few concerns. There has undoubtedly been a huge unregulated introduction of nanoparticles into consumer products, including those for human consumption in food and on-line "medicines".

Although the human gut is pretty resistant to what it takes in, the bacteria within it are not and may have a much greater influence on our health than we think – indeed are essential to life! Dosing oneself with anti-bacterial nanoparticles is not something I would do, but many people are. Neither would I use any aerosol household spray containing nanoparticles, as we know something of the toxicity to the lungs and heart of inhaling large numbers of such particles in air pollution.

Until there is convincing published research to the contrary, I would remain wary of putting nanoparticles (as opposed to larger particles of the same chemical) on skin in cosmetics or sunscreens with respect to possible allergies and photosensitization. And finally, I would urge the Health and Safety Executive to carry out an audit and life cycle analysis in all facilities making and using nanotubes in order to ensure appropriate protection of manufacturers, users and those who ultimately dispose of them. If necessary, I would post a notice at such facilities stating "Caution – asbestos-like materials in use."

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Reflections from Professor Richard Jones FRS

The Royal Society/Royal Academy of Engineering report was important in a number of respects. It signalled a new openness from the science community, and a new willingness by scientists and engineers to engage more widely with society. This was reflected in the composition of the group itself, with its inclusion of representatives from philosophy, social science and NGOs in addition to distinguished scientists, as well as in its recommendations. It accepted the growing argument that the place for public engagement was "upstream" - ahead of any major impacts on society; in the words of the report , *"a constructive and proactive debate about the future of nanotechnologies should be undertaken now – at a stage when it can inform key decisions about their development and before deeply entrenched or polarised positions appear*." Among its specific recommendations, its highlighting of potential issues of the toxicity and environmental impact of some classes of free, engineered nano-particles has shaped much of the debate around nanotechnologies in the subsequent five years.

The impact in the UK has been substantial. We have seen a serious effort to engage the public in a genuinely open way; the recent EPSRC public dialogue on nanotechnology in healthcare gives a demonstration that these ideas have gone beyond public relations to begin to make a real difference to the direction of science funding. The research that the report called for in nanoparticle toxicity and eco-toxicity has been slower to get going. The opportunity to make a relatively small, focused investment in this area, as recommended by the report, was not taken and this is to be regretted. Despite the slow start caused by this failure to act decisively, however, there is now in the UK a useful portfolio of research in toxicology and ecotoxicology.

One of the consequences of the late start in dealing with the nanoparticle toxicity issue has been that this has dominated the public dialogue about nanotechnology, crowding out discussion of the potential far-reaching consequences of these technologies in the longer term. We now need to learn the lessons of the Royal Society report and apply them to the development of the new generations of nanotechnology now being developed in laboratories around the world, as well as to other, potentially transformative, technologies. Synthetic biology, which has strong overlaps with bionanotechnology, is now receiving similar scrutiny, and we can expect the debates surrounding subjects such as neurotechnology, pervasive information technology, and geoengineering to grow in intensity. These discussions may be fraught and controversial, but the example of the Royal Society nanotechnology report, as a model for how to set the scene for a constructive debate about controversial science issues, will prove enduring.

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Dr David Santillo responds point by point to the 21 Recommendations

"I've tried to be positive...but it is actually quite difficult when you read the recommendations in detail…"

Industrial application of nanotechnologies

R1 Life cycle assessment thinking is now beginning to get off the ground, though is far from widely applied. The OECD conference last week included a whole session on the opening day on life-cycle analysis, but was still at the stage of discussing 'is LCA a good idea for nano or not, and if so, how should it be applied?' There is, of course, the Woodrow Wilson Centre report on LCA (the conclusions of which I reflected upon in my presentation to OECD) which gives some cause for optimism (and a special issue of the Journal of Industrial Ecology from last year), but it is still at the theoretical stage, not at the stage at which it is a commonly applied assessment methodology in nano, as recommended in the Report.

Moreover, where it has been applied, there are instances in which the energy and resource (and waste) intensity of the manufacturing stage have really come into focus...that's the value of an LCA approach, of course, but in the words of the RS/RAEng, is LCA already ensuring '*that savings in resource consumption during the use of the product are not offset by increased consumption during manufacturing and disposal*'? There are some success stories that we heard about last week (and it's worth taking a look at some of the presentations once they go up on the OECD web-site) but it is far from widespread in terms of practical application.

So, in short, some cause for hope...but we are not yet as far ahead as RS/RAEng perhaps aspired.

R2 LCA tools as a research priority? Again, I think this is beginning to happen, but the calls for such research are still ongoing...there's a long way to go yet before we can have confidence in them.

Possible adverse health, safety and environmental impacts

R3 Recommends that Research Councils UK establish an interdisciplinary centre. Some consortia of research institutes and research councils are now in place, in the UK at least (but I also get the impression from my limited engagement with the SKEP process that this is relatively common across Europe). However, once again the research itself is in its infancy.

For example, the joint EPSRC/NERC/DEFRA/EA/CEH/CEFAS work on nanomaterials in the environment (fate and effects) is still at the stage of communicating the unknowns and the aims of the research. Progress is being made all the time, but I suspect the RS/RAEng anticipated being a bit further ahead in terms of actual results by now.

R4 The recommendation that release to the environment be avoided as far as possible was a laudable one, but there is no indication that this is what has been happening. Development of applications has proceeded well in advance of having the right test methods in place even to monitor distribution and trends in different environmental compartments, let alone ultimate fate and effects.

R5 (i) I'm reasonably confident that most manufacturers (in the West and in the richer countries in the East, at least) have taken workplace exposure controls seriously, though it is still hard to verify that exposure is minimised as a result, and there are some reports in the literature of airborne nanoparticles in the workplace nonetheless. What happens in less controlled conditions is anyone's guess. A big issue is, of course, the availability of data to verify one way or another - they are generally not in the public domain.

(ii) there is no evidence that such restrictions are in place or are planned. See 4. above

R6 Recommends life cycle assessments and disclosure to the relevant authorities. If such assessments have been done, it is not clear how far they have been shared with the relevant regulatory authorities. There seems still to be far too much emphasis on voluntary reporting schemes even for the manufacture and use of nanomaterials, so it seems we are some way from this arrangement also.

R7 There is still far, far too little information on uses, benefits, risks and unknowns in the public domain. Commercial confidentiality remains a major barrier to getting information to the public. I had to come to the defence of the public (in general) at the OECD meeting, as 'they' were accused of having irrational suspicions and fears about nano. The point I made was that if uncertainty breeds fear and suspicion, lack of access to information perpetuates the uncertainty - so don't blame the public if you feel they are reacting strongly to nano in the current climate of confidentiality.

Regulatory issues

R8 Consideration of whether existing regulations are in place is underway, including at EU level, though the outcomes are far from clear in terms of their practical implications. We still have the outstanding factor of how to address the tonnage thresholds, for example, which could well be meaningless for many nanomaterials. Furthermore, when I look at the current discussions within CASG on the classification of nanomaterials, the arguments between member states, industry reps and NGOs are still stuck on whether carbon nanotubes are the same as or different from graphite. Of course they are different - fundamentally different - but the CNT industry is seeing the chance to argue on a technicality that multi-walled CNTs are just rolled up graphite and should not, therefore, require any separate registration. If they wanted to feed fears and suspicions, there are few better ways of doing it!

R9 Horizon scanning seems to be underway in many ways. The main problem is often that these exercises are understandably vague, partly again because so much information on current and emerging uses is commercially sensitive and therefore not in the public domain.

R10 This recommendation that nanoparticles and nanotubes are treated as new substances picks up on the same points as under R8 above, i.e. thresholds and the distinctive identity of nanotubes, etc.

R11 Workplace

(i) In terms of review of regulation and exposure levels in the workplace, I'm not so familiar with the work of the HSE on this, though clearly Unions remain very concerned about workplace exposure to nanoparticles...so if the HSE is working towards such an evaluation, it is not yet providing for sufficient reassurances among the workforce or communicating it appropriately to their representatives.

(ii) I've no knowledge of whether HSE and EA have reviewed their management of accidental release...though I've certainly not seen anything publicised

(iii) Again I've no knowledge of whether HSE have reviewed their current exposure assessment methods - could be underway, but I don't know

R12 Consumer products

(i) full safety assessment before being permitted for use in products...what can I say? IF ONLY! SCCNFP is, of course, no more...but I haven't had chance to trawl the minutes and opinions of the new committees to see if this was ever specifically addressed and what the outcome was.

(ii) manufacturers publishing details of safety testing and how they have taken the different properties into account - this is still not happening

(iii) labelling as containing nano...once again - IF ONLY!

(iv) SCHENIR does seem to have focused some time on this. I haven't looked at the details of all the opinions, but I think it is fair to say that they have taken the issue fairly seriously.

(v) This does seem to have happened - see answer to (iv)

R13 No idea on the DoH recommendation on new medical devices - have they done that?

R14 I'm not aware that this has happened either, but I might be wrong

R15 Measurement

(i) likewise on this - not sure, I'm afraid

(ii) this seems to be well underway with lead from BSI (which, by all accounts, has had significant influence over the ISO standards for classification, etc.)

Social and Ethical Considerations

R16 I've seen little evidence that these issues have been given serious consideration so far. See also responses to 18 and 19 below.

R17 Ditto

R18 So many of the stakeholder dialogues and other discussions I have attended have started from the point of view that nano (as a whole) is an inherently good thing and that it is just a question of either convincing the public of that or of simply introducing nano solutions with little fanfare so that the public simply get used to them and don't know any different.

There is still a real lack of appetite on the part of government or industry to have anything other than a highly technical debate on this, and to look at things from the single perspective of how to make nano happen.

R19 As above

Ensuring the responsible development of nanotechnologies

R20 The Council on Science and Technology 2007 Report was the first of these - not sure when the next will be, though we have had the Royal Commission on Environmental Pollution Report in 2009 and soon the House of Lords Select Committee Inquiry on Nanotechnologies in Food.

R21 Can't comment again, I'm afraid - I simply don't know.

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Reflections unattributed - industry

The RS/RAEng report was one of the first reports that explored both the uncertainties and the opportunities of nanotechnology, and it is still seen as the seminal report on this topic. Many countries have built entire billion-dollar national nanotechnology strategies on that report (i.e. it is mentioned in the opening statement of numerous national nanotechnology initiative papers that later on prompted funding), while one of the only countries that still doesn't have a nanotechnology initiative or, indeed, a strategy, is the UK.

In the last 5 years, UK nanotechnology stakeholders have participated in numerous surveys, consultations, etc. ... what good has it done?

...We have read the Taylor Report (which essentially was a strategy, but was not implemented) ...

...We have commented on the 1st DEFRA Characterisation Report ...

...We have given evidence and feedback to the CST study ...

...We have participated in the NEG ...

...We have participated in the Horizon Scanning Exercise ...

...We have contributed to the TSB Strategy ...

...We have contributed to the DEFRA NSF review ...

...We have contributes to the RCEP study ...

...and now we are asked to contribute to another strategy ... which is going to end up how, exactly?

Maybe, instead of running a costly evidence gathering process for a new strategy, somebody should sit down and read all of the above and then read the RS/RAEng report...and then do something about it?

Unattributed - industry

Reflections from Tim Harper

We have spent the five years since the RS/RAEng report worrying about the possible safety, social and ethical implications of nano, and about its effects on industry, healthcare and our daily lives. However, the global economy has always been driven by technology, from the Spinning Jenny to the Transistor, and all of this discussion is moot unless the conditions exist for British Entrepreneurs to spin out world-beating companies from our undoubtedly excellent research base - and the UK's record in this field is poor compared to many other countries.

The problem is that the funding is simply not there at the level of a few tens of thousands of pounds to get things moving. Companies at this early proof-of-concept stage are not interesting to venture capitalists and it is government (both local and national) who need to shoulder this early risk. If they don't, the entrepreneurs will move to the US and the Far East and we will see the fruits of British academic research commercialised under licence everywhere from Korea to California.

Instead of spending tens of billions of dollars bailing out failing industries, the government should be putting significant cash into scientific spin outs that will be creating value in the next five to fifty years. Now is the time to stop throwing good money after bad and invest in the future.

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Reflections from Dr Qasim Chaudhry

Before the RS/RAEng review, the pros and cons of nanotechnologies were being raised in a haphazard way. On one hand were projections for the enormous (and sometimes unrealistic) claims for benefits, and on the other were scenarios associating every imaginable risk with nanotechnologies. The review set the wide range of issues in perspective, and discussed the technological, health and safety, environmental, ethical, societal and regulatory aspects in a comprehensive way, highlighting the knowledge gaps and needs for research."

One argument used again and again was that nanomaterials were no different from conventional bulk equivalents, and for that reason did not need any new regulation or safety testing. The RS/RAEng review made it clear that, because nanomaterials may behave differently, they should be treated as new substances under (the then) Notification of New Substances (NONS) regulations, and in the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation (now in force).

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Reflections from Dr Elen Stokes, Professor Robert Lee and Lori Frater

In their report, the RS/RAEng made a number of recommendations – eight in total – relating to the regulation of nanotechnologies. These recommendations touch upon a range of regulatory issues, although we may usefully divide them into three general categories: (i) regulatory review, (ii) regulatory substance and (iii) regulatory procedure. Progress has been made in each of these areas, particularly the first which, arguably, has produced the most tangible results.

The RS/RAEng recommended that all relevant regulatory bodies consider whether existing regulations are appropriate to protect humans and the environment from potential risks associated with nano-enhanced products and processes.

The Health and Safety Executive (HSE) was the first regulatory body to report, followed in quick succession by the Department for Environment, Food and Rural Affairs (Defra), the Food Standards Agency (FSA), and the then-Department of Trade and Industry (DTI). Other regulatory bodies (such as the Medicines and Healthcare Products Regulatory Agency) conducted reviews by contributing to the Government's response to the RS/RAEng report in 2005.

Although they vary, both in respect of the particular regulatory provisions under review and in terms of outcome, each report reaches the broad conclusion that existing regulations apply in principle to nanomaterials and that there are no major regulatory gaps. The HSE, for example, described regulations as 'appropriate and applicable to nanomaterials', although added that the absence of data made it difficult for all involved in the regulatory process to confidentially discharge their responsibilities. Similarly, the FSA concluded that, even though there was uncertainty in some areas as to whether they would always be picked up, 'most potential uses of nanotechnologies that could affect the food area come under some form of approval process before being permitted for use'. More recently, following its own review of provisions at EU level, the European Commission issued a Communication on Regulatory Aspects of Nanomaterials which found that:

'[o]verall, it can be concluded that current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework.'

This conclusion has emerged as a dominant theme in the regulatory debate. It is not, however, unproblematic nor has it gone unchallenged. The European Parliament in particular has become increasingly uneasy with the rate of progress on the regulatory front (see European Parliament Resolution on Regulatory Aspects of Nanomaterials).

Regulatory reviews have tended to focus on whether nanotechnologies and their applications are caught within the remit of existing provisions. This issue is indeed relevant and should be addressed, if only as a means of highlighting loopholes which may result in the exclusion of nanotechnologies from regulatory control. By itself, however, an analysis of regulatory coverage provides only a partial account of how current measures apply to nanotechnologies.

The problem with this approach is that it overlooks the question of regulatory effectiveness. The fact that existing regulations can extend to cover nanotechnologies offers little indication of their ability to afford adequate protection. We must inquire as to whether, in practice, those measures are capable of achieving an acceptable level of safety given the possibility that some nano-enhanced materials may be more toxic than their bulk-scale equivalents. Only by considering questions of coverage and of effectiveness can we begin to obtain a fuller picture of the regulatory reality.

Without doubt, regulatory reviews published in the aftermath RS/RAEng (2004) have been vital in understanding which provisions apply to nanotechnologies. The more pressing matter now is gaining insights into how those provisions operate and whether they adequately deal with safety concerns surrounding certain types of nanomaterial. A range of regulatory tools for nanotechnologies already exist; the question is whether their capacity to protect health and the environment is being fully realised (for further discussion of adaptive governance in this context, see the Royal Commission on Environmental Pollution report Novel Materials in the Environment).

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Reflections unattributed - Investment Management Company

The RS/RAEng report was one of the first publications that put nanotechnology on our radar screen. As a large investment manager, with a strong commitment to responsible investment – meaning, inter alia, that we aim to take into account companies' performance on environmental, social and governance (ESG) issues in our investment decisions – it made it clear to us that we needed to do further research to understand the full range of ESG risks and opportunities associated with investing in companies developing or utilising nanotechnologies.

The RS/RAEng report provided an excellent exposition of the issues surrounding these rapidly developing and exciting technologies. It also provided a clear road map for government and others to follow to ensure that nanotechnologies were developed responsibly and in such a way as to avoid the pitfalls that had beset other technologies in the recent past.

Our research revealed several problems, most of which related to a lack of information and a lack of transparency. As investors, we need clear and comparable information from highly credible and objective sources, e.g. government or independent bodies or laboratories, about the nature and level of the environmental and health risks of individual nanotechnologies. This was lacking five years ago, and still seems to be lacking. Moreover, insufficient effort and funding seems to be being committed to this kind of research, which is essential to many stakeholders for a variety of reasons.

If this information were available, we (and other investors and insurers) could then assess the extent to which companies in which we invest (or insure), or hope to invest (or insure), are utilising those technologies and the extent to which they understand and manage any risks and opportunities associated with them. Given ongoing regulatory uncertainty, and the fact that many aspects of nanotechnology are not necessarily suited to regulation (such as how companies market such products, consult with stakeholders or address the ethical dimensions of the technologies' development), we need a way to assess whether companies have adopted best practice policies and practices to govern and manage their use of them.

We very much welcome the development of The Responsible NanoCode and similar initiatives – though we are concerned that a profusion of such guidance will simply serve to confuse investors and other stakeholders. Our preference would be for one principles-based Code, applicable to a wide range of companies in a wide range of sectors and markets, supported by key stakeholders and adopted by all businesses involved in nanotechnologies. We would also like to see a regular, objective evaluation of companies' performance against that Code, so as to be able to assess their commitment to responsible nanotechnology and their progress in that regard.

We continue to track the evolution of nanotechnologies. We will actively support initiatives that aim to ensure that nanotechnologies are developed responsibly. For our part, we plan to host a series of events to help other investors (specifically, those that are signatories to the Principles for Responsible Investment, or PRI, representing $18 trillion of assets around the world) understand the issues surrounding nanotechnologies and begin to ask companies in which they invest for much more information about their approach to commercialising them.

Nanotechnology is developing at a rapid pace. It has the potential to add economic value, create jobs and improve a wide range of products. It is therefore essential that governments keep up with – and ideally keep ahead of - this pace.

The RS/RAEng report laid out a clear road map and basis for a strategy which, disappointingly, appear not to have been pursued; five years on the UK government has only just launched a consultation on its strategy. If investors are to support these exciting but potentially risky and controversial technologies, they need clarity about whether they are legal, safe, ethical, efficacious and acceptable to consumers.

We therefore urge the UK and EU governments to urgently clarify their plans for regulating nanotechnology over the next 5-10 years and to dedicate many more resources to environmental, health and safety research and to clear communicating the results of such research. Much greater, ongoing consumer and public engagement with the science and with companies developing these technologies would also be valuable. To address the non-regulatory aspects of nanotechnology development, we hope to see companies involved in this field adopt clear policies to demonstrate their commitment to corporate responsibility in this area. These should address not only potential environmental and health risks, but also the ethical and social dimensions of development of these technologies, as well as issues relating to marketing, advertising, labelling, transparency, disclosure and stakeholder consultation.

Unattributed - Investment Management Company

Reflections from Dr Rob Reid

This was an important report that clearly highlighted key areas of concern in a rapidly developing and increasingly commercialised field of research. Unfortunately, many of the issues that the report raised in 2004, for example around the lack of evidence on potential risks posed by manufactured nanoparticles, the development of methodologies for measurement of nanoparticles, and the need for safety assessment of nanoparticles before application to consumer products remain issues today, despite being highlighted since in several other reports. People in government seem to spend a lot of time and effort acknowledging gaps and problems but without doing anything substantial about them. Of course we need a coherent plan, but it appears like nothing happens beyond lots of talking about strategy.

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Reflections from Dr Adrian Henriques

Businesses using nanotechnology face a significant challenge in using this developing technology responsibly. There are numerous technical and health and safety uncertainties the technology still presents – and it is not at all clear how a responsible business can address them effectively. The greatest need is for transparency as to how these challenges are currently being addressed by the business and the scientific communities.

Adrian Henriques,
Professor of Accountability
Middlesex University Business School”

Reflections from Dr Rob Aitken

The lack of progress since the publication of the RS/RAEng report in 2004 can only be described as disappointing. Despite increasing levels of funding and greatly increased activity both in the UK and elsewhere, few if any of the key issues relating to exposure, toxicology and risk of nanoparticles and nanotubes have yet been answered in a satisfactory way. Although some important studies have been published, we still require for example basic information about relationships between dose and effect, distribution kinetics of nanoparticles which enter the body, safe levels of exposure, measurement methods for nanotubes and agreed protocols inter alia.

Undoubtedly, one reason for this has been the lack of a focused research funding strategy such as that called for in the report. It is worth reflecting how much progress would have been made if one of the key recommendations of the report, to establish a properly funded interdisciplinary research centre, had been implemented.

To some extent this co-ordination of research is now beginning to happen more effectively, particularly in Europe, through the activities of the FP7 programme and through the activities of the OECD Working Party for Nanomaterials and these efforts should be supported.

It remains to be seen whether this delay will prove to be critical either to the industry or the users of these materials in whatever form. Certainly applications using nanoparticles seem to be increasing rapidly, particularly in the consumer area and it must be acknowledged that at this point no one has been identified as becoming ill from using these products. However, health effects may take some time to emerge and so this must not be taken as an excuse for any complacency or reduction in effort to resolve these difficult challenges. I look forward to seeing what the next five years will bring.

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Reflections from Dr Steffi Friedrichs

Following the recommendations of the RS/RAEng report (and the recommendations of the CST report, and in line with the recommendations of the RCEP report), the NIA and its members have initiated the development and establishment of a targeted research programme, worth £3.7 Million: http://www.nanotechia.org/news/press/nia-wins-major-grant-for-nanomaterials-test.

The programme is one of the largest contributions to the OECD Sponsorship Programme, assuring added-value and coordination of the research with the OECD Sponsorship Programme (i.e. largest, internationally agreed nanomaterials safety test programme).

We are grateful to the Nanotech Team at DEFRA for making this project happen by using the tool of a public-private partnership to implement a large-scale coordinated nanomaterials safety research project, as called for in the RS/RAEng report (and CST report, etc); it might not be the UK Government-led project that the expert committees had in mind when they talked of 'ring-fencing a proportion of funds for risk assessment', but it essentially fulfils the same purpose, and – in addition – has put the UK on the map of major contributors to the global effort in safety testing of nanomaterials.

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Reflections from Professor Ken Donaldson

Five years after its appearance, there is no doubt that the report had a remarkable effect in the nanotubes/ asbestos issue. We and other groups were posed a very clear question by Anthony Seaton, who wrote that section– can nanotubes act like asbestos? In Edinburgh we set about testing carbon nanotubes against the current fibre pathogenicity paradigm. By persuasively demonstrating that carbon nanotubes and asbestos shared a similar pathophysiologically relevant characteristic of length-dependent toxicity [2], attention was further drawn to this issue and the paper had a large impact on the particle toxicology, nanotoxicology, regulatory and risk assessment community globally. The answer to the question is not yet clear, and has been broadened to a more generic form 'can high aspect ratio nanoparticles act like asbestos?' to embrace fibrous nanoparticles other than carbon nanotubes such as nanowires and nanorods. However advances have been made, funding is flowing and the question is at least now high on the agenda for nanotoxicology, exposure measurement and risk assessment.

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[2] Reference List

1. Poland CA, Duffin R, Kinloch I, Maynard A, Wallace WA, Seaton A *et al.*: **Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study.** *Nat Nanotechnol* 2008, **3:** 423-428.

Reflections from Mr Frank Barry

Where are we today with nanomaterials and how are we protecting people in the workplace based on the recommendations made in the RS/RAEng 2004 Report?

R3 Workers exposure to nanomaterials

The earliest and most extensive exposures to engineered nanoparticles are likely to occur in the workplace. Therefore, evaluation of the potential health risks associated with exposure to nanomaterials is essential to ensure their safe handling. It is important to note that almost all of the toxicological concerns that have been raised relate to free, rather than fixed manufactured nanoparticles. As many different types of nanomaterials are already used in the workplace, across a wide range of applications, there is a need to determine what action needs to be taken in order to protect workers in the workplace. This is still the position today.

R8 Trade Union view on current EU / National legislation/ regulatory issues.

It is currently the view of the Trade Unions that the European legislative framework fails to adequately address nanomaterials and that the implementation of the legislation needs further elaboration. This is as existing legislation and international occupational safety and health standards do not specifically address nanotechnologies, nor are there accepted standard methods for measuring occupational exposure to nanomaterials.

The position within the Trade Union movement is that there is a need, an urgent need, to evaluate the suitability of current regulatory frameworks with respect to nanotechnologies. In particular, it is concerned whether occupational exposure to engineered nanoparticles poses a risk to human health.

Workers are already engaged in processes using engineered nanoparticles however, it is not yet possible to identify any systematic rules for the toxicological characterisation of all nanomaterials, due to the knowledge gaps that currently exist related to their properties. Diverse stakeholders have agreed that research to address these gaps is essential for the responsible development of nanotechnology.

Scientific evidence indicates that both ingested and inhaled nanoparticles have the capacity to have localised and systemic effects. However, traditional validated toxicological techniques, designed for chemical substances may be insufficient in the analysis of nanoparticle toxicity.

The challenge for the toxicological study of nanoparticles arises mainly because of difficulties in the reliability, comparability and reproducibility of materials on this dimension scale. Therefore, each nanoparticle type must be examined on a case-by-case basis. The key question is how to control exposures of nanoparticles and protect workers given the potential health concerns and the uncertainties that currently exist. It is crucial for the Trade Unions to keep abreast of developments in this field.

Information gap

As an emerging technology, it is a must to investigate the potential hazards and ascertain if there is a risk to workers from a health and safety point of view.

In our opinion, despite the rapid growth of nanotechnology both in Europe and Internationally, none of the existing global level occupational safety and health standards or Regulations specifically addresses nanotechnologies, nor are we aware at this time that there accepted standard methods for measuring human exposure to nanomaterials in the workplace. To provide direction on this, the European Commission's (EC) Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR, 2006, 2007, 2009) points to major gaps in the knowledge necessary for conducting such risk assessments.

R15 Measurement

We recommend that researchers and regulators looking to develop methods to measure and monitor airborne manufactured nanoparticulates liaise with those who are working on measurement of pollutant nanoparticles from sources such as vehicle emissions etc. The EU reports highlight data gaps in nanoparticle characterisation, the detection and measurement of nanoparticles, the dose-response, fate, and persistence of nanoparticles in humans and in the environment, and all aspects of toxicology and environmental toxicology related to nanoparticles. Of special importance to workers are the questions concerned with the transport of nanoparticles in the human body. The monitoring and measurement of occupational exposure and the epidemiological data on the potential impact of nanoparticles on human health are a must for further research in order to ensure the health and safety of workers health into the future.

It is also important to note that with respect to risks to safety, health and welfare in the workplace, almost all toxicological concerns that have been raised to date, relate to free, rather than fixed, manufactured nanoparticles. The risk analysis and subsequent safety measures employed in relation to free nanoparticles may therefore be very different than the safety measures for fixed manufactured nanomaterials, given the widespread application of nanotechnologies.

R10 EU Legislation

As outlined in the Commission's paper on the Regulatory Aspects of Nanomaterials (2008), whilst the Community legislative framework generally covers nanomaterials, implementation of legislation needs further elaboration. Important elements are the test methods and the risk assessment methods that serve as a basis for implementing legislation, administrative decisions, manufacturer's obligations or employer's obligations. The scientific basis to fully understand all properties and risks of nanomaterials is not sufficiently available at this point in time, therefore it would be advisable that the precautionary approach[3] should be applied where nanomaterials are being manufactured or used in a workplace.

The application of the REACH regulations (EC) NO. 1907/2006 and amendments (R10), we recommend that chemicals in the form of nanoparticles or nanotubes be treated as new substances under REACH,

The REACH Regulation (EC) No 1907/2006 aims to ensure a high level of protection for human health and the environment, its provisions being underpinned by the precautionary principle. The provisions of the Regulation apply to the manufacture, placing on the market and use of substances on their own, in preparations or in articles.

Under REACH, if the substance is manufactured or imported in quantities greater than one tonne per year, there is a requirement for it to be registered. The tonnage triggers for registration apply to the total volume of a substance manufactured or imported by a registrant. Thus, for substances which exist both in a conventional form and in a nanoform, the total volume determines the need to register. For quantities manufactured or

[3] A precautionary approach means that protection is layered in a system or process and layers are only removed when evidence indicates that particular level of protection is not required. It does however involve professional judgement in order to determine adequate precautions in a workplace. Essentially it means a practical approach that both protects workers and supports enterprise, *i.e.* it protects the people and the product.

imported at quantities less than one tonne per year there are no such requirements, hence the demand of the Trade Unions and their call for the tonnage to be reduced to allow for all nanomaterials to be registered under REACH. Since this the position of REACH it fails to meet the intention of the recommendation in the report.

The Trade Union position which accepts the recommendations as a positive way forward, but have not in the 5 years been totally addressed by those manufacturing nanomaterials to protect workers.

It is therefore questionable whether current EU / National occupational legislation covers the associated risks in relation to nanomaterials. It is our view that employers must undertake continuous and dynamic risk assessments in relation to the use and application of nanomaterials in the workplace.

There must be proactive discussions on the physico-chemical characterisation techniques, health effects and risk assessment developments at a national, European and International (e.g. OECD) level.

There must be a European wide system for monitoring new data in the nano-sciences as it emerges, including monitoring available epidemiological data generated from individuals exposed to nanoparticles and to evaluate research findings. Until such time as the impact of nanoparticles on human health has been established, Employers must adopt the precautionary approach in the workplace and, that nanomaterials are treated on a case-by-case basis when conducting risk assessments.

There must be a process designed at EU level to facilitate the communication of best practice to employers/ employees and to engage with them to ensure the safe and transparent development of nanotechnologies.

It is also our view that there must be discussions by National Governments with DG Enterprise on the subject of nanotechnologies to develop a single over-arching approach and strategy for the overall coordination of nanotechnology activities in Europe and at National level. There is also a need to develop mechanisms for effective coordination and communication on nanotechnologies between multiple Agencies and NGOs and the Trade Unions

The need to liaise with relevant public bodies and/or academic institutions on appropriate methods to engage the public on issues related to the socially acceptable development of nanotechnology. (the Ethics of Nanotechnology, R16 We recommend that consideration of ethical and social implications of advanced technologies should form part of the formal training of all research students and staff working in these areas). In our opinion this is not happening except in a small number of cases in Europe.

The Trade Union demand that funding be provided in research projects and stand alone health and safety projects to enable research to be carried into the Health and safety aspects of nanomaterials

The Trade Unions call for the tonnage of hazardous substances to be reduced to allow for all nanomaterials to be registered under REACH.

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Reflections from Dr Peter Hatto

Whilst only one of the 21 recommendations, number 15, in the RS/RAEng report specifically referred to standards and standardisation, it is clear from the body of the report that consensus-based standards would be required to satisfactorily address many of the others. Besides recommending that "*the Department of Trade and Industry supports the standardisation of measurement at the nanometre scale*", the authors reported that they were "*pleased to learn that initial steps in this area are being undertaken by the British Standards Institution (BSI), as part of the European Committee for Standardisation Technical Board working group on nanotechnology*".

So what has happened in the area of standardisation for nanotechnologies in the last 5 years and how did the Government respond to recommendation 15?

Well, for a start the "initial steps" being undertaken by BSI continued apace and were well rewarded by its securing the chair and secretariat of both the ISO (International Organisation for Standardisation) and CEN (European Committee for Standardisation) technical committees for nanotechnologies – ISO/TC 229 and CEN/TC 352 - positions that it still holds. Through the UK committee, NTI/1, established months before the RS/RAEng report was delivered, BSI has published 10 National standards documents[1], including guidance for labelling of products containing nanoparticles (PAS 130) and for the safe handling and disposal of nanoparticles (PD 6699-2), the need for which were highlighted in the report. Although none of these documents specifically addresses standardisation of measurement at the nanoscale, referred to in recommendation 15, the DTI and its successor, DIUS, were generous in support of these and other BSI activities in the area, enabling the UK to take and maintain a decisive leadership position in standardisation for nanotechnologies.

Although many people will be unaware of current standardisation activities, it is worth noting that the ISO committee represents probably the biggest international collaboration on nanotechnologies in the world, with 41 countries, 25 other ISO Technical Committees and six international organisations contributing to its work. The committee has so far published two standards: ISO TS 27687 Terminology for nano-objects – nanoparticle, nanofibre and nanoplate; and ISO/TR 12885 – Nanotechnologies - Health and safety practices in occupational settings relevant to nanotechnologies; and has nearly 40 projects under development, with many more to come, in four "horizontal areas": terminology and nomenclature; measurement and characterisation; health, safety and the environment; and materials specifications. Up-to-date information about the committee, its structure, membership, and work programme can be found at *http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983*.

CEN TC 352, whilst cooperating closely with TC 229, was established to develop standards of specific interest to Europe and the European single market.

It has two working groups: *measurement, characterisation* and *performance evaluation*; and commercial and other stakeholder aspects. It is participating in the joint development of several projects with ISO TC 229 and is leading three of these. The committee is currently awaiting a response from the European Commission to a mandate report (M409) that elaborated a programme of standardisation taking account of the specific properties of nanotechnologies and nanomaterials, which it prepared on behalf of the three European standardisation bodies (CEN, CENELEC and ETSI). The response is expected to be in the form of a further mandate for the preparation of a cross cutting suite of standards to support the safe and responsible exploitation of nanotechnologies in Europe and internationally. The committee is also working closely with the NMP (nanotechnologies, materials and processing) division of DG Research to identify outputs of Framework projects that could be effectively exploited through their incorporation in European standards. Either one of these future opportunities, i.e. a new mandate and the dissemination and exploitation of research outputs, will constitute a significant increase in work load for the committee, and would provide substantial benefits for European industry. For the leader of the committee, they would also represent a significant opportunity to influence the future development and exploitation of nanotechnologies in Europe.

Leading and influencing standards-making provides an ideal opportunity for a country to maintain itself at the forefront of technical and commercial developments, despite a significantly lower national expenditure in the area than its competitors. Such a leadership role can also help secure opportunities to compete effectively in an increasingly aggressive global market. By being at the vanguard of nanotechnologies standardisation, the UK is well placed to take full advantage of standards developments, recognised as being an effective tool for and enabler of innovation. Continued vigourous and active engagement in the whole of the nanotechnologies standards arena will additionally provide valuable technology and business intelligence, from which the UK could gain considerable benefit.

One would therefore think that the Government and BSI would be keen to maintain the leadership currently enjoyed by the UK by continuing to support these activities until the business community is in a position to take responsibility for the standardisation effort. Unfortunately that does not appear to be the case, as in May plans were announced whereby support for these leadership activities would be reduced by around 50% this year and withdrawn completely next year. Whilst this can be seen as simply “normalising” the leadership positions for the UK, European and international committees, i.e. making them entirely dependent on support from industry, it fails to recognise the early stage of development of most nanotechnology based enterprises and the foundational and horizontal nature of the standards currently under development. So having invested in leading the various activities over the last five years, the UK is about to remove support just at the time when the work load is expanding rapidly and before the benefits are realised. Have we heard this story somewhere before?

Dr Peter Hatto
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[1] the ten UK National standards documents can be downloaded free of charge from www.bsigroup.com/nano

Reflections from Professor Geoffrey Hunt

Nearly everyone agrees that standardisation, either European or international, is one of the most pressing issues in the development of nanotechnology. The challenge of standardisation was recognised in the Royal Society/ RAE report of 2004, yet structures and processes remain outdated and inadequate standardisation is still an obstacle. You might say that the whole process of standardisation is itself in need of a standard! At the moment, the process is slow, bureaucratic, under-funded, fragmentary and uncommunicative. A new Commission Mandate (M/409) promises some change in the development of European nanotechnology standards, but does it get to the root of the problem?

For example, one might be forgiven for thinking that there must be some systematic integration of the numerous FP7 nanotechnology projects and the standardisation process of national standards bodies, CEN and ISO – but there is no such integration. Any relationship between FP7-CEN is, one might say, casual.

One might also think that standardisation is supported by government according to national technological priorities and that corporations and businesses are encouraged to follow this leadership – but there is neither such leadership nor such encouragement. Indeed compliance with national standards is not even a requirement for public procurement.

Another widespread assumption might be that once they are published standards would be freely available and vigorously disseminated. Wrong again. Most standards are copyrighted, expensive and not widely disseminated. Therefore many of them are not even generally known, let alone adopted and promoted.

Is standardisation properly funded? No, it is not. Experts sitting on vital standardisation committees are volunteers and provided with no real incentive to do this vital work except for the support provided by their employers.

And what about research? Surely researchers in universities, research institutes and corporate laboratories are fully aware of standards when they publish their findings and meet at conferences? The answer is No. Most nanotechnology research publications ignore international standards in terminology, for example.

Standards are essential for cross-disciplinary and cross-national communication, for the interoperability of applications, effective regulation, research cooperation and data-sharing, and for the commercialisation of applications, especially perhaps by SMEs.

The EU has been aware of this issue for some time. The Commission's Enterprise & Industry Directorate-General produced an 'Action Plan for European Standardisation' in 2005. It states that "standardisation has been identified as a priority issue for the competitiveness of a number of industrial sectors". However, four years later real implementation strategies are still largely absent. This is not the fault of the individuals currently working hard in national, regional and international standards bodies. It is a failure of political will. What can be done, how and when?

Professor Geoffrey Hunt

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Reflections from Prof Nick Pidgeon

The report was ground breaking and innovative for both Societies in the ways it brought together and synthesised leading thinking from the (traditional) natural sciences and engineering with that of the social sciences in a very constructive engagement. Not only did the Royal Society itself follow this up with further highly innovative work at the interface of 'Science and Society' on other topics, but as a result the UK has established itself as a world-leader in research and practice around public engagement and nanotechnologies. Only now are countries such as the USA beginning to catch up.

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Reflections from Dr Donald Bruce

Several things about this report which made people sit up and take notice. One was the fact that it flagged up potential concerns about some types of nanoparticle, and that it stressed the need to consider the social and ethical aspects. Coming from the two bodies representing the science and engineering communities, this was significant. It earned them a lot of respect and has had wider international influence. For example, the European Commission code of conduct on nanotechnology, and the EC's stress on including ethical and social aspects in its nanotechnology scientific programmes have both been influenced by the Royal Society/RAE report.

A second point was that the study took the unusual step of doing some preliminary public engagement and recommending that the research councils build upon it 'by funding a more sustained and extensive programme involving members of the general public and members of interested sections of society'. This stimulated various such initiatives in the UK, but the report's implicit recognition that physical scientists and engineers also need to consider wider issues was a factor in the EPSRC setting up an expert panel on societal issues. This produced a notable piece of public engagement which provided unexpected and valuable insights on priorities for a research in nanomedicine.

The success of this latter study showed that, with hindsight, we should have focused earlier in these engagements on specific areas of nanotechnology, rather than treat it as thought it was a phenomenon in itself. Many of the early dialogues were too general. It also showed that engagement is expensive and so has to be targeted carefully to key issues. It also suggests a role for more inexpensive methods that also contact a much wider spread of people, such as the New Economics Foundation's 'Democs' card games and its 'Open Up' Argument Maps.

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Reflections from Dr David Grimshaw, Practical Action

The RS/RAEng report raised concerns that there was a potential for nanotechnologies to intensify the gap between rich and poor countries. Practical Action was consulted by the Royal Society working party and the following letter was published in The Guardian (20 August 2004): *"Our concern is that yet another new technology will over-promise and under deliver; that in addition to the already apparent "digital divide", we may be on the verge of a "nanodivide". We should ensure that nanotechnologies are harnessed for the benefit of all peoples in the world not just those who can afford to fuel a consumer boom of new products. Many poor people in the world have basic requirements - for water, energy, and food - that are as yet unfulfilled. We need to ensure that nanotechnologies are used to achieve wider social and environmental goals (eg sustainable energy), rather than meeting short-term or developed world "market opportunities" for products such as sunscreen*." (http://www.guardian.co.uk/science/2004/aug/20/nanotechnology.guardianletters)

Five years on what progress has been made in harnessing nanotechnology for the benefit of poor people? It is true that there have been further nano-dialogues, including those undertaken by Practical Action in Zimbabwe, Peru and Nepal. Some engagement with scientists in developing countries has been made, for example Practical Action in Peru has been a catalyst for the development of a nanotechnology network (see http://www.nanotecnologia.com.pe/). However there is scant evidence of specific applications of nanotechnology being developed for use in developing countries. Some solar power applications have been developed in South Africa and elsewhere and some novel methods of removing arsenic from drinking water are being tested in Mexico but to date few, if any of these innovations have been applied and certainly not at any scale.

You might think this position is fine because it is "early days". But experience suggests that if efforts are not made around a research agenda on social and ethical issues it could be too late to affect the overall business model. Perhaps of even greater importance is conceiving research projects that will include partnerships in developing countries. Such partnerships should include scientists, NGO's, Government agencies, and beneficiary communities.

A much more proactive policy of engaging developing countries is needed not only from NGOs but also from Government.

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Reflections unattributed - Pharmaceutical company

I participated in the NTI meeting at the BSI in Chiswick yesterday, and what astounds me is that 5 years on we are still talking about the following issues as though no progress has been made at all, namely:

* The establishment of an ethics framework.
* Societal engagement on nanotechnology uses: we have moved from open disclose to fear of the public finding out that nanotechnologies are employed in products. Sorry to say this, but we are repeating the genetically modified food debacle.
* Standardisation - in its widest sense i.e. material characterisation, definitions, and the opportunity to develop 'kite mark' standards
* Defining nanomaterial lifecycles
* The establishment of good, easily assessable references to information on nanotechnology
* Strategies: too much effort is being spent by too many desperate parties on defining strategies instead of completing work tasks. This may be money driven though, as it is easier to talk about something then complete practical tasks!

Unattributed - pharmaceutical company

Reflections from International organisations

At the time of its publication in 2003 the RS/RAEng report raised a range of issues that demanded follow-up and gave many detailed recommendations for action, notably by governmental and research institutions in the UK and EU. Perhaps most important is the attention it drew to nanotechnology itself.

What has been most encouraging is how many of the recommendations have led to action at a wider, global scale. Many organisations have become involved in the ongoing debate which has permeated throughout many governmental, industry and non-governmental organisations both internationally and in many countries. These have been at governmental (eg the OECD's creation of the two Working Parties) and other (eg ISO's Technical Committee 229; the International Council on Nanotechnology) levels. Swiss Re's contributions have been one of many from industry. IRGC has played a part through its two projects looking at aspects of nanotechnology's risk governance. There has been a lot of participative debate and the RS/RAEng report has been crucial in galvanising and providing an initial focus for much of it.

Whilst the level of involvement has been truly impressive, I am less convinced that it has led to our knowing a great deal more about nanotechnology (or should I say nanotechnologies) or the associated benefits and risks. This lack of knowledge has created a degree of uncertainty that will only be overcome with the publication of a body of rigorous risk assessments, particularly of nanomaterials in commercial use now, which account for the full life-cycle of the materials in question. The 2004 report refers on a number of occasions to the need to better understand the potential sources of uncertainty. This remains a priority, but there is also now, from my perspective, a need to work to reduce the level of uncertainty if nanotechnologies are to fulfil their full potential.

Unattributed

Information from Pieter van Broekhuizen

Pieter Van Broekhuizen of IVAM (an independent research and consultancy organisation of the University of Amsterdam in the Netherlands) contributed the following information on the very recent developments in the Dutch Parliament relating to nanotechnologies. The RS/RAEng 2004 Report had an important influence in the Netherlands, contributing to the developments outlined below. It also, he can confirm, gave a significant impulse to start the thinking (early 2005) about setting up a project on the capacity building for trade union and NGOs on nanotechnologies which became the NanoCap.

Nano in the Dutch Parliament

In March 2009 the Social Economic Council of the Netherlands advised the minister on safe working with nanoparticles (Advisory report 09/01 - Nanoparticles in the Workplace: Health and Safety Precautions). The three ministers of Social Affairs, Environmental Affairs and Economical Affairs gave their reactions to this advice, consequently leading to an intense discussion in the Dutch Parliament. This resulted in several motions in the Parliament of which the following three motions were accepted by a majority of the Parliament:

- Motion on a notification obligation
- Motion on nano reference values
- Motion of speeding up of risk research
- Now the Dutch Government will have to come up with a practical elaboration of these motions.

Detail of the motions are as follows:

Notification Obligation - PROPOSED AND AGREED MOTION IN THE DUTCH PARLIAMENT 2nd July 2009

- Considering the fact that the Dutch Social Economic Council emphasizes the importance of a notification obligation to their customers for companies that produce or import products containing nanoparticles, to inform companies in the production chain about the content of nanoparticles in their products;
- considering that the development of and research on nanotechnology may bring large economical and scientific chances for the Dutch knowledge society;
- the opinion that the development and opportunities of nanotechnology can only come to full growth on the condition that possible effects and risks of nanoparticles are clear and thoroughly assessed;
- the opinion that employees as well as consumers have the right to information on the content of nanoparticles in the products they use or purchase;

- asks the Government to regulate, in short term, a notification obligation for the use of nanoparticles in products, and to assign a central independent institute that can provide an overview of nanoparticle containing products at the market.

Nano Reference Values - MODIFIED PROPOSED AND AGREED MOTION IN THE DUTCH PARLIAMENT 2nd July 2009

- Considering the fact that the Dutch Social Economic Council in the advice "Nanoparticles in the Workplace: health and Safety Precautions" states that the government has a task wherever possible to stimulate the development of health-based recommended occupational exposure limits and has a task to stimulate research to identify if nano reference values can be used as a practical tool as long as scientifically based occupational exposure limits are lacking.
- considering that the Social Economic Council has the opinion that the National Health Council can play a role in the assessment of health risks and the establishment of occupation exposure limits for nanoparticles;
- the opinion that nanomaterials can give a contribution to the solution of many various questions, but that uncertainty of companies, employees and consumers on the exposure to, or the emission of the particles in the environment can lead to social concern;
- consequently the opinion that reliable regulation is a primal requirement;
- asks the government to commission the expert centre KIR Nano to develop, before Christmas 2009, nano reference values for the most frequently used nanoparticles, to be used by companies until the National Health Council is able to establish occupational exposure limits for the various nanoparticles.

Speeding up of Risk Research - PROPOSED AND AGREED MOTION IN THE DUTCH PARLIAMENT 2nd July 2009

- Considering that the government has indicated that they think that research on the hazards and risks is essential and that research results can be expected around 2012;
- considering that the development of and research on nanotechnology may bring large economical and scientific chances for the Dutch knowledge society;
- the opinion that the development and chances of nanotechnology can only come to full growth on the condition that possible effects and risks of nanoparticles are clear and thoroughly assessed;
- the opinion that the actual time scale that research results are expected to become available is too long, taking in mind the concern on the risks and the economical and scientific developments;
- considering that the Netherlands also in risk research can be an important international frontrunner;
- asks the government to give more urgency to and speed up the planned risk assessments of nanoparticles;
- additionally asks the government to demand the manufacturers of products with nanoparticles for a first (publicly available) risk assessment, in order to have the first researches on possible risks started the beginning of 2010.

July 2009

Reflection from Lynn L. Bergeson, Bergeson & Campbell, Washington DC, USA

Having just returned from Paris, France to attend the Organization for Economic Cooperation and Development (OECD) conference on *Potential Environmental Benefits of Nanotechnology: Fostering Safe Innovation-Led Growth* on July 15-17, 2009, several impressions come to mind in light of the five-year anniversary of the issuance of The Royal Society & The Royal Academy of Engineering report. They are noted below in no particular order.

First, the prophetical nature of the Report is clear. The passage of time has confirmed, to a very considerable extent, the clarity and prescience of the Report's core conclusions.

Second, significant progress has been made by nano stakeholders in addressing the nanoscale materials knowledge gaps. Significant work remains, however, and we must pick up the pace of our collective efforts, and proceed on multiple levels. While considerable research on the environmental, health, and safety implications of nanomaterials is underway, it is not nearly enough. The Report concludes that existing regulatory frameworks within which to manage these implications "are sufficiently broad to encompass nanotechnologies." The Report also calls for "prompt and appropriate revision of regulation" to address responsibly the implications of nanotechnologies. Careful review of existing regulatory frameworks has not, in all cases, proceeded as robustly as needed to invite and maintain the public's trust in the utility and efficacy of these frameworks. As we survey the technological horizon, it is apparent that passive, first-generation nanotechnologies are destined quickly to yield to second-, third-, and fourth-generation active nanotechnologies that will, in turn, merge with other technologies to form "complex and innovative hybrid technologies."[4] The pace of these innovations will inevitably quicken, further expanding the divide between regulatory guidance and commercialization fueled by race to the market realities. We need to get on with it.

Third, to address the growing divide between regulatory guidance and commercialization, proactive, voluntary measures by industry must continue and expand. They must demonstrate more clearly how potential risks are being mitigated, what the benefits are of emerging nanotechnologies, and how exactly benefits have been determined to outweigh potential risks, once we know what they are. To do so competently, more effort must be devoted to developing a cogent life-cycle assessment to ensure a meaningful risk/benefit calculus is performed at every step of nanoscale product development, use, and disposal. While efforts in this regard are underway, they need to be fortified and expanded, quickly.

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4 T. Davies, Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies Oversight of Next-Generation Nanotechnologies, p. 12 (2009), available at http://www.nanotechproject.org/process/assets/files/7316/pen-18.pdf.

Fourth, the Report urged "early stakeholder and public dialogue about nanotechnologies." Public engagement in the process of technological innovation is not nearly at the level that it needs to be. The absence of engagement is puzzling as "the public," and its elusive acceptance of a particular technology, really is the 800-pound gorilla in the room. The electronic tools available to private entities and governments are underutilized. Internet-based tools can and should be used more broadly to solicit the public's engagement in a discussion about nanotechnologies -- what they offer, what is uncertain, how to mediate these uncertainties, how to assess costs and benefits, and so forth.

The Report serves as a useful standard against which to assess progress and, on the whole, we should be proud of what has been accomplished to date. We have a long, long way to go, and need to pick up the pace to achieve more before our next anniversary.

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Reflection from Anders Baun, Technical University of Denmark

Our comment is related to the Royal Society's statement on "Possible adverse health, safety and environmental impacts - The lack of evidence about the risk posed by manufactured nanoparticles and nanotubes is resulting in considerable uncertainty.

Going through the published literature 2004-2009 we have found that knowledge gaps still pervade nearly all aspects of basic EHS knowledge even now five years after the Royal Society report was published. Our analysis, published online in Nanotoxicology in June 2009 (Grieger, K.D., Hansen, S.F., Baun, A. (2009) The known unknowns of nanomaterials: Describing and characterizing uncertainty within environmental, health and safety risks.

Nanotoxicology, http://dx.doi.org/10.1080/17435390902944069), shows that the following areas are of particular concern when it comes to uncertainty in the form of recognized ignorance:

- Lack of reference materials and standardisation;
- environmental fate and behaviour;
- human and environmental toxicity;
- test methods to assess effects and commercial or industrial-related aspects including life cycle analyses

However, when mapping the nature of the uncertainty we find that further empirical research will be able to reduce most areas of uncertainty, although it is likely to be very time-consuming and expensive.

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Reflection from Dr Kirsten Kulinowski, Rice University

The Royal Society report's impacts on the nanotechnology policy and research communities were felt immediately and continue to reverberate even today. It remains one of the most thorough, sober and balanced analyses of nanotechnology's risks and benefits in print. A lot has happened in five years. Awareness and, one might even go as far as to say, acceptance of the importance of EHS research to the future of nanotechnology have grown considerably, as has the amount of funding for EHS-relevant research and, consequently, the community of nano-EHS researchers exploring the many critical questions that remain.

Simply put, this genie is not going back into its bottle. The emphasis shifts now to the hard work of differentiating, with some predictability, those nanoparticles or nanoparticle applications that are relatively benign from those that will require closer scrutiny or control. The dialogue is much richer and complex than it was 5 years ago and the report's contributions to this dialogue cannot be denied.

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Reflection from Dr Padraig Murphy

Whilst in the UK conversations about risk dominate the debate, here in Ireland there is not enough being said about risk, and probably less than 5 years ago. The 'green growth' narrative has taken hold - nano and emerging technologies for green innovation - making it more difficult to explore the negative health implications while the ecological positives are promoted. There is also little scope for public engagement as converging technologies advance, which is contrary to the vision of RA/RAE. Not mainstream Irish opinion as I said, but there is an undercurrent of social scientists/NGOs who are uncomfortable with the current framing.

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Reflections from Dr Barbara Herr Harhorn

The 5 years since the publication of the 2004 Royal Society Nanotechnologies report reflect in a number of respects the challenges posed by "upstream" regulation of new technologies. The report was thoughtful in its inclusion of explicit attention to the societal dimensions of technological change and provided at a relatively modest budget the kind of social research involving citizen engagement and survey on public views that others of us have now pursued in greater depth in a number of countries. It anticipated through its insistence on disaggregating 'nanotechnology' into 'nanotechnologies' the view strongly endorsed by social research today, that different applications will elicit different responses and therefore demand specific regulatory policy. And it took an early aggressive stance on the need for particularly careful approach to 'unbound particles' such as the metal oxides found in many cosmetics and sunscreens already in the marketplace.

However, this forward looking document arguably did not necessarily produce any meaningful change in regulatory practice or social engagement in the UK. Its forward-looking approach was not carried through into regulatory or industry practices. Our comparative UK-US deliberation research in 2007 (Pidgeon, Harthorn, et al. Feb. 2009 /Nature Nanotechnology/) found the UK participants deeply skeptical not about the benefits of nanotechnologies but about government's ability to responsibly and safely manage them. How much impact can a single report have? On policy? On public views? On industry practices? From my US-centric position as a societal implications researcher, I think the report provided a wonderful beginning to a process that was then left in idle for too long, risking turning thoughtful empirically based recommendations into empty rhetoric. It is an object lesson for the rest of us in how enduring the commitment to assessing new technologies in societal context must be to go beyond first steps to a fully realised engagement of science, science policy, and society.

Dr Barbara Herr Harthorn

Director
NSF Center for Nanotechnology in Society
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Appendix 1 - List of Contributors - alphabetical

1. Dr Rob Aitken, Director, SafeNano, Institute of Occupational Medicine
2. Mr Frank Barry, UNITE Trade Union, Ireland
3. Mr Anders Baun, Head of Innovation, Dept Environment Engineering, Technical University of Denmark
4. Ms Lynne Bergeson, Managing Director of Bergeson & Campbell, PC Washington, DC, USA
5. Mr Pieter Van Broekhuizen - IVAM, University of Amsterdam, Netherlands
6. Dr Donald Bruce - Edinethics Ltd
7. Mr Christopher Bunting - Secretary General, International Risk Governance Council, Geneva, Switzerland
8. Dr Qasim Chaudhry, Senior Scientist, Central Science Laboratory
9. Prof Ken Donaldson FRCPath, Prof Respiratory Toxicology, University of Edinburgh
10. Dr Steffi Friedrichs, Director, Nanotechnology Industries Association
11. Dr David Grimshaw, Head of International Programme: New Technologies, Practical Action
12. Dr Adrian Henriques, Professor of Accountability, Middlesex University Business School
13. Dr Peter Hatto, Director of Research, IonBond Ltd
14. Professor Barbara Herr Harthorn, Director, NSF Center for Nanotechnology in Society at Univ California SB
15. Prof Geoffrey Hunt, Professor of Technology Ethics, St Mary's University College, London
16. Prof Richard Jones FRS, Pro-Vice-Chancellor for Research and Innovation, University of Sheffield
17. Dr Kristen Kulinowski, Center for Biological and Environmental Nanotechnology, Rice University, USA
18. Dr Andrew Maynard, Chief Science Advisor, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars
19. Dr Padraig Murphy, Research Fellow, School of Communications, Dublin City University, Republic of Ireland
20. Prof. Nick Pidgeon, School of Psychology, University of Cardiff
21. Dr David Santillo, Senior Scientist, Greenpeace Research Laboratories
22. Mr Tim Harper, Director, Cientifica
23. Dr Rob Reid, Scientific Policy Advisor, Which?,
24. Prof Anthony Seaton, CBE, MD, DSc, FMedSci, University of Aberdeen
25. Dr Elen Stokes, Prof Bob Lee, Ms Lori Frater, ESRC Research Centre for Business Relationships, Accountability, Sustainability & Society
26. Unattributed - Investment Management Company
27. Unattributed - Pharmaceutical company
28. Unattributed