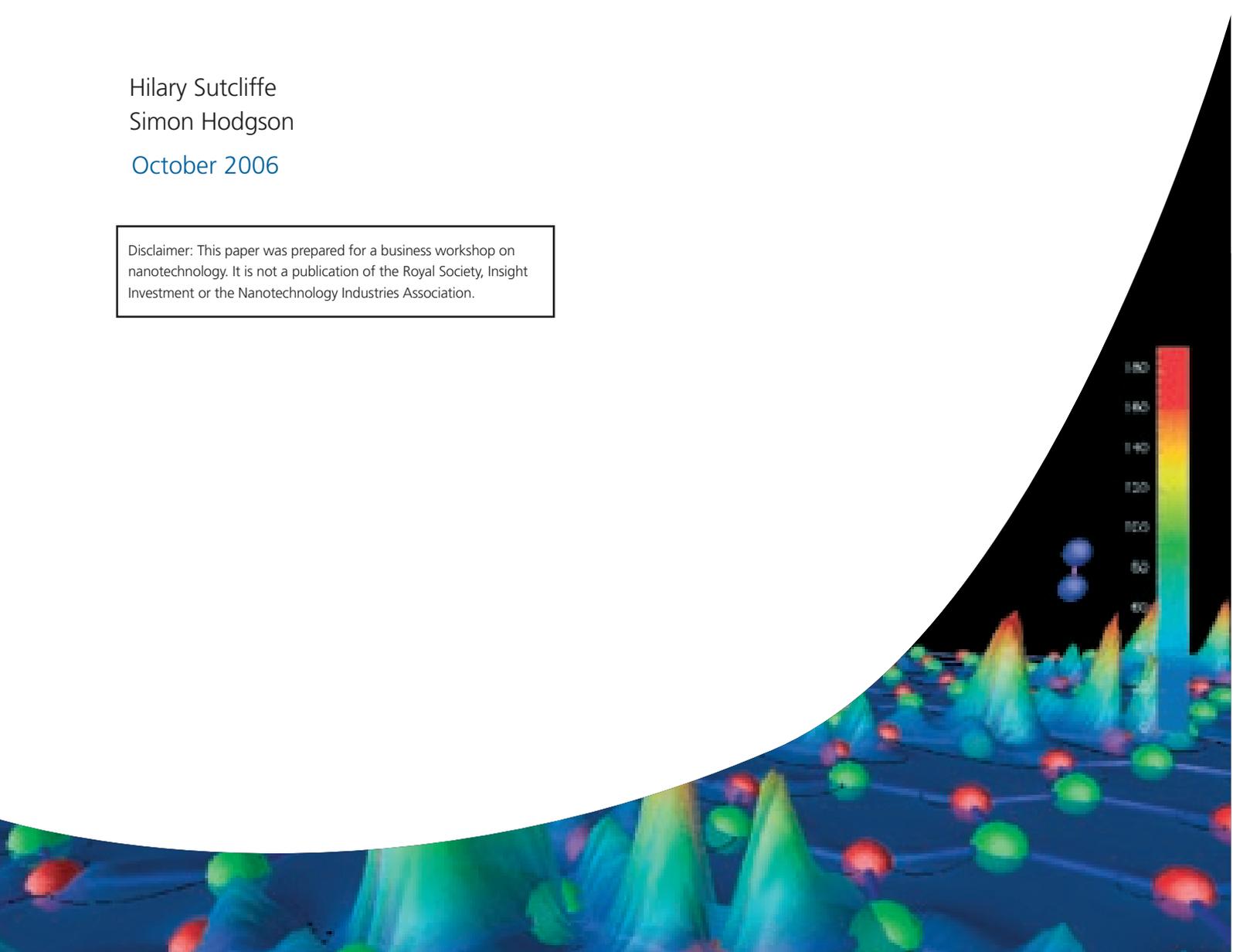


Briefing paper:  
**An uncertain business:**  
the technical, social and commercial challenges  
presented by nanotechnology

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Disclaimer: This paper was prepared for a business workshop on nanotechnology. It is not a publication of the Royal Society, Insight Investment or the Nanotechnology Industries Association.



# 1. Introduction

## 1. Introduction

### Why this paper?

Commercialising nanotechnologies presents huge opportunities for business. But at the same time - while the evidence of harm is currently limited - there is real uncertainty over the potential environmental, health and safety (EHS) risks of some nanoscale materials, particularly the impact of free nanoparticles and nanotubes. The development of nanotechnologies also gives rise to a variety of social and ethical issues - both in relation to their governance and the impact of specific applications.

All businesses with an interest in this area will need strategies for dealing with these uncertainties. It is still early days in the development of nanotechnologies and the environment in which they will be commercialised is not fixed. There is still time to reduce uncertainty through research into potential hazards posed by nanomaterials. Public opinion is still positive to nanotechnologies, the majority of NGO's have not made it a campaign issue and regulations haven't been fully set.

But the window of opportunity is closing. A key question for business is what are the consequences of inaction?

This paper explores these issues and acts as a stimulus for a workshop on 7th November 2006, which brings together a range of companies with interests in the field. The workshop (and therefore this paper) has three objectives:

- To highlight the wider scientific, social and commercial issues surrounding the technology
- To stimulate discussion among and within companies on these topics
- To introduce companies to a more holistic approach to nanotechnology development

The workshop has been arranged and funded by Insight Investment, the Royal Society and the Nanotechnology Industries Association (NIA). Acona prepared the supporting materials and will facilitate the discussion.

Insight Investment is a large institutional investor with holdings in many companies developing or considering nanotechnology. Its primary interest is therefore to understand how companies are managing the risks associated with these developments and – if necessary – to stimulate improvements.

The Royal Society is the UK's leading scientific body, and in 2004 prepared a comprehensive report on nanotechnologies which highlighted the 'importance of identifying as early as possible new areas of science and technology that have an impact on society' and of 'a constructive and proactive debate' on the technology. In supporting this workshop, the Royal Society is helping to facilitate that process.

The NIA's members are companies involved in researching and developing nanotechnology, who wish to engage in debate and communicate their current activity to these other important stakeholders. A prime purpose of the NIA is to promote the responsible use of and raise awareness about nanotechnology.

After a brief introduction this paper summarises the key uncertainties surrounding nanotechnology in three areas; technical, social and commercial. Each is the subject of a separate section, which brings together the current state of understanding (a bibliography is attached at Appendix 4) and explores the implications of these uncertainties for business. It then concludes by looking at the current view of nanotechnology among the public, NGOs and the media.

***Uncertainty not risk:** We use the word 'uncertainty' following the approach adopted in the Royal Society and Royal Academy of Engineering Report on Nanoscience and Nanotechnologies in 2004. We prefer this to the more precise alternatives of 'risk' or 'hazard' or the vaguer term 'issue', primarily because it reflects the very early stages of understanding of the effects of manufactured nanoparticles and nanotubes on human health and the environment, as well as the methodologies and instrumentation for monitoring them. These large gaps in knowledge need to be addressed before these uncertainties coalesce into risks.*

### The scale of the prize

There is a good deal of hype surrounding nanotechnologies - which have been trumpeted as the 'new dot com', the 'new biotech', 'the new industrial revolution' and the 'greatest business opportunity of the century'.

While the reality is likely to be far less sexy, researchers have estimated that by 2008 the global demand for nanoscale materials, devices and tools will cross \$28 billion<sup>3</sup> and by 2014 the market for innovations sparked by various types of nanotechnology could reach \$2.6 trillion.<sup>4</sup>

A recent inventory developed by the Project on Emerging Nanotechnologies in the US indicates that over 320 nanotechnology-enabled consumer products identified by companies from 15 Countries are presently on the market.<sup>5</sup> Investment advisors Innovest suggest there are actually 700 products containing fixed and free nanoparticles now available.<sup>6</sup>

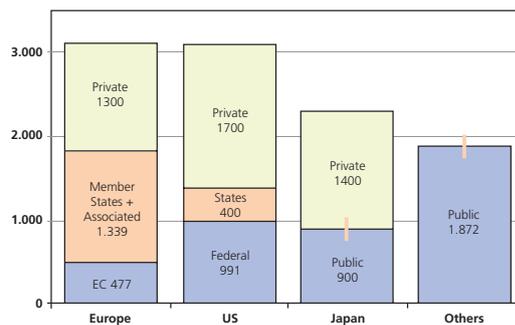
*“Nanotechnology will likely have a broad and fundamental impact on many sectors of the economy. Some have even suggested that this impact will surpass the combined impact of both biotech and information technology.”<sup>1</sup>*  
*Richard Russell*

*“Every nation in the world is looking at nanotechnology as a future technology that will drive its competitive position in the world economy.”<sup>2</sup>*  
*Anne Thayer*

In 2005 alone governments, companies and venture capitalists spent \$9.6 billion on nanotechnology R&D worldwide, up 10% on 2004 with a regional breakdown as shown.<sup>7</sup>

This isn't just a developed-world phenomenon: research is taking place in developing countries, with India, Brazil and China making major funding commitments.

If they reach their full potential, nanotechnologies open up major commercial and social benefits in areas as diverse as medical applications, construction materials, information and communication technologies, textiles and electronics. A table showing a range of potential applications is shown in Appendix 1.



**Not all nanoparticles and not all uses of nanotechnologies will necessarily lead to new human health or environmental hazards. A distinction can be made between free and fixed nanoparticles. Fixed nanoparticles are less likely to pose a problem.<sup>8</sup>**  
OECD

### Worldwide Funding of Nanotech R&D

Source: European Commission (2005): Private figures based upon Lux Research

### The origins of the uncertainty

The very properties that make nanotechnologies so commercially exciting (see box), such as increased reactivity and potential to cross cell membranes, may also have negative EHS impacts. Many nanotechnologies pose no new EHS risks and almost all concerns relate to the potential impacts of deliberately manufactured nanoparticles and nanotubes that are free rather than fixed to or within another material. The issue is that we don't yet have enough evidence to be certain one way or the other.

#### Nanoproperties

Nanomaterials may behave differently than the same materials at a larger scale due to an increase in the surface area relative to volume (making them more reactive) and quantum effects (potentially changing optical, magnetic or electrical properties). Nanotechnologies are concerned with exploiting these effects to create structures, devices and systems with novel properties and functions due to their size.

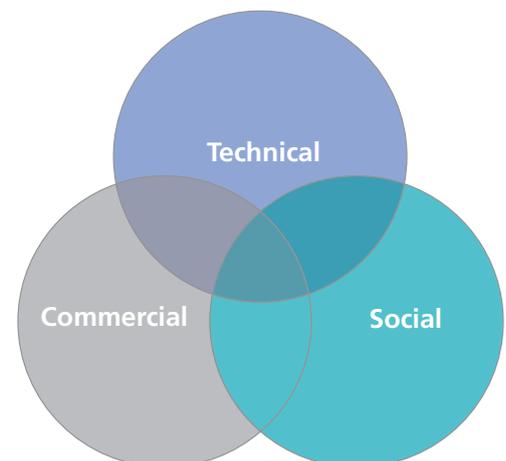
But this change in properties is not automatic and there may well be no change until a critical size is reached. For example moving from a 500nm (nanometre =  $10^{-9}$ m) particle to a 75nm particle may have no effect on the properties of interest, but moving to a 20nm particle might do so. The consequence is that the 75nm particle can be treated in the same way as the current larger material while the 20nm will need further examination to fully understand its properties.

There is a wider suite of social and ethical concerns relating to how society views the use to which the technology is put, who wins and who loses, the openness and transparency with which business conducts its affairs and so on. There may also be ethical issues forged by specific applications of the technology, for instance civil liberty issues arising from applications in sensor devices.

There is a range of literature on these topics, containing a number of different views on the benefits, risks and issues raised by nanotechnology. Each uses slightly different definitions and it is not simple to combine them. But the uncertainties fall into three broad categories:

- **Technical:** our understanding of the technology and how it behaves; manifest in our ability to manufacture, develop, control and measure it and ultimately to accurately predict its behaviours.
- **Social:** society's view of the technology, based on complex factors including: the perceived benefits compared to the perceived risks; levels of trust and confidence in business, regulation and governance; and previous experience of new technologies.
- **Commercial:** the specialised questions raised by the need to commercialise the product, including matters of regulation, litigation and intellectual property.

None of these can be considered in isolation: for example, the public's view of risk depends on how organisations handle technical uncertainties, and the public's view in turn affects the regulatory climate and regime. And the permissiveness of regulation, and public views on the company's brand and reputation will affect the financial return on R&D investment for companies and investors.



The three areas of uncertainty overlap each other

## 2. Technical uncertainties

“One of the biggest challenges facing firms commercialising nanotechnology innovations today is managing environmental health and safety risks.”<sup>9</sup>  
Lux Research

### 2. Technical uncertainties

Most of the uncertainties surrounding nanotechnology stem from the limitations to our technical knowledge. The tables that follow show the principal uncertainties that have been identified in the literature (left hand column). Each is explained in a little more detail in the right hand column, with supporting evidence referenced from the bibliography.

Technical uncertainties	
‘We currently lack information to conduct the most basic risk analysis for simple or first generation nanomaterials, even less is known about later generation materials under development.’ <sup>10</sup>	
Human Health	
<p><b>Uncertainty</b> The size of nanoparticles and changes in surface chemistry have the potential to make them behave differently in the body, possibly making them make them more toxic<sup>11</sup> than the same substance in larger forms.<sup>12</sup></p> <p>Those working with nanomaterials may potentially be exposed to some risk<sup>13</sup></p> <p>Possible explosive effects<sup>14</sup></p>	<p><b>Commentary</b></p> <ul style="list-style-type: none"> <li>• Evidence from studies of exposure to small particles and fibres, including air pollution, mineral dusts and pharmaceuticals, suggest that some manufactured nanoparticles and nanotubes are likely to be more toxic per unit mass than larger particles of the same chemical. And some of the small number of published studies looking at the effects of manufactured nanoparticles and nanotubes on the body suggest that nanoparticles could have a different, and possibly more harmful, impact than the same chemicals in larger form.</li> <li>• As a result, there are a number of unanswered questions concerning the possible impacts of nanomaterials on human health. How are they metabolised and eliminated? How do they affect cell and tissue function? Can and might they accumulate to a level which causes unforeseen biological effects?</li> <li>• We know that free nanoparticles can enter the body as a result of being inhaled or ingestion. But it is not known whether nanopaticles can penetrate the skin and very little is known about the pathways nanoparticles might travel within the body.</li> <li>• On the other hand, the ability of nanoparticles to penetrate certain protective membranes is the key to some significant benefits for many drugs and medical treatments: they can be used as carriers for targeted drug and nutrient delivery with potential benefits in a huge variety of treatments including cancer.</li> <li>• Overall, the understanding of both the beneficial and deleterious effects of free nanoparticles on human health is at a very early stage.</li> <li>• The risks associated with nanoparticles depend on exposure and dose as well as potential toxicity. Workplaces developing products containing nanoparticles and nanotubes are likely to be the greatest source of exposure. The Health and Safety Executive (HSE) has undertaken work examining the possible risks and advising on minimising exposure. It has reviewed regulation and concluded that current regulation is adequate given current knowledge, but that many knowledge gaps exist which need to be addressed.</li> <li>• There is some evidence to suggest that combustible nanoparticles might cause an increased risk of explosion. The Royal Society report suggested that until this hazard has been properly evaluated large quantities should be prevented from becoming airborne.<sup>15</sup> The HSE has recognised this concern and acknowledged the need for research in this area.</li> </ul>

“The dearth of information on risks is troubling because... about a third of the hundreds of nanotechnology-related consumer products now on the market are intended to be ingested or applied to the skin”<sup>24</sup>  
Nanotech Project

**“Researchers are unsure about how to work safely with new nanomaterials, nano-businesses are uncertain about how to develop safe products and public confidence in these emerging applications is in danger of being undermined”<sup>23</sup>**

**David Rejeski**

<b>Environment</b>	
<p><b>Uncertainty</b> Unknown lifecycle, longevity and accumulation</p>	<p><b>Commentary</b></p> <ul style="list-style-type: none"> <li>• Little is currently known on how nanoparticles combine with existing materials and toxins in the environment, nor on how they move through the biosphere.<sup>16</sup></li> <li>• Many nanomaterials are particularly durable; they will remain in the environment long after product disposal. This has the potential to lead to long-term environmental effects, including accumulation.<sup>17</sup></li> <li>• These factors combine to create uncertainties over the long term environmental fate of free nanoparticles, and as a consequence The Royal Society and others suggest that factories and research laboratories treat manufactured nanoparticles and nanotubes as if they were hazardous and reduce or eliminate them from waste streams.</li> </ul>
<p>Possible harm to other species</p>	<ul style="list-style-type: none"> <li>• In the same way that there are uncertainties over human health effects, free nanoparticles may have biological effects in other species.<sup>18</sup></li> <li>• It is already well understood that conventional materials entering the bottom of the food chain affect organisms, including people, higher up, raising questions over how nanomaterials will affect these organisms.<sup>19</sup></li> <li>• One early example is the increasing use of silver nanoparticles as an antimicrobial agent, which raises questions over possible harm to beneficial microbes in the environment.<sup>20</sup></li> </ul>
<b>Research and standards</b>	
<p><b>Uncertainty</b> Current and proposed future chemicals regulations do not recognise that nanoparticles may have different health and environmental impacts per unit mass compared with larger substances.</p>	<p><b>Commentary</b></p> <ul style="list-style-type: none"> <li>• Many nanomaterials and products have been approved as existing structures, but the differences which manifest themselves at the nanoscale are felt by many scientists and commentators to require approval as new substances.</li> <li>• Approval as a new substance has implications for time and cost, particularly if extensive public consultation is required. The converse is that incorrect assessment may result in products being approved based on partial risk assessment. This could well have undesirable long-term effects (e.g. product recalls, public backlash) if proved to be inadequate. It is also not yet clear whether current risk assessment methodologies used are suitable for nanoparticles.</li> <li>• Some leading companies are therefore using independent labs to complete screening on their products or making their research available for peer review. Others have introduced new substances containing nanoparticles under existing legislation (e.g. nanoparticles of zinc oxide in sunscreens) with the possibility that this may leave unanswered questions.<sup>21</sup></li> <li>• A new initiative in the UK from DEFRA, the Voluntary Reporting Scheme invites industry, research organisations and others to provide Government with information on the engineered nanoscale materials with which they are working.</li> </ul>

**“There is virtually no information available about the effect of nanoparticles on species other than humans or about how they behave in the air, water or soil, or about their ability to accumulate in food chains.”<sup>25</sup>**

**Royal Society**

## 2. Technical uncertainties

In summary, the evidence of harm is currently limited, but the key point is that there is very little published research knowledge to justify opinions either way. There is significant uncertainty over the behaviour, potential hazard and long term effect of nanomaterials, particularly free nanoparticles. Radical changes at the nanoscale challenge existing systems of risk assessment, and much more research is considered necessary in this area.

The Woodrow Wilson Institute illustrates the situation neatly: 'If there is a silver lining in our past experiences with industrial hazards, it is that we now know that an

important first step in safeguarding the public from such threats is to invest in objective research that can properly define the nature of the risk. Everyday, in a variety of situations, hazardous chemicals and materials are used safely because we have invested in the scientific research that shows us how to avoid their dangers. Most likely, the risks of nanotechnology also can be safely managed, if we understand what those risks entail.'<sup>22</sup> Despite this, the proportion of the research budget being spent to support regulation by investigating the underlying science seems very small (e.g. estimated at less than 3% of the total US expenditure).

### **Remember asbestos?**<sup>27</sup>

*The widespread use of asbestos, and its subsequent effect on human health has had a huge impact on business<sup>28</sup>: 6000 independent entities have been named as asbestos liability defendants, 61 companies have filed for bankruptcy due to asbestos claims and 1.1 million claims have been issued with 75% of plaintiffs not suffering any negative health impacts. It is estimated that the total cost to insurers has been between \$200 and \$275 billion.*

*Perhaps as a consequence, insurer Swiss Re<sup>29</sup> has conducted a simple comparison, which is shown in the table. They conclude that all companies involved in the research, development, manufacturing, marketing, retailing, distribution and disposal of products containing nanomaterials may be held liable if nanoparticles are found to cause health or environmental hazards.<sup>30</sup>*

Aspect	Nanotechnology	Asbestos
Manufacturer known	Yes	Yes
Defined substance	No	Yes
Worldwide dissemination	Yes	Yes
Wide range of use	Yes	Yes
Acutely toxic	No	No
Persistent	In some cases	Yes
Long term effect	Conceivable	Yes
Risks	Unknown	Cancer
Claims series potential	Yes	Yes
Loss accumulation potential	Yes	Yes
Agent analytically provable	Yes	Yes

### **Swiss Re's comparison between asbestos and nanotechnology**

### Technical uncertainties: Conclusions and implications for business

Organisations involved in the development and commercialisation of nanotechnology must be aware of the current level of uncertainty surrounding its health and environmental effects. The commercial concern must be that this may result in a major business liability, and as we shall demonstrate later, how companies handle and communicate uncertainty is an important factor in public acceptance or rejection of new technologies. Around the world, the level of research into these uncertainties is low.

The key questions which arise are:

- Is it true - as the evidence seems to suggest - that there is a commercial imperative for better research in this area? Is it in the interests of business to accelerate the work on hazards and risks?
- What is the role of business in the risk and hazard assessment for nanotechnologies? Is there more it could do to support research in this area through increased funding or information sharing? How best should it work with other actors such as governments?
- What steps are companies involved in nanotech development taking to assess risk and hazard? What methods are they using, and are these adequate? How are the results of this work being communicated, and is there a case to make them more widely available?
- What steps are companies taking to control their exposure to risk from their current operations, arising through (for example) worker health and safety, discharges of waste and product releases?

### 3. Social uncertainties

**“We suggest that... corporations and start-ups developing nanotechnology applications have as much to lose from perceptual risks as to real ones. Real risks apply to specific materials and applications, but perceptual risk could make commercialisation of any nanomaterial unfeasible.”**  
*Lux Research  
 Testimony to the House  
 Committee on Science.  
 USA Nov 2005<sup>31</sup>*

**“Some possibly harmful commercial applications, such as in cosmetics, already exist and are subject to little new control, while potentially beneficial technologies may be retarded.”**  
*OECD*

**“Once certain opinion has become socially established, it is an extremely difficult, tedious and costly undertaking to persuade people of the contrary.”**  
*Swiss Re*

### 3. Social uncertainties

The social uncertainties surrounding nanotechnology stem from society’s view of the technology, based on complex factors including: the perceived benefits compared to the perceived risks; levels of trust and confidence in business, regulation and governance; and previous experience of new technologies. Unlike the technical uncertainties which mainly affect free nanoparticles, this ‘perceptual risk’<sup>32</sup> can influence the success of all types of nanotechnology.

<b>Social uncertainties</b>	
‘the development of a new technology tends to outpace the development of methods to ensure a more egalitarian sharing of its benefits or even the analysis of its associated risks’ <sup>33</sup>	
<b>Risk Perception</b>	
<p><b>Uncertainty</b>                  The public perception of the risks associated with nanotechnologies could have a major impact on their development.</p>	<p><b>Commentary</b></p> <ul style="list-style-type: none"> <li>• When individuals make judgements about risks, they are usually describing not a static quantity, but their own perceptions which are influenced by their beliefs, knowledge, circumstances and experience. Public perception of risks is thus a dynamic process related to the role and behaviour of institutions and their abilities to minimise unintended consequences and adequately regulate. Researchers in the fields of psychology and ‘risk perception’ have attempted to understand how people judge risks and benefits and how that judgement influences their behaviour.<sup>34</sup></li> <li>• The case study of Genetically Modified Organisms and comparisons with nanotechnology below illustrate that nanotechnology possesses some of the triggers for public concern.</li> <li>• Public awareness of the term nanotechnology in the UK, though still relatively low, has increased over the past two years from 29% in 2004<sup>35</sup> to 44% in 2006 (Eurobarometer 2006).</li> <li>• Currently attitudes are positive towards the technology, with 70% of respondents to the Eurobarometer survey who had heard of nanotechnology believed it would improve our way of life in the next twenty years.</li> <li>• The situation is highly dynamic. A major NGO campaign, perhaps focusing on the uncertainties around free nanoparticles, may feed on other uncertainties such as issue dread, lack of trust and past experience, and public opinion could move from its current largely positive<sup>36</sup> position of nanotechnologies to one which is fearful and risk averse.</li> </ul>
<b>Beneficial vs commercial applications</b>	
<p><b>Uncertainty</b>                  Nanotechnologies have many potential socially beneficial applications. Public acceptance will be influenced by a sense of the scale of the good and the nature of the beneficiaries.</p>	<p><b>Commentary</b></p> <ul style="list-style-type: none"> <li>• The public expect great things from nanotechnology, and it appears that it has the potential to deliver. But this opinion may change if applications are felt to be frivolous or offer too little social benefit.</li> <li>• There are concerns that commercial priorities will take research skills and funding away from the development of more socially beneficial, but not commercially lucrative technologies.<sup>37</sup></li> <li>• Royal Society and Royal Academy of Engineering recommended a coordinated programme of public and stakeholder engagement.<sup>25</sup> In response the government has set up a series of public engagement initiatives.<sup>26</sup></li> </ul>

*“Although nanotechnology may have the potential to solve global problems, this will not happen without social shaping of the research.”<sup>47</sup>*  
**Woods Jones and Geldart**

*“Only by encouraging scientists to work in the global public interest can a system of open and reliable and replicable science be maintained.”<sup>48</sup>*  
**UNESCO**

Impact on developing economies	
<p><b>Uncertainty</b>                      The development of nanotechnologies has the potential for both benefit and harm to developing economies.</p>	<p><b>Commentary</b></p> <ul style="list-style-type: none"> <li>• The OECD has suggested that research driven by the perspectives of developed economies may pose problems for the developing world with few projects targeted at the needs of the poor.<sup>41</sup></li> <li>• Early signs are that though developing countries have many of their own nanotechnology initiatives the focus may be on technologies for export markets at the expense of pro-poor developments at home.<sup>42</sup></li> <li>• The widespread use of patents to protect innovation has been compared with the situation that occurs in the pharmaceutical industry, which has resulted in real problems of access and licensing in the developing world.</li> </ul>
Social impact of controversial innovations	
<p><b>Uncertainty</b>                      Some innovations using nanotechnologies may be controversial.<sup>43</sup></p>	<p><b>Commentary</b></p> <ul style="list-style-type: none"> <li>• One possible application is the linking of complex networks of nanotech remote sensing devices and computational power to provide either much enhanced personal security and individually tailored healthcare, or conversely for sophisticated surveillance and tracking products which may raise profound questions over civil liberties.</li> <li>• There is speculation that nanotechnology will converge with biotechnology to offer the potential of human enhancement, which itself is the subject of a separate ethical debate<sup>44</sup>.</li> <li>• There are also potential military applications including the development of nanotech weaponry.</li> </ul>

### 3. Social uncertainties

#### **Parallels with Genetically Modified Organisms**

*Parallels are often drawn between the emerging development of nanotechnologies and the introduction of Genetically Modified Organisms (GMOs). It can be argued that technology was introduced without a clear understanding of public and stakeholder views, and the resulting consumer backlash profoundly influenced its commercial success, arguably depriving society of some benefits in the process.*

*Building on the work of Peter Bennett of the UK Government's Department of Health and Lux Research we have explored the similarities and differences between nanotechnologies and GM food crops using some of Bennett's 'fright factors'<sup>49</sup>; (See Appendix 3 for the full chart) these are the triggers which are likely to cause alarm to*

*the general public and influence their behaviour, and are based on research over many years in the so called 'psychometric' tradition. They include the exposure being **inescapable** (i.e. cannot be avoided through individual choice), the topic being unfamiliar or **novel**; **man-made** rather than natural; and the technology being **poorly understood** by science, and subject to **contradictory statements**. Clearly, many of these 'fright factors' may be associated with nanotechnology.*

*However, perception depends strongly on application. For example, the GMO-enabled development of pharmaceuticals has not been the focus of campaigns, and has not felt the repercussions of a public backlash<sup>50</sup> and there are indications that genetic modification to create biofuels may also be seen to be an 'acceptable' risk.*

#### **Social uncertainties: Conclusions and implications for business**

Nanotechnology offers the potential for dramatic social benefit, opening up a range of new products and technologies which may revolutionise manufacturing, healthcare and computing among others. But companies need to consider the social and perceptual uncertainties surrounding nanotechnologies as carefully as they consider the technical uncertainties. A backlash of negative opinion from consumers, governments and civil society could prove incalculably damaging to the success of all types of nanotechnology.

The key questions which arise are:

- What steps are nanotech companies taking to understand the uncertainties associated with societal and perceptual risk? What methods are they using and are they adequate?
- What steps are companies taking to control their exposure to risks in the area?
- Is there more that business could do to engage with the general public, governments and civil society to anticipate and respond to new priorities?

## 4. Commercial uncertainties

Companies developing nanotechnology face the normal commercial challenges, compounded by the specialised questions raised by the nature of the technology, including matters of regulation, litigation and intellectual property. These uncertainties present commercial risks, which may manifest differently at different places in the supply chain. For example, the manufacturer of a product may meet all legal requirements, but the retailer may still struggle to defend themselves against public questions and the pressure of campaign groups. Similarly, large companies with a portfolio of products and a conspicuous brand may be the subject of more vigorous scrutiny and campaigning than a small private company supplying a single business-to-business nanotechnology application.

<b>Commercial uncertainties</b>	
<p>'the inattention to nano-specific risk research puts more than consumers and the environment in danger. It also sets up a scenario in which the future promise of nanotechnology could suffer serious set-backs, as what could have been predictable and preventable problems instead emerge as market-jarring surprises.'<sup>51</sup></p>	
<b>Regulatory uncertainty</b>	
<p><b>Uncertainty</b> The current lack of consensus on regulation makes the business environment particularly uncertain, even more so for multinational companies given possible international variations in approach.</p>	<p><b>Commentary</b></p> <ul style="list-style-type: none"> <li>• Globally accepted nomenclature and characterisation standards are currently being addressed by a consortium of scientists, regulators and government agencies from around the world under the auspices of the International Standards Organisation.</li> <li>• However regulatory approval is still being given under existing legislation which may later be shown to be inappropriate.</li> <li>• There is a strong possibility that regulatory approaches may differ in different territories; for example the European Union may well adhere more closely to the precautionary principle than the US, driven perhaps by differences in public opinion in the two regions.</li> <li>• The problem may be further compounded by rapid investment and development in the emerging economies, where regulatory efforts have historically been much weaker. These factors have the potential to conspire together to damage competitive advantage for the industry in Western countries.</li> </ul>
<b>Consumer take-up and labelling</b>	
<p><b>Uncertainty</b> Consumer acceptance of new technology cannot be guaranteed, which directly affects potential market size and financial returns.</p>	<p><b>Commentary</b></p> <ul style="list-style-type: none"> <li>• Consumers make a calculation of benefit versus cost, but there is good evidence to show that - in some segments of the market at least - they evaluate non-financial costs in this equation; perceived environmental harm or social inequity can damage a brand and limit its market.</li> <li>• In extreme cases (e.g. GM crops, so-called 'risky' chemicals) this reaction can be extreme, with the result that consumers may take active measures to avoid the product.</li> <li>• This is often linked to demands for rigorous product labelling.</li> </ul>

*“Nanotech companies are telling patent examiners and venture capitalists that they are taking advantage of nanoscale, quantum effects to create novel materials while telling the EPA that these chemicals are just the same-old, same-old”<sup>57</sup>*  
ETC Group

## 4. Commercial uncertainties

Research Transparency	
<p><b>Uncertainty</b></p> <p>In this intensely competitive environment, company research is often proprietary making it unavailable to the public and to the scientific community for peer review.</p>	<p><b>Commentary</b></p> <ul style="list-style-type: none"> <li>• Lack of transparency in research may be a significant contribution to societal unease.</li> <li>• The Royal Society report recommended that both results and methodology on ingredients containing nanoparticles be placed in the public domain or at least shared with other scientists or research bodies for the purposes of peer review.<sup>52</sup></li> <li>• It also recommended that researchers collaborate across disciplines and even companies to assist in the effective research of nanoparticle toxicity.<sup>53</sup></li> </ul>
Litigation Risk	
<p><b>Uncertainty</b></p> <p>Uncertainties around the regulatory approval systems are fuelling litigation fears.</p>	<p><b>Commentary</b></p> <ul style="list-style-type: none"> <li>• The mix of scientific and regulatory uncertainty leaves companies potentially liable for damages in the event that products are eventually discovered to present safety or environmental problems.</li> <li>• Shareholders are already questioning the due diligence required for nanotechnology product development.<sup>54</sup></li> </ul>
Insurance and underwriting	
<p><b>Uncertainty</b></p> <p>Insurers are questioning how they are to judge the hazard from nanotechnologies.</p>	<p><b>Commentary</b></p> <ul style="list-style-type: none"> <li>• Companies normally offset risk through insurance, but insurers are uncertain over how to quantify or cost liability.</li> <li>• This may lead to insurance becoming more expensive or companies being faced with unprecedented demands for information in support of insurance applications.<sup>55</sup></li> </ul>
Reputation and brand	
<p><b>Uncertainty</b></p> <p>Large companies with established brands may find them exposed to public criticism.</p>	<p><b>Commentary</b></p> <ul style="list-style-type: none"> <li>• The mechanism of brand criticism and reputation damage is well-demonstrated by other issues such as sweat-shop labour, and environmental pollution. Consumer campaigns target well-known offenders who are then forced to respond in order to protect their reputation.</li> <li>• Nanotech companies may be susceptible to similar campaigns, particularly if some of the uncertainties discussed elsewhere result in risks or hazards, or there is a perception that the companies are not acting responsibly.</li> <li>• This uncertainty would principally affect companies with established public brands.</li> </ul>

## 4. Commercial uncertainties

Intellectual property	
<b>Uncertainty</b> The understandable desire for water-tight intellectual property around nanotechnologies may have a number of important effects <sup>56</sup>	<b>Commentary</b> <ul style="list-style-type: none"><li>• Over-liberal granting of patents may result in increasing litigation and complexity of licensing.</li><li>• 'Business method' patents used in IT may also apply to nanotech, making the development of new products a minefield of competing and overlapping patents.</li><li>• These may restrict the ability of smaller or developing world companies to innovate, and inhibit the sharing of research to create beneficial development</li></ul>

### Commercial uncertainties: Conclusions and implications for business

Any new technology presents commercial risk, and companies are usually well equipped to manage this. However, the commercial uncertainties for businesses working with nanotechnologies are inextricably linked with the technical and societal uncertainties. Public perceptions will influence regulation, which may result in a very uneven playing field if public views diverge strongly in different regions. Consequently, there may be a case to be freer with the results of research than would normally be commercially advisable. It will be important for businesses to make sure they are taking a sufficiently holistic view of the commercialisation process to effectively manage these uncertainties.

These are concerns for other commercial stakeholders. Investors are affected by the impact on company valuation if these uncertainties are handled badly, especially if the products form a large part of the company's current or future business, or if it has a valuable public brand. Similarly lenders and insurers

will require detailed information to allow them to assess risk, and costs of capital and policies may rise if this is not forthcoming or ambiguous.

The key questions which arise are:

- What should business and industry lobby for? Is it in the best interests of business to have a lax regulatory structure or would a precautionary approach pay off in the longer term? Should business be taking a more active role in the development of national and international regulation?
- How can companies ensure the appropriate levels of scrutiny and peer review of their research?
- What steps are companies taking to understand and mitigate the litigation risk involved in the development of nanotechnologies?
- What is the role of business in ensuring an intellectual property regime which stimulates innovation without putting inappropriate restrictions on product or materials development?

## 5. Societal views on nanotechnology

### 5. Societal views on nanotechnology

The preceding sections consider how the uncertainties affecting nanotechnology may affect its future development. But to gain a complete picture we must also look at the starting point - what is today's position? How does society currently see the issue? Is it aware of the technology, and how does it balance risks and opportunities?

This section presents the results of current studies looking at public awareness, and the current views of two important agenda-setting groups; Non-Governmental Organisations (NGOs) and the media.

The results are UK-focussed: most of the public dialogues considered were held in the UK (with two in the US), and the media survey is limited to the UK. The US data that is available does tend to mirror that from the UK, and leads to similar conclusions. Nonetheless opinions may develop differently in different regions, which may lead to very different regulatory climates between Asia, the US and Europe.

#### What does the public currently think of nanotechnologies?<sup>58</sup>

The development of nanotechnologies has been the stimulus for public dialogue - particularly in the UK and US - with a view to involving the public in the shaping of research and development. (See list in Appendix 2)

Current public awareness of the term is 44% in UK (Eurobarometer biotechnology survey 2006) and 42% in the US (cited in Lux research 2006).

In depth research has examined the technology with public groups through the use of stimulus material. Their views are remarkably consistent across a number of projects and fall into four categories:

#### 1. They expect exciting benefits

Initially people see the potential for the benefits to society and to them as individuals. Risks and negative aspects of the technologies are not their first concern.

*'Major benefits are anticipated. The top two anticipated benefits from nanotechnology are major medical advances and improved consumer products, which accounted for 31% and 27% of all the benefits identified, respectively. General technological progress was also seen as a significant benefit, as were advances in environmental protection, lower cost energy, and improved food and nutrition.'* (Macoubrie, page 3)

#### 2. They are sceptical of the thoroughness of current regulation and the monitoring of unintended consequences

Very few of the issues raised were specific to nanotech, but reflected unease about how societies collectively manage technological innovation.

*'Small Talk discussions leave us with the distinct impression that public concerns about safety are couched not in terms of the technology itself but almost wholly in terms of the social structures in place to ensure that hazards will be identified and products regulated. It's not grey-goo that people worry about or any specific hazard, but rather whether funding will be available to test new products adequately and whether regulation will prevent untested products from coming to market.'* (Small Talk, page 23)

#### 3. They are concerned that technologies will be developed in the short term interests of industry at the expense of socially beneficial applications\*

\*By which they mean environmental sustainability; health and job creation

*'Suspensions of Industry. Past safety issues with specific products, ranging from drugs to a widespread perception that industry pushes products to market without adequate safety testing, makes too many errors affecting people's health, and put its own motives ahead of consumer safety. In general the participants felt there are 'unscrupulous risks taken by the medical community,' and overall there exists 'a race with too many mistakes.'* (Macoubrie, page 4)

#### 4. They are eager to see more open debate about the direction of technological innovation

Consultees request more openness about policy process and greater opportunities for citizens to contribute meaningfully to policy formation.

*'Public wants to be included. The need for a voice for the public and the lack of information available to consumers about technology decision-making were strong threads through the study... Participants presented an overarching desire to both be informed and to have a role in decision-making.'* (Macoubrie, page 3)

So the public are not hostile to the technology per se. The consultations so far demonstrate openness to new ideas and even excitement over the benefits. The concerns expressed relate principally to the governance of technology in general (rather than specifically to nanotechnology). They are real nonetheless, and cannot be ignored by companies in the field.

**68% of people who had heard of nanotechnology thought it would improve life in the future, compared to only 4% who thought it would make things worse.<sup>59</sup>**  
BMRB Research

**Blind faith in the men in white coats has gone and isn't coming back<sup>60</sup>**  
B Page

## 5. Societal views on nanotechnology

### What do NGOs currently think of nanotechnologies?

Non-Governmental Organisations (NGOs) will have a significant influence on the debate around the development and impact of nanotechnologies. They are among the most trusted institutions in society, according to Globescan's tracker survey of 20,000 people in 20 countries 2001-2005<sup>61</sup> (in which global companies and national governments are the least trusted). Some have power and funds which rival governments and international agencies. Amnesty International, for example, has more staff and funds than the UN's Human Rights Commission and the Red Cross, Greenpeace and the World Wildlife Fund are bigger than most intergovernmental organisations such as the WTO, UNCTAD or UNIDO.<sup>62</sup>

NGOs were surveyed by the International Risk Governance Council as part of a report on Nanotechnology Risk Governance.<sup>63</sup> While they were at an early stage of involvement in nanotechnology, NGOs had been heavily involved in associated issues such as GMOs and biogenetics which informed their perspectives.

The research found that none were coming out against nanotechnology as a whole, as they had with GMOs, and all saw considerable benefits for the technologies in their particular area of operation - e.g. renewable energy, water treatment, environmental clean up etc.

Their concerns fell broadly into the four key areas which have also been raised by other commentators, namely:

- Governance, regulation and ethics
- Specific HSE risks
- Equitable development
- Public engagement.

However though they were able to identify their concerns for the purposes of the survey, few at that stage had programmes to support their position, leading to a slight suspicion that they were 'shooting from the hip' and that these positions could change in future.

The key NGO's are as follows:

- **ETC Group**, a small NGO originating in Canada, is the most vocal of the NGOs, and the only one to conduct public campaigns against nanotechnologies. They are the only NGO to date to call for a moratorium on the development of nanomaterials. They recently announced a consumer competition to design a 'Nanotechnology Hazard' symbol to identify the presence of nanomaterials.

- **Greenpeace Environmental Trust** in the UK produced a mapping report (NB this is the public information body associated with Greenpeace and not

the campaigning group which to date have kept an open view on the technology in the UK).

- **Friends of the Earth Australia/USA** produced a paper on nanomaterials, sunscreens and cosmetics risks.

And two think tanks which are involved are:

- **Demos UK** has taken a lead on public dialogue in the development of nanotechnologies.

- **Woodrow Wilson International Center for Scholars** in the US ran a project on emerging technologies to focus on risk and benefits.

### What do the media currently think of nanotechnologies?

Regardless of NGO activity, public dialogue or regulatory frameworks, the media can be regarded as an opinion shaper in its own right. Newspapers and TV news programmes are increasingly developing their own campaigning positions on relevant topics (The Independent, Guardian and Sun in the UK have created their own campaigns on climate change for example) and many are taking on a self-appointed role as 'people's champion', quite aside from their function as a conduit for news.

Research by the Universities of Plymouth and West of England for the Economic and Social Research Council shows that media coverage in the UK featuring references to nanotechnologies in 2003 and 2004 was polarised between radically utopian commentaries about nanotechnology saving the world and radically dystopian focusing on doom laden scenarios, particularly the 'grey goo' vision of Drexler<sup>64</sup>. The broadsheet newspapers, particularly the Guardian, but also Times, FT and Independent featured the most news articles in that period, focused mainly on features and news items. The tabloids barely covered it at all.

Scientists surveyed as part of the same study felt that the media sensationalised coverage of nanotechnologies, though they were fairly evenly split on whether the overall coverage was inaccurate or accurate.<sup>65</sup>

There have yet to be any focused anti-nanotechnology campaigns, coverage to date has only responded to concerns of other actors.

All of this presents a picture of the media waiting in the wings, ready to wade in to the debate at a time of their choosing. It seems their contribution will be to amplify the arguments and polarise the discussion.

## 6. Summary and conclusion

### 6. Summary

This paper draws on dozens of references in an attempt to present an overview of nanotechnology development and the challenges faced by businesses. It is itself a summary, and therefore to attempt to abbreviate it further runs the risk of meaningless generalisation. However, we can make a number of points:

1. Nanotechnology offers enormous social benefits, and so is a huge commercial opportunity, with businesses all over the world racing to position themselves for the future.
2. The very early stage of scientific knowledge leads to uncertainties over the behaviour, toxicity and eco-toxicity of nanomaterials, particularly those of free nanoparticles.
3. Public awareness of the technology is growing and people currently are broadly supportive. However, many of the same factors are present as derailed the smooth introduction of GM agriculture: concerns over the inequity of benefit; the long-term health and environmental impacts; the potential for frivolous applications.
4. Experience has shown that public opinion changes rapidly, and that public perception of risk is contingent upon the role and behaviour of companies and institutions and their action to minimise unintended consequences. The whole effect can be amplified by hostile NGOs and the media.
5. The public climate and the tenor of debate on the issue may have a strong effect on the nature and extent of regulation, the consumer take up of the technology and even on the cost of insurance and capital.
6. These three sets of uncertainties - the technical, the social and the commercial - interact and interplay, meaning that none can be considered in isolation.

The challenge for business, therefore, is whether its technology development and commercialisation process is sufficiently inclusive to understand and mitigate risks from these wider uncertainties. There is an essential need for good quality transparent research into the environmental and health risks, and it may be in the long-term interests of business to play a role in filling this gap. Business must convince investors, insurers, NGOs, government, the media and perhaps most importantly the general public that it understands the technology and is taking a responsible approach, which will require a very open style. There is also a case that business has a role in helping get the right legislative and commercial framework to allow it to bring the technology to market safely and profitably.

There seems to be a real opportunity to engage in the debate now before positions become entrenched. Nanotechnology has immense potential for good, but presents a large range of uncertainties. There may well

be a case for a radically new approach to managing them in support of this radically new technology.

The questions for business to consider are as follows:

#### Technical

- Is it true - as the evidence seems to suggest - that there is a commercial imperative for better research in this area? Is it in the interests of business to accelerate the work on hazards and risks?
- What is the role of business in the risk and hazard assessment for nanotechnologies? Is there more it could do to support research in this area through increased funding or information sharing? How best should it work with other actors such as governments?
- What steps are companies involved in nanotech development taking to assess risk and hazard? What methods are they using, and are these adequate? How are the results of this work being communicated, and is there a case to make them more widely available?
- What steps are companies taking to control their exposure to risk from their current operations, arising through (for example) worker health and safety, discharges of waste and product releases?

#### Social

- What steps are nanotech companies taking to understand the uncertainties associated with societal and perceptual risk? What methods are they using and are they adequate?
- What steps are companies taking to control their exposure to risks in the area?
- Is there more that business could do to engage with the general public, governments and civil society to anticipate and respond to new priorities?

#### Commercial

- What should business and industry lobby for? Is it in the best interests of business to have a lax regulatory structure or would a precautionary approach pay off in the longer term? Should business be taking a more active role in the development of national and international regulation?
- How can companies ensure the appropriate levels of scrutiny and peer review of their research?
- What steps are companies taking to understand and mitigate the litigation risk involved in the development of nanotechnologies?
- What is the role of business in ensuring an intellectual property regime which stimulates innovation without putting inappropriate restrictions on product or materials development?

## Appendix 1: Potential Applications for nanotechnologies

<p><b>Automotive Industry</b>            Lightweight construction            Paints            Catalysts            Tyres (fillers)            Sensors            Coatings for windshields and auto bodies</p> <p><b>Chemical Industry</b>            Fillers for paints            Composite materials            Impregnation of papers            Adhesives            Magnetic fluids</p> <p><b>Engineering</b>            Protective coatings for tools and machines            Lubricant-free bearings</p> <p><b>Electronics</b>            Displays            Data memory            Laser diodes            Fibre optics            Optical switches            Filters            Conductive, antistatic coatings</p>	<p><b>Construction</b>            Materials            Insulation            Flame retardants            Surface coatings for wood, floors, stone, tiles, roofing, etc.            Mortar</p> <p><b>Medicine</b>            Drug delivery systems            Contrast medium            Rapid testing systems            Prostheses and implants            Antimicrobial agents            In-body diagnostic systems</p> <p><b>Textiles</b>            Surface coatings            Smart textiles</p> <p><b>Energy</b>            Fuel cells            Solar cells            Batteries            Capacitors</p>	<p><b>Cosmetics</b>            Sunscreens            Lipsticks            Skin creams            Toothpaste</p> <p><b>Food and Drinks</b>            Packaging            Sensors for storage life            Additives            Clarifiers (for juices)</p> <p><b>Household</b>            Ceramic coatings for irons            Odour removers            Cleaners for glass, ceramics, metals, etc.</p> <p><b>Sports/Outdoors</b>            Ski wax            Tennis rackets, golf clubs            Tennis balls            Antifouling coatings for boats            Antifogging coatings for glasses/goggles</p> <p><b>Ref: The Meridian Institute<sup>66</sup></b></p>
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## Appendix 2: Public Dialogue Projects reviewed

All public engagement projects reviewed here sought to provide balanced information and opportunities for discussion. They allowed participating members of the public to learn about current state of development of nanotechnologies and to articulate their attitudes about what they learned.

### **Nanodialogues (UK)**

Co-ordinated by: Demos

Funded by: DTI (Sciencewise)

\* People's Inquiry on Nanotechnology and the Environment, Demos, 2006

### **Small Talk (UK)**

Co-ordinated by: Think-Lab

Funded by: DTI and Royal Society (Copus)

\* Small Talk Final Report, 2006

### **Nanotechnologies, risk and sustainability (UK)**

Co-ordinated by: Lancaster University

Funded by: ESRC

\* Kearnes, Machnaghten and Wilsdon, Governing at the Nanoscale, 2006

### **NanoJury (UK)**

Co-ordinated by: University of Newcastle

Funded by: IRC in Nanotechnology, Greenpeace UK, University of Newcastle, The Guardian

\* Report of Jury findings, September 2005

### **Informed Public Perceptions of Nanotechnology and Trust in Government (US)**

Co-ordinated by: Wilson Centre Project on Emerging Nanotechnologies

Funded by: Pew Charitable Trusts

\* Macoubrie, Informed Public Perceptions of Nanotechnology, September 2005

### **Madison Area Citizens Consensus Conference on Nanotechnology (US)**

Co-ordinated by: University of Wisconsin

Funded by: Nanoscale Science and Engineering Centre, University of Wisconsin

\* Report of the Madison Area Citizens Consensus Conference on Nanotechnology, April 2005

## Appendix 3: Comparison between GM and Nanotechnology

<b>Fright Factor</b>	<b>GM Food</b>	<b>Nanotechnologies<sup>67</sup></b>
Involuntary – e.g. exposure to pollution as opposed to dangerous sports or smoking	Present in foods initially without labelling	Consumers are likely to use products containing nanomaterials without knowing it
Inequitably distributed – some benefit while others suffer the consequences	General public felt that companies and farmers would benefit while the risks would be born by consumers and the environment	In some cases individuals may be exposed to nanoparticles without experiencing the benefits of their use
Inescapable – even by taking personal precautions	Farmers were not able to avoid cross pollution from gm pollen and lack of labelling meant that consumers could not choose to avoid gm foods	Some precautions can be taken to avoid exposure, but they are unlikely to be well understood or trusted
Unfamiliar or novel – particularly from a new source	Technology promoted initially as 'new and improved'	Nanotechnology is certainly novel and remains mysterious to most of the public
Man-made not natural	Seen as 'man tinkering with nature' despite arguments that the process also occurred in nature	Applies particularly to engineered nanoparticles and to possible applications offering human enhancement.
Hidden and irreversible damage – e.g. onset of illness many years after exposure	Uncertainties around the long term damage to human health and environment	Nanoparticles could accumulate in the body or environment unbeknownst to consumers, leading to chronic effects
Danger to children, pregnant women or future generations	Future generations in particular considered to be potential burdened by gm contamination  Farmers in developing countries were considered by some to be being particularly vulnerable and exploited by business interests	While specific applications may differ, in most cases these populations will not be at greater risk  (There are similar concerns about exploitation or inequalities about vulnerable developing economies)
Death by a form arousing particular dread	Not a concern	No 'nuclear threat' exists, but the possibility that exposure to nanoparticles could cause cancers or other conditions does
Damage identifiable not anonymous victims	Focus on individual farmers and implications for livelihoods	Consumers would likely be anonymous, but factory exposure would affect specific individuals and likely to be widely publicised. (Media also likely to focus on individuals)
Poorly understood by science	Initially concerns about scientific uncertainties, still questions about mixing of GM and wild plants to produce new species	Both researchers and regulators are plainly struggling to understand the possible effects of nanotechnologies
Subject to contradictory statements – from responsible sources, or worse, the same source	Polarised debate as 'the saviour of the agricultural community' and the 'downfall' of the same technology	Consumers are confronted with both wildly utopian and wildly apocalyptic visions of nanotech's effects

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