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EXECUTIVE SUMMARY

1 A POTENTIALLY LARGE MARKET The report focuses on nanotechnology; a class of products containing materials built on the atomic scale. Nanotechnology represents an entire scientific and engineering field, and not just a single product or even group of products. Market research suggests that products valued between US$30 billion - US$200 billion contained nanotechnology in the year 2005. One estimate by the Lux Research says that 15% (by value) of all products will contain nanotechnology by the year 2014. A project on Emerging Nanotechnologies, set up in part by the Woodrow Wilson International Centre for Scholars now has 580 products in its database, an increase of 175% since the database was released in March 2006. Currently most nanotechnology products are found in the sports, household and food industry though others are using them to a growing extent. This is a rapidly growing and potentially large future market.

2 NANO PARTICLES, DIFFERENT MATERIAL PROPERTIES The chemical reactivity of a material is related to its surface area when compared to its volume. Dissecting a 1 centimetre cube of any material into 1 nanometer cubes increases the total combined surface area some ten million times. Nano particles can therefore be much more reactive than larger volumes of the same substance. They are relatively cheap and can be manufactured in large quantities. They are already used in consumer products and can be highly reactive. Such particles often have unknown toxicity which can be difficult to quantify. They can disperse easily in air or water. Researchers believe this form of nanotechnology is the most risky at present and the insurance industry should monitor developments in this field closely.

3 UNKNOWN IMPACTS ON HEALTH It is unclear whether nanoparticles can cause chronic health effects. There are several ways that nanoparticles can enter the body, these include: inhalation, ingestion, absorption through the skin and direct injection for medicinal purposes. The skin is surprisingly permeable to nanomaterials. Carbon nanotubes are strong and can have a similar shape to asbestos fibres; several reviews conclude that carbon nanotubes are potentially toxic to humans. Given that nano-sized objects tend to be more toxic than their large scale form it would be unwise to allow the unnecessary build up of nanoparticles within the body until the toxicological effects of that nanoparticle are known. Such studies are still speculative but insurers would be prudent to consider adverse scenarios when agreeing terms and conditions and when determining pricing and capital. In particular whether a claims made trigger as opposed to an occurrence trigger is appropriate and whether limits should have an aggregate limitation.
4 UNKNOWN IMPACTS ON THE ENVIRONMENT Removing nanoparticles from the environment may also present a significant problem due to their small size. If absorbed, the particles may travel up the food chain to larger animals in a similar way to DDT though there is no evidence either way that this is a valid mechanism. There is still too little research into the potential negative impacts of this technology on the environment. However, some nanoparticles (such as copper or silver) have been shown to be harmful to aquatic life. Given the large pollution losses faced by the insurance industry in the past this is cause for concern although there are now many exclusions in place to limit such losses. As for health impacts, where there is cover, insurers may want to consider the terms and conditions carefully and, in addition whether to exclude losses due to the reduction of property values.

5 MANY POSITIVE EFFECTS Nanotechnology could also bring direct benefits to risk mitigation in the form of new materials that are stronger or more adaptive than before. Cars could be made to absorb more of the impact during a crash; building materials could be made stronger and more flexible to resist damage from earthquakes, fire, flood and corrosion. Environmental clean-up operations could be made easier and cheaper with the use of specialised nanoparticles. Medicine could also be transformed by nanotechnology allowing cheaper and more sensitive diagnostic tools for diseases giving insurance professionals better statistics to determine pricing. However, this is perhaps one of the great dangers; because the benefits are so seductive society may rush to capitalise on them before adequately assessing safety. The insurance industry must ensure that its own financial health is not compromised by systemic aggregations of loss from these technologies.

6 LACK OF REGULATION Currently almost all regulation of nanotechnology is done using existing mechanisms. Stakeholders in nanotechnology are divided on whether specific regulation is required. However, the “wait and see” approach is increasingly becoming a dangerous way to determine the risks. There is progress in this area and the Economic Co-operation and Development (OECD) have released a “Nano Risk Framework” which provides a framework for risk managers to address this. The precautionary principle is now accepted to apply to the degradation of human health as well as the environment, and suggests the use of this technology should be risk assessed appropriately before consumption by the public. This approach is being recommended within the EU, though the US and Japan prefer a lighter regulatory touch. In the past a vacuum of regulation has proved unhelpful to insurers. The insurance industry should lobby for clarity in this area.
CONTENTS

Purpose 06
Emerging Risks Team 06

Background 07
Uniqueness of the Nanoscale 08
Types of nano-objects 09
Nanoparticles 10
Overview of nanotech market as it is now 11

Hazards to Humans 13
Inhalation of nanoparticles 14
Ingestion of nanoparticles 15
Absorption through skin 16

The Environment 16
Nano-remediation 17
Hazards to aquatic life 18
Accumulation in the environment 18

Commercial Products 19
Which products use nanotechnology? 19
Nanoparticles in cosmetics 20
Nanotechnology in fabrics 21
Nanotechnology in medicine 21
Nanotechnology in electrical goods 22

Direct Benefits to Insurance 23

Possible Scenarios 23

Regulation 24
Risk assessment 24
Case study: Nano Risk Framework 26
The precautionary principle 27
Case study: REFNANO project 28
International regulation 29
  Europe 29
  USA 29
  Japan 30

The Energy Sector 31

Public Perception 31

Conclusions 32

Further Reading 33
PURPOSE

This report will focus on nanotechnology; a class of products containing materials built on the atomic scale. It promises to be one of the technologies that will change the world and this report aims to provide an up-to-date view to inform the Lloyd's market and the wider insurance industry about the risks and opportunities that may exist in this developing area.

Nanotechnology is already in use and has the potential to become as commonly used as plastic. It is relatively new and its risk assessment has barely begun. Due to the potential impact to the insurance industry if something were to go wrong, nanotechnology features very highly in Lloyd's top emerging risks. We will therefore continue to monitor research into the risks of nanotechnology, in particular where they relate to environmental and health effects.

These areas will have the most impact in terms of liability insurance, if the most extreme events such as mass nano-pollution were to be realised. We hope that our monitoring and reporting in these areas will enable insurers to make better informed decisions regarding any nanotechnology risks they may have written or intend to write. The risks are unknown and the exposures are latent, it is hoped that the additional details we have supplied will also help insurers to determine the terms upon which the cover should be provided. Capital requirement calculations should also consider emerging risks too; this report will highlight the potential of nanotechnology to lead to large scale latent claims.

The insurance industry is a risk mitigating tool for many stakeholders in nanotechnology. But insurers must consider where systemic aggregates of risk may arise and take appropriate action to mitigate those risks.

EMERGING RISKS TEAM

The Emerging Risks team is part of the Franchise Performance Directorate at Lloyd’s. We define an emerging risk as an issue that is perceived to be potentially significant but which may not be fully understood or allowed for in insurance terms and conditions, pricing, reserving or capital setting. Our objective is to ensure that the Lloyd’s market is aware of potentially significant emerging risks so that it can decide on an appropriate response to them.

The Lloyd’s emerging risk team maintains a “radar” of emerging risks which is updated regularly through conversations with the Lloyd’s emerging risks Special Interests group, which consists of experts within the Lloyd’s market put together with help from the Lloyd’s Market Association. The team also maintains contact with the academic community, the wider business community and government. Contact with academics is often facilitated through the Lighthill Risk Network an organisation that is run as not-for-profit and co funded by Benfield, Guy Carpenter and Catlin.

More details can be found at www.lloyds.com/emergingrisks.
BACKGROUND

The word “nano” itself refers to the length scale (one nanometre is one billionth of a metre) that is one thousand times smaller than the micro scale, the scale that was traditionally associated with the electronics industry. Viruses and DNA are examples of natural objects on the nano scale, in contrast a human cell can appear enormous.

The term nanotechnology refers to the engineering, measurement and understanding of nano-scaled materials and devices. Manipulating matter atom by atom and creating features on the atomic or “nano” scale is now a proven technology and there is an ever growing catalogue of products that utilise nanotechnology. The National Nanotechnology Initiative, which coordinates the nano-scale science of 26 federal US agencies, defines nanotechnology:

“The understanding and control of matter at dimensions of roughly 1 to 100 nanometres, where unique phenomena enable novel applications”

But what are the unique phenomena and novel applications that this statement refers to and what impact will this have on the insurance industry? This report will answer these questions.

To give an idea of the size of a nanometre (nm) here are some examples:

- Typical red blood cell, 7000 nm in width, 2000 nm in height
- Common cold virus, 25 nm
- Width of DNA molecule, 2 nm
- Silicon atom, 0.2 nm

Nanotechnology inhabits the world of cells, viruses and even DNA. For example, by volume, a nanoparticle 2 nm in size would be over 10 billion times smaller than a red blood cell. To put this into context if the nanoparticle in question was the size of a person, then that blood cell would be approximately the size of the City of London. This means that when dealing with the risks, the effect on cells should be considered.
**Uniqueness of the nanoscale**

There are many uses and applications available using nanotechnology that are not possible using conventional materials which make it unique. For applications that use a substance’s chemical properties, substantially less nanomaterial may be required to do the job of a conventional material. The chemical reactivity of a material is related to its surface area compared to its volume and the surface area for a nanoparticle is enormous per unit volume. The diagram below illustrates how surface area increases when a material is dissected into nano-sized particles.

Therefore, dissecting a 1 cm cube of any material into 1 nm particles increases the total combined surface area to approximately the size of a football pitch, some 10 million times larger. This has applications in the use of catalysts, clean-up and capture of pollution and any application where chemical reactivity is important such as medicine. Products can be coated in thin films only a few atoms thick to produce a desired property, like waterproofing or being anti-microbial, while at the same time appearing invisible, leaving the product looking and feeling unaltered. This is already being used widely in the clothing industry.

The nano world is very different from the world around us where the physical model known as quantum mechanics can become dominant over classical physics. Quantum mechanics is a large and complicated field where matter can behave very differently in terms of its electrical and mechanical properties. Other properties such as temperature can also become ill-defined and have to be considered in new ways. This has huge implications to the electronics industry as quantum electronics could open up untapped computing power, while at the same time providing a challenge as quantum effects are undesirable in some types of electrical components.
**Types of nano-objects**

Nanotechnology represents an entire scientific and engineering field, and not just a single product or even group of products. As a consequence of this there are several different types of nanotechnology, and many applications associated with each type. There are also several other types of nano-sized objects which exist in our environment, both natural and unnatural. The table below summarises the main types of nanotechnologies and nano-objects and examples of current or future application.

<table>
<thead>
<tr>
<th>Type of nano-object</th>
<th>Examples of application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embedded nanotechnology</td>
<td>Electronics, optoelectronics, building materials, sports equipment</td>
</tr>
<tr>
<td>Films and coatings</td>
<td>Self-cleaning coatings, waterproofing, anti-microbial coatings e.g. medical equipment, food containers and appliances.</td>
</tr>
<tr>
<td>Biologically natural DNA, viruses</td>
<td></td>
</tr>
<tr>
<td>Unintentionally created particles</td>
<td>Metal smelting, burning fossil fuels including petrol and diesel.</td>
</tr>
<tr>
<td>Biological nanotechnology</td>
<td>Nano-sized motors, medical diagnostics</td>
</tr>
<tr>
<td>Natural particles</td>
<td>Particles emitted from volcanic eruptions and forest fires.</td>
</tr>
<tr>
<td>Manufactured particles</td>
<td>Food and cosmetic additives including sun screens, anti-microbial uses, pollution clean-up</td>
</tr>
<tr>
<td>Nano-electrical mechanical systems (NEMS)</td>
<td>Drug delivery and diagnostics, smart sensors</td>
</tr>
</tbody>
</table>
Nanoparticles
While there are many types of nanotechnology, nanoparticles deserve a special mention as, according to the Royal Society’s seminal report in 2004 entitled “Nanoscience and nanotechnologies: opportunities and uncertainties”:

“Currently we see health, safety and environmental hazards of nanotechnologies as being restricted to discrete manufactured nanoparticles and nanotubes in a free rather than embedded form.”

This report suggests that we need to watch nanoparticles most carefully as risk managers. Nanoparticles are typically free particles 1 to 100 nm in size. Carbon nano-tubes are also classed as nano-particles as their width is on the nano-scale, even though their length can be much greater. The definition of 1 to 100 nm is somewhat arbitrary as some determine the upper boundary to be anywhere between 100 nm to 300 nm or even 1000 nm (equivalent to one micrometre).

Nanoparticles are believed to present the greater risk because:

- They are relatively cheap and can be manufactured in large quantities
- They are already used in consumer products
- Their properties can be very different to the larger forms of the material they are made from
- They can be highly reactive
- The particles often have unknown toxicity
- Their toxicity can be difficult to quantify
- They can disperse easily in air or water

The importance of nanoparticles being considered as the most potentially hazardous type may change in the future as other forms of nanotechnology become more common and nanoparticles become better understood. Monitoring developments in this field will be key to ensuring the highest potential risks remain at the top of the agenda for risk assessment.

Many materials can be engineered into nanoparticles; the most common are silver, carbon, zinc, silica, titanium dioxide, gold and iron. Typically these are small clusters of atoms. Carbon can also be made into hollow balls or tubes of atoms collectively known as fullerenes. The image to the left is an example of a nanotube. The properties of these particles vary greatly. For example, silver is effective at killing microbes and is used to keep food appliances hygienic; while iron is being used to remove pollution from contaminated land. Fullerenes have a wide variety of electrical and mechanical properties and have a wide variety of potential applications.
However the properties of these particles can be further modified when scientists and engineers add additional molecules or functional groups as they are known. Carbon nanotubes seem to be the most popular nanoparticle to add these molecules too.

Therefore it’s important when assessing the risk of a particle to be aware that these properties may have been substantially altered. For example, a carbon nanotube that is normally insoluble in water can be made soluble by the addition of a few molecules to its surface. This altered particle will behave very differently in the environment or the human body and yet both versions will be labelled a carbon nanotube, and this could potentially cause confusion or even a mis-pricing of the risk.

Overview of nanotech market as it is now
According to the Royal Society:

“Nanotechnologies are widely seen as having huge potential in areas as diverse as healthcare, IT and energy storage.”

Currently most nanotechnology products are to be found in the sports, household and food industries, with the products originating mostly from the US and East Asia. However, as the Royal Society states, the scope of products that could make use of nanotechnology is enormous. Current and potential areas of application include transport, manufacturing, biomedicine, sensors, environmental management, information and communications technology, materials, textiles, equipment, cosmetics, skin care and defence, though this list is by no means exhaustive.

Market research undertaken by Lux Research and Research and Markets suggest that US$30 billion to US$200 billion worth of products contained nanotechnology in the year 2005. While the amount of nanotechnology they contain is typically only a fraction of the total value of the product, these figures do indicate the significant penetration of nanotechnology into commercial products. To give an indication of the predicted growth of the sector according the Project on Emerging Nanotechnologies the number of products containing nanotechnology has doubled between April 2006 and May 2007. One estimate by Lux Research says that 15% (by value) of all products will contain nanotechnology by the year 2014.

2005 government spending – total US$4.6bn

In terms of government spending, North America, Asia and Europe are spending significant amounts (US$1.1 billion to US$1.7 billion each in 2005) on researching and developing nanotechnology. Similar amounts are invested by industry in each region. In 2006 worldwide funding for nanotechnology reached US$11.8 billion, which is a 13% increase from 2005 according to the latest report by Lux Research. This is an indication that nanotechnology is viewed as a serious and important element to the world’s future economy.
HAZARDS TO HUMANS

In terms of liability cover, the insurance industry needs to know which nanoparticles are hazardous to humans, and what levels of concentration are required to cause harm. Can nanoparticles cause chronic health effects similar to asbestosis? The short answer is that we simply do not know.

Initial investigations carried out show some nanoparticles are acutely toxic when compared to larger particles composed of the same material, such as ultra-fine carbon and diesel exhaust particles respectively. Certain organs in mice have been shown to be adversely affected by some nanoparticles as well as significantly reduced offspring production in some aquatic life. If these effects are caused in other animals they may be possible in humans, though there have been no human studies to confirm this. Studies looking at the chronic effects of nanoparticles are much less common, though some are underway. The UK Council for Science and Technology highlighted that there is insufficient research into the toxicology, health and environmental effects of nanomaterials. This call has been taken seriously and there are now efforts to increase the amount of research into nanotoxicology.

There are several ways that nanoparticles can enter the body. These include inhalation, ingestion, absorption through the skin and direct injection for medicinal purposes. Once the particles are in the body they may be transported throughout the body before they are ejected, if at all. The blood brain barrier, which protects the brain from harmful chemicals in the blood, can be no barrier at all to certain nanoparticles. This is an advantage for medicine as drugs can be engineered to enter the brain, an area that is traditionally very difficult to deliver drugs to. Conversely, unwanted nanoparticles in the blood could also cross the blood brain barrier and accumulate there. This has been observed in mice in a study by Kai Pelkonen et al.

The question of accumulation of nanoparticles over a long period of time is an important one for insurers. Could workers or consumers be exposed to very low doses of nanoparticles over many years? Might there be a build up in the body as their may be no mechanism for removing certain nanoparticles? If this was possible and the nanoparticles proved toxic, this could impact a suite of liability covers.

Insurers would be prudent to consider adverse scenarios when agreeing terms and conditions and when determining pricing and capital. In particular whether a claims made trigger as opposed to an occurrence trigger is appropriate and whether limits should have an aggregate limitation.
Inhalation of nanoparticles

Damage caused by inhalation of nanoparticles was one of the first areas to be researched by toxicologists. The driver behind this research was that the Royal Society believes the largest hazard posed will come from nanoparticles rather than embedded forms of technology and that some similarities exist between asbestos fibres and carbon nanotubes. This is supported by the increasing association between unintentionally created ultra fine particles, for instance car exhaust, which may trigger breathing related illnesses such as asthma.

Particles breathed into the lungs can cause damage and scarring, which over long periods of exposure can lead to long term breathing difficulties. This is an analogous process by which asbestos fibres cause asbestosis. The fibres lodge deep within the lungs and trigger the local immune system, which sends specialised immune cells that try to digest the fibres and repair any damage by depositing new tissue. As the fibres are highly resistant, the immune cells cannot digest them, die off, cause more immune cells to attack the foreign body, and yet more tissue to be deposited. In some cases this can also cause the cells to become cancerous. Over many years of exposure this leads to thickening of the lung walls and reduces the amount of oxygen that can be absorbed from the air and decreases the amount of carbon dioxide that can be breathed out. This causes a shortness of breath and hence a reduced ability to perform any activities that require exertion and costly oxygen therapy may be required.

Carbon nanotubes can be very similar to asbestos fibres; they are strong and can have a similar shape to asbestos fibres. There has been much research into the potential applications of nanotubes; however research into their toxicity is currently fragmented. Some studies refute any negative effects of carbon nanotubes, but several of the reviews conclude with statements similar to the following:

“...carbon nanotubes are potentially toxic to humans and that strict industrial hygiene measures should be taken to limit exposure during their manipulation”. Julie Muller et al.

This statement was from a study that found carbon nanotubes cause inflammation in the lungs and scarring. This is a similar effect to asbestos exposure and gives clear indication that the potential risk from carbon nanotubes should be taken seriously.

Titanium dioxide and carbon nanoparticles also show detrimental effects when inhaled. Carbon nanoparticles in this sense refer to a small cluster of carbon atoms and not in the form of tubes. Mice suffered inflamed lungs when exposed to these particles. One study by Tobias Stoeger et al showed that if the total surface area of all the particles of each dose was progressively reduced, by using larger particles, a surface area threshold was found. Beyond this threshold, in effect if the particles became too large, no short term adverse effects were observed. While this is only one study it may indicate a safe level for short-term exposure to nanoparticles.

Cerium oxide nanoparticles are added to some diesel fuels to reduce nitrogen oxide emissions and increase engine efficiency. Nitrogen oxide has been linked to acid rain and smog, and a reduction of this pollutant is an important goal for car manufacturers. Use of cerium oxide will release it into the atmosphere through car exhaust; and there are concerns that it may damage the lungs if inhaled and one study appears to lend weight to this theory. This is another nanotechnology where a debate is required to
determine if the gain offered by the new technology outweighs the potential risks.

Long term exposure is still a big unknown however. If these nanoparticles can cause a similar short-term response in the lung as asbestos it is possible that they may induce the same long term effects as well. Workers who produce these particles would be at the greatest risk and appropriate safety precautions, such as wearing nano-rated masks would reduce their exposure. This is still speculative and studies will have to be conducted to find a stronger link, but as an insurer it would be prudent to include this as a potential scenario when determining pricing and reviewing capital requirement.

Ingestion of nanoparticles
As an example of how scaling down a material from the large scale to the nano scale increases its toxicity or ability to damage organs, a study of copper nanoparticles ingested by mice found that:

“Nanoparticles induce gravely toxicological effects and heavy injuries on kidney, liver and spleen of experimental mice, but micro-copper particles do not”. Zhen Chen et al.

Another study found that silver atoms quickly saturated tissues and organs including the brain of mice given a dose 3-fold lower than the World Health Organisation (WHO) recommended level for safe drinking water. The study concluded that “A re-evaluation of the present recommendations on the use of silver salts for disinfection of drinking water might be necessary.” Silver atoms may not be considered true nano-particles by some, as a nano-particle would have to contain several atoms; however silver nano-particles would be a source of silver atoms once they are within the body. It therefore seems plausible that the conclusions of the study are also relevant to silver nano-particles.

Nano-silver is being used as an anti-bacterial agent in food containers and kitchen appliances. Whilst it is intended that this be fixed in position there is always the concern that the particles work free. Given their close proximity to food it seems plausible that such particles could cause contamination so that ultimately humans are at risk ingesting the particles. Once the silver has been digested they may also plausibly interfere with bacteria required for a healthy gut. It would be unwise to allow the unnecessary build up of this type of nano-particle within the body until the toxicological effects of that nano-particle are known. For example the effect of organs storing nano-particles over a long period of time is unknown. Further research in this field appears necessary.
Absorption through skin

There are problems facing scientists when trying to determine the toxicity of nanoparticles as highlighted by a paper entitled "Challenges for assessing carbon nanomaterial toxicity to the skin" by Nancy A. Monteiro-Riviere. The paper describes how standard toxicity tests for chemicals, when used on nanoparticles may give conflicting results and that multiple types of tests should be used as a single test may be unreliable. Another study concluded that nanoparticles “…can penetrate intact skin at an occupationally relevant dose within the span of an average-length work day. These results suggest that skin is surprisingly permeable to nanomaterials…”

Nanoparticles are being used in a number of products which are placed in direct contact with skin, including clothing, cosmetics and sun cream. Once absorbed through the skin if the nanoparticles come into contact with blood vessels they may behave in a similar way as if they had been ingested, namely collecting within certain organs or cells within the body. This again is another call to determine the toxicity of widely used nanoparticles.

THE ENVIRONMENT

According to the Royal Society in 2005:

“There remains virtually no data on the potential negative impacts of nanomaterials on the environment. Research into the ecotoxicology is urgently required”.

Research has started in this area but there are still significant gaps in the knowledge. Some nanoparticles (such as copper or silver) have been shown to be harmful to aquatic life, which has environmental consequences if a large amount of the material were to be released into the environment. Removing nanoparticles from the environment may also present a significant problem due to their small size. Particles could conceivably be absorbed quickly into plants and soil or transported large distances in the air or suspended in water; and how do you filter out of the environment particles only a few atoms wide? Insurers may want to consider the terms and conditions of any cover carefully and, in addition whether to exclude losses due to the reduction of property values.
Nano-remediation
Remediation in this context is the restoration of contaminated land to a state for which it is safe for future use. A substantial part of this process is the removal of toxic and hazardous materials from the land site.

Research has shown that iron nanoparticles are especially effective at removing toxic metals such as chromium and lead from contaminated water. When injected into the land the iron oxidises (the effect that causes iron to rust) with the contaminants and makes them less or non toxic. One study showed that, weight for weight, nano-scale iron worked five times better than conventional iron filings or powder. Nanoparticles which are suspended in a slurry can be injected directly into contaminated ground. This is much more convenient and cheaper than some current methods, which require digging up the ground and then treating it. In some cases it may be the only way to remove contamination.

Nano-remediation has clear advantages over conventional methods as it is more convenient, uses less material and potentially cheaper. However, long term studies have not been carried out and it is unknown what happens to the nanoparticles after the treatment has finished.

In the UK, there is no ban on using nanoparticles for environmental use; however, the Government encourages the industry to take a responsible approach. Within the UK it is very unlikely that any companies are using this technology. The US is also looking into the risks, and the Environmental Protection Agency (EPA) recently published a white paper outlining its research needs. The EPA is also conducting test studies, one of which injected 100 kilograms of iron nanoparticles suspended in approximately 10,000 litres of water. The study showed promising results in terms of removing contamination and the EPA is planning a full-scale system. As far as we are aware, the information produced so far makes no mention of the possible ecological effects or any attempts to measure them.

While this has the benefit of removing toxic metals and other unwanted chemicals, it is not known whether society is solving one problem and replacing it with another, namely the unknown effect of placing large amounts of nanoparticles into the environment. It is not clear how these particles will affect the microbial ecosystem. The property of iron that makes it useful for removing contaminants could also be lethal to cells and micro-organisms and a recent paper found that iron nanoparticles are toxic to neural cells. Micro-organisms are essential for healthy soil as they recycle nutrients by decomposing dead matter. If the use of iron in remediation proved too effective and damaged the micro-organism part of the ecosystem it could have a domino effect on the surrounding area and cause unintentional damage to plant and animal life. Society needs to decide if on balance the rewards of nano-remediation outweigh the potential risk of possibly causing ecological damage.
Hazards to aquatic life

Fish are susceptible to copper nanoparticles, which induce gill injury and acute lethality according to current research conducted with concentrations of 1.5 mg/litre. A fraction of the particles will dissolve to produce soluble copper, which is known to be toxic, but the toxic effects seen could not be explained solely by exposure to soluble copper. This implies that the additional effects were caused because the copper was present on the nanoscale. Titanium dioxide nanoparticles have also been investigated but preliminary studies show that, while the particles do cause respiratory stress, it was not considered a major toxicant at the concentrations of one mg/litre. The carbon fullerene, C_{60}, has also been shown to significantly reduce offspring production for freshwater shrimp which would have negative implications for populations of species further up the food chain.

Accumulation in the environment

At the nanoscale particles, can stick together (aggregate) or fuse (agglomerate) effectively creating larger particles. This could reduce any property of the particle that is directly related to its size, chemical reactivity for example.

As an example, one study found that when copper nanoparticles were added to water, 50-60% of the particles aggregated and sank to the bottom, leaving the water column. It seems plausible that this could have implications if large amounts of nanoparticles were released into a water system. On the one hand, this would reduce the amount of nanoparticles in the water and hence reduce the range of transportation and any toxic effects on aquatic life. However, on the other hand, the aggregated nanoparticles that sink, for example to the bottom of a river bed, could then be absorbed by plants and animals that live there. Once absorbed the particles then may travel up the food chain to larger animals in a similar way to Dichloro-Diphenyl-Trichloroethane (DDT) or Polychlorinated biphenyl (PCB). DDT and PCB are persistent pollutants that remain in the environment for long periods of time. These chemicals are absorbed by micro-organisms which are then fed on by larger organisms and the chemical continues up the food chain increasing in concentration. The concentrations in large animals and birds can then reach toxic concentrations or cause problems such as birth defects and organ injury. There is no evidence either way that such "biological magnification" would occur, but given how chemicals like DDT and PCB have negatively affected the environment in this way in the past it would be prudent to study any mass manufactured nanoparticles for similar effects.
COMMERCIAL PRODUCTS

Which products use nanotechnology?
Knowing what products contain nanotechnology will assist in determining exposure to consumers and workers. The Project on Emerging Nanotechnologies, set up in part by the Woodrow Wilson International Center for Scholars, is maintaining a nanotechnology consumer products inventory. As of October 2007 there were 580 products in the database, an increase of 175% since the database was released in March 2006.

Products by category

![Graph showing products by category]


The biggest category, with 61% of products, is health and fitness which includes clothing, cosmetics and sunscreens. This category also includes sports equipment that includes improved tennis balls and stronger rackets. These are examples of embedded nanotechnology in the same way that carbon nanotubes could be used to reinforce car bodies for extra safety and strength. Embedded nanotechnologies are considered potentially safer than free nanoparticles, however it is unclear what happens when the product reaches the end of the useful stage of its life cycle. The concern is that nanoparticles within the product could enter the environment once it has been discarded, and affect the environment in some unknown way.

Food and beverage products make up 11% of the database. The most common nanoparticles used in products are silver and carbon. As previously mentioned, silver is used mainly for its anti-microbial properties, and carbon has many uses but is mostly used for strength or wear-resistant enhancement of materials and its electrical properties. It is also important to note that products are rarely 100% nanotechnology; nanotechnology will be added to a product and form a part of it.

Nanoparticles in food
Silver is currently the most common nanoparticle that is used in the food industry. Silver has long been known as an effective anti-microbial agent, and with the introduction of its nanoparticle form it can now be easily impregnated invisibly into almost any product to aid in the destruction of bacteria and viruses. This has important applications in the food industry in terms of manufacturing, preserving and storage.

Although the use of nanotechnology directly in food products is limited there are at least 38 food supplements at the time of writing this report
that contain nanoparticles as the main active ingredient. The most common particles used in these supplements comprise of silver, gold, copper or calcium, though other more unusual elements are available such as iridium, palladium and titanium. It is unknown what effect these metals may have on cells and the body as a whole.

Fridges and food containers are also now available with a silver nanoparticles lining to deter the growth of bacteria and mould. It is not known whether these silver nanoparticles can be absorbed by the food while it is being stored and later ingested. Nanoparticles may leach or dissolve from the products into the environment as it is washed or cleaned. Once in the environment the particles may build up and harm microbial life which could cause a negative knock on effect up through the food chain.

Nanoparticles in cosmetics

The fascinating group of nanoparticles known as fullerenes include C60 which resemble small “footballs” of carbon atoms and are being used in cosmetics in the form of face creams to remove other unwanted particles, such as free radicals, which are believed to cause damage to the body and skin. While these properties of C60 may exist it has also been found to damage human skin, liver and brain cells at doses of 50 parts per billion after only two days of exposure. While this study was performed on cells in a dish and not in a live subject, the low dose required is indicative of the damage these particles could do. Research also suggests that the toxicity of fullerenes is highly dependent on how much the particles have been altered, for example whether they have been made soluble water by the addition of extra molecules.

Sun creams are now available with titanium dioxide nanoparticles. The larger particle form is used as a sun-block, but is white in colour and is not used in sun creams that need to be invisible when applied. The nanoparticle form is colourless as the particles are too small to reflect visible light, but still retain their ultraviolet sun-blocking properties that are highly desirable for a sun cream. There is concern that the nano-sized particles, once rubbed into the skin, would be able to enter cells and damage them. This is because when titanium dioxide is exposed to sunlight it can act as a photo-catalyst, which can make it very toxic to the surrounding cell. Larger particles should not share this problem as they would be too large to enter the cell. The short term effect on cells is that if the nanoparticles can penetrate the dead layer of skin that protects the body then titanium dioxide may be toxic when exposed to sunlight. The long term effect is unknown and requires further research.
Nanotechnology in fabrics
Clothes are also receiving the nano-treatment. Again, nano-silver is playing a lead role due to its anti-microbial properties, with the risk being that the nanoparticles will be in direct contact with skin over prolonged periods of time. Clothes can also be treated with nano-films to make them stain, water and static resistant. These films, which are only a few atoms thick, could be in contact with skin over prolonged periods. Very little information is available as to the composition of these nanotechnology products or what the long term effect could be, though in the short term most products appear safe as nanotechnology has been used in clothes for several years now.

Another concern is that the nanotechnology within clothes could become washed out over time and cause nanoparticles to accumulate within the environment and it is not known what effect they would have.

Nanotechnology in medicine
The use of silver nano-particles for use in medical devices is a hot topic. Nano-silver kills a broad range of harmful microbes and has been shown to be effective against the MRSA super-bug and the HIV virus. This could prove beneficial in terms of providing sterile equipment, beds and wound dressings that limit the spread of harmful bacteria. However, the same properties in silver that kill bacteria may also prove harmful to cells within the body as highlighted by a recent review paper, and it is important to get the balance right between the two effects. This is especially true for wound dressings where cell health is critical for recovery.

Nano-medicine is not limited to simple single element nanoparticles like silver. More complicated nanoparticles can perform certain tasks, like homing in on cancer cells to destroy them or drug delivery that can send drugs directly into cells. Nanotechnology could also be used to produce new sensors that can detect whether a person has certain types of cancer from only a few drops of blood.
Nanotechnology in electrical goods

For the majority of electrical goods nanotechnology has come from a natural evolution of micro-technology. In order to fit more components into an electronic chip to make it more powerful, the components are made to be smaller. Over time, components that used to be several hundred micrometres are now several hundred nanometres. In this respect, nanotechnology only represents an arbitrary milestone, as a micro-sized transistor works in the same way as a nano-sized transistor. Virtually all forms of nanotechnology used in electronics are embedded and are believed to pose a low human health risk and no additional risk to the environment over micro-technology. However, there are many areas that are having a greater impact including: quantum computing; nano-electrical mechanical systems (NEMS); and new display technologies.

Quantum computing uses the quantum mechanical effects available at the nanoscale that gives new ways of performing computational operations. Essentially, some computing tasks that have to be performed sequentially with a standard computer can be performed all at once using a quantum computer. This could dramatically increase the speed of databases, which underpin businesses and increasingly the internet. The greatest impact on risk managers could be the immense computing power quantum computers could provide to those who could misuse it, namely terrorists, hackers and electronic thieves. Internet crime and the associated loss would increase and hence so would the burden on the insurer. This technology is still in the development stage and will not be of immediate concern to insurers for several years.

Nano-electrical mechanical systems (NEMS) are effectively nano-sized machines that currently perform simple tasks. This type of nanotechnology is currently one of the closest analogies to nano-sized robots, the other type being biological nano-machines that are made from biological molecules. These can produce nano-sized motors and sensors. Applications for NEMS could be very broad for example monitoring the environment or even medical nano-robots for targeting cancers or repairing tissues. These examples are still very much in the preliminary or theoretical stage, but once developed could have a huge impact.

Some new display technologies use carbon-nanotubes or nano-sized structures to efficiently emit electrons to be used to excite a phosphor display. This type of technology should have the advantage of being lightweight and efficient. Another new display technology is the organic semiconductor film. The term organic is used as the semiconductor material is made of organic or carbon based polymers. These films may one day be printed off like plastic to provide cheap flexible displays. The nanotechnology element, which lies in the structure of the semiconductor, is not thought to pose any particular new risk over conventional plastics.
DIRECT BENEFITS TO INSURANCE

Aside from providing a new industry to insure, it is also important to note that nanotechnology could also bring direct benefits to risk mitigation in the form of new materials that are stronger or more adaptive than before. Cars could be made to absorb more of the impact during a crash; building materials could be made stronger and more flexible to resist damage from earthquakes, fire, flood and corrosion. Environmental cleanup operations could be made easier and cheaper with the use of specialised nanoparticles. Medicine could also be transformed by nanotechnology allowing cheaper and more sensitive diagnostic tools for diseases giving insurance professionals better statistics to determine pricing. Most of these examples are not realised as yet, but a significant amount is being invested worldwide each year to develop products like these.

POSSIBLE SCENARIOS

The events below represent possible large-scale impacts to the insurance industry if disaster were to occur. The likelihood of any of these events is unknown due to lack of available research and knowledge of the risks and is purely speculative. However, they do seem plausible if extreme and those considering management of exposure in our industry may wish to consider how their organisation would be impacted by the following events:

- Pollution spill from a nanoparticle production facility
- Nanoparticle manufacture workers develop chronic illness
- Nanoparticles leach from products to accumulate in the environment
- Product recall due to research findings indicating product is a hazard
- Liability claims on a company, directors and officers regarding a product that was indicated by research to be unsafe, but subsequently released to the consumer market.

Each of these scenarios may require the insurer to pay for:

- Clean-up costs of land and water contamination
- Medical costs of treatment of human exposure
- Liability claims from persons directly affected, environmental groups and shareholders
- Unexpected life, health and workers compensation
- Latent liability claims of persons affected
- Business interruption while facility is investigated
- Cost of product recall
REGULATION

Faced with little or no regulation or definition of a nanotechnology product, any exclusion to prevent large latent losses has to be wide enough to encompass any future definition. Claims can be ruled, through a mass tort, for example, to be exempt from the exclusion. With a regulated and well defined product, exclusions can be written with increased contract certainty, as it would be less likely for a third party to contest the validity of the exclusion. Therefore, it is in the interests of the insurer that products are regulated and well defined. Currently almost all regulation of nanotechnology is done using existing mechanisms. Regulation specifically for nanotechnology is still under development with stakeholders in nanotechnology having opinions ranging from the belief that “nano-specific regulation is not needed” to those who believe that there is a “regulatory void that could harm both human health and the economic stability of the nanotechnology industry”. A recent example of a lack of regulation is that some manufacturers of carbon nanotubes are selling their product with hazard information that describes them as having similar chemical properties as graphite. Given there are studies that show that inhalation of carbon nanotubes can cause damage to lungs, which we understand graphite does not, such an approach may be misleading. A big concern is whether existing regulation can cope with nanotechnology, and if changes do need to be made how should this be done?

Risk assessment
The UK Government’s Guidelines for Environmental Risk Assessment and Management states.

“A key unifying principle within problem formulation and throughout risk assessment is the connection between the source [of the hazard], the pathway, the receptor and the impact.”

Finding a link, if indeed one exists at all, between the sources of the nanoparticles through to a suspected impact will take time and resources and no doubt some errors may be made along the way. The key is to identify the most likely problem areas and deal with them openly and quickly. Most nanoparticles may be no more hazardous than many other chemicals that are known to be dangerous, such as bleach or rat poison, but the risks of these products are widely known and are handled appropriately. In contrast, nanoparticles could be treated and used like their non-nano counterpart material, for example carbon nanotubes could be treated like graphite. The assumption that nanomaterials behave like the equivalent conventional material could lead to a gross miscalculation of the risk.

Human kind is increasingly developing technologies with greater potential impact (for example, nuclear energy, biotechnology, genetics and nanotechnology) and the “wait and see” approach is increasingly becoming a dangerous way to determine the risks of these technologies. This is because if the risks are miscalculated the negative consequences can be on a grand scale. Many stakeholders in nanotechnology recognise this, even though they may not agree on how to approach it. According to a review paper on the toxicity of industrial chemicals and airborne contaminants:

“Exposure to occupational and environmental contaminants is a major contributor to human health problems.”
An important step was undertaken recently when the Organisation for Economic Co-operation and Development (OECD) released their Nano Risk Framework. To evaluate and address the potential risks the document gives recommendations of what studies are required to determine the health and environment hazards and exposure. They accept that there are areas where information is incomplete or uncertain, but they do provide a framework for risk managers to address this. Insurers operating in the field of nano technology would do well to seek evidence of whether projects they are covering have followed this framework. In particular whether smaller companies have sought the necessary advice.

Groups like the European Nanotechnology Trade Alliance (ENTA) which actively encourage their members to develop nanotechnology responsibly. Until specific regulation is developed they are promoting proposed codes of conduct, such as the Responsible Nano Code, that companies can follow to ensure best practice. Ultimately ensuring that the diverse applications of nanotechnology have a regulatory framework is the challenge facing governments and industry.
DuPont, the global chemical manufacturer, and Environmental Defense a US based environmental advocacy group teamed up in 2005 to create a framework for the safe use of nano technologies. They brought together experts from within their organisations from a variety of disciplines including scientists, engineers, health and safety, legal and regulatory and product development.

The partnership set out to design a framework that covers appropriate risk management of the process of developing a new nano product from initial conception through sales to eventual recycling or disposal. They restricted their project to nano materials below 100 nanometers in any one dimension.

They recommend that any company developing nano products has a team of experts who cover the fields of risk management, toxicology, industrial hygiene and environmental issues. They recognise that smaller organisations may struggle with this but conclude that appropriate expertise is vital for safety; they recommend such organisations purchase consultancy advice for any areas of expertise they lack.

DuPont carried out a number of pilot studies to test the framework in practice and have shared their experiences at www.NanoRiskFramework.com.

In June 2007 the partnership published the framework in a 104 page document covering all aspects of their proposed process including very practical suggestions for action. In summary this framework recommends:

1 **Describe Material and Application.** Basic descriptions of the material including: its chemical structure, its size and expected consumer uses. This step allows all stakeholders to become familiar with the material.

2 **Profile Lifecycle(s).** At all points during the lifecycle of the proposed product consider what its properties may be; qualitatively list what hazards may arise and how might the public or natural environment be exposed. This step is crucial for deciding how to handle the material.

3 **Evaluate Risks**. This is a quantitative step which considers the frequency and severity of incidents.

4 **Assess Risk Management Actions.** A multidisciplinary team should consider how to mitigate the risks identified in the previous steps, according to their materiality. Their purpose is to minimise risks throughout the product’s lifecycle.

5 **Decide Document and Act.** Based on the previous steps, experts on the project team take decisions on next steps including termination of the project if risks are unacceptable.

6 **Review and Adapt.** The above steps should be carried out regularly throughout the project. Decisions should be reviewed and decisions revised as new information comes to light.
The precautionary principle

The UN defined the precautionary principle as “where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.” The principle is now accepted to apply to the degradation of human health as well as the environment, and suggests the use of this technology should be risk assessed appropriately before consumption by the public. This approach is being recommended within the EU, though the US and Japan currently prefer a lighter regulatory touch.

The precautionary approach can add extra financial pressure on small to medium enterprises (SMEs). SMEs are the main developers of new nanotechnology [ref] but the relatively higher costs and resources required to test nanotechnology can make research into the toxicological effects of the nanomaterial being developed prohibitive. This is where international collaboration between industry and academia is ideally suited to offset the research and development financial load on SMEs.

A key consideration when evaluating nanoparticles is to ensure there are a set of benchmarks by which the particles can be compared. Every time a person walks down the street or works in an office they are exposed to by-product nanoparticles produced by cars and printers, for example, and natural nanoparticles within the air and soil. One might consider some of the natural nanoparticles to be “safe” at low concentrations as human physiology would be adapted to cope with them. These particles and concentrations can then provide a benchmark to compare manufactured nanoparticles too. Some benchmark materials are being used to compare against, for example there are standard diesel exhaust particles, which can be used to benchmark carbon based nanoparticles. However, more benchmark particles are required, and there are organisations taking up this challenge, such as the REFNANO project run by the Institute of Occupational Medicine (IOM).
"Reference" materials are important for scientists who are testing the chemical properties of new materials. Such reference materials have well understood, stable properties that other materials can be compared against. ISO Guide 35 (2006) defines a reference material as: “A material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.” Finding nano reference materials is particularly challenging due to: their often enhanced reactivity which makes them difficult to handle and store; and also to their minute size which means that many current measurement methodologies are operating at the limits of their applicability.

The REFNANO project sought to respond to these challenges. The project was funded by DEFRA and carried out by a consortium lead by the Institute of Occupational Medicine (IoM). Initially a survey of 22 thought leaders in the field was carried out; who agreed that a bank of reference materials was a crucial next step. Two facilitated workshops were then carried out which led to a number of proposals. The first was held at Central Science Laboratory, York, and sought to capture the needs of those working in the field of nano-toxicology. The second was held at the National Physical Laboratory (NPL) which concluded there was a need for new measurement techniques, new validating techniques and more detailed characterisation of the surface chemistry of the particles.

The project has set out a number of recommendations which it hopes other bodies (such as DEFRA and the UK Research Councils) will take forward.

1. Identify which existing reference materials are already capable of meeting requirements. The project identified several of these and believes there could be many more. This will be a cheaper than developing new materials.

2. Where necessary seek out or create new reference materials and apply the testing methodology proposed by the project, including inter-laboratory testing.

3. Narrow down the number of toxicology tests that are carried out; agree some standardised details of these tests and then do pilot studies.

4. Define and carry out studies on measurement techniques to determine particle size.

5. Agree a set of standards for handling nano–reference materials.

6. Ultimately develop a nano reference material library.
International regulation

Europe

The European Commission’s stance on regulation is that in principle current regulation addresses concerns about health and environmental impacts and that an incremental process appears as the only realistic option. Therefore existing legislative structures such as dangerous substances legislation, classification and labelling and cosmetic legislation will be used when possible, and amended only if necessary. The new “Registration, Evaluation, Authorisation and Restriction of Chemical substances” (REACH) regulations on chemicals, based around the precautionary principle, will be heavily used in this respect. There are views that this approach will be insufficient and in a recent paper the authors found that the applicability of environmental laws is limited and that “thresholds are not tailored to the nanoscale; and toxicological data and occupational exposure limits cannot be established with existing methodologies”. They conclude that the incremental approach can only be applicable with the implementation of due amendments.

USA

The USA is the world’s largest producer of products containing nanotechnology, and by some accounts the largest single stakeholder. The National Nanotechnology Initiative (NNI) was set up to coordinate efforts between 26 federal government agencies. More than 2 million workers in the USA are exposed to ultrafine particles and the National Institute for Occupational Safety and Health (NIOSH) and the Department of Energy (DOE) have separately issued guidelines on occupational health and safety for working with nanotechnology. The NIOSH does admit that the studies are currently preliminary and limited and more research needs to be carried out. The Food and Drug Administration (FDA), like virtually all other regulators, does not regulate technologies, but regulates on a product-by-product basis. In addition, the FDA only regulates with respect to claims made by the manufacturer. For example, if a product claims that its nanotechnology ingredient provides that product with an edge over a rival brand. Therefore, if a product contains nanotechnology but does not use that fact to promote the product, the FDA may be unaware that the product does contain nanotechnology. This may lead to certain nano-products reaching the shelves without their nanotechnology constituents being examined for risks. Generally, the USA prefers a lighter regulatory touch. This is because it believes it puts SME’s at a disadvantage due to the relatively higher costs and resources required to meet the regulations.
Japan

Japan’s history of electronics manufacturing and thirst for cutting-edge consumer goods has provided an ideal platform for producing nanotechnology products. In many ways, Japan is leading the development of new applications for nanotechnology, with Mitsui producing tons of carbon nanoparticles a year that, for example, are being used in car bumpers and doors to make them stronger. Like many other countries, no single department controls the regulation of nanotechnology, and products are regulated depending upon whether they are classed as food, construction material, medical drugs etc. The Ministry of Economy, Trade and Industry (METI) through the national institute of Advanced Industrial Science and Technology (AIST) is supporting nanotechnology. The New Energy and Industrial Technology Development Organisation (NEDO) set up by METI is conscious of the safety issues surrounding nanotechnology.
The energy sector

Nanotechnology may produce and improve technologies such as fuel cells, portable energy sources, efficient energy storage, improving power transmission, efficient lighting, renewable energy and clean coal burning. Improving the efficiency of fuel cells is seen as a good candidate for nanotechnology as fuel cells rely on catalysts. Nano-sized structures have an enormous surface area and, for a catalyst, the greater the surface area the better it works. In addition to improving conventional fuel cells, micro and nano-sized fuel cells are being developed for use in portable devices.

In terms of large scale energy production, nanotechnology may improve efficiency of fossil fuel plants and transmission of power from the plant to the consumer. Working applications are still in their infancy, though research is underway. For example, the Australian Research Council funds a number of projects looking at using nanotechnology to extract carbon dioxide from burning fossil fuels for storage. These are new technologies and it is unclear whether they will change the underlying risk.

Public perception

Public opinion on nanotechnology differs between regions, though some studies show that in general the public are either not aware of nanotechnology or if they are aware then it is viewed positively due to its potential applications. A recent paper summarised:

“While several studies on the public opinion of nanotechnology have pointed to a rather enthusiastic U.S. public, the public uptake of nanotechnology in Europe is more contained”.

The potential negative impact of public opinion cannot be underestimated as demonstrated with the genetically modified organism (GMO) industry. The EU, which took up a precautionary approach in part response to public opinion, contrasts with the US, where the public accepted the GMO technology. This disparity has resulted in very different regulation and use of GMO; the same could occur with nanotechnology. It is quite likely that in order for nanotechnology to thrive the public would have to be engaged throughout the development of nanotechnology to ensure it remains ethical and acceptable and retains its viability as a market. It is in the interest of insurers that any debates on the health effects or possible risks of nanotechnology are discussed in an open, transparent and public format.
CONCLUSIONS

Nanotechnologies have the potential to provide society with great benefits. Many products or services our industry currently insures will be adapted to contain such technology in future. An environment of such innovation is to be encouraged and has certainly led to many improvements in the past.

However, due to the relative infancy of this field there are many issues that have yet to be resolved. What are the impacts to human health? There may be short, medium and long term impacts and the latter can take many years to emerge and then be clarified. Could nanotechnologies harm the environment? How can any ill effects be repaired and what would this cost?

Insurers will wish to keep pace with this rapidly developing field. Liaison with the academics working in this area is one way to do this. The Lighthill Risk Network, an organisation co-funded by Lloyd’s, Benfield, Guy Carpenter and Catlin can help put insurers in touch with the relevant experts who have helped us with this report.

There is currently a vacuum of regulation in this field. In part this is because some stakeholders do not believe it is necessary. Others however think it is vital. This is because nano-materials behave differently to large scale versions of the same substance and so existing regulation may not be applicable. Lack of regulation is never helpful to liability insurers and the insurance industry should lobby for clarity.

As part of their management of exposure, insurers should, if applicable to their business, consider adverse scenarios such as the cost of product recalls including any D&O claims that might arise. If exposures are large the potential costs may feature in capital requirement calculations and when deciding on terms and conditions and pricing.

Society must decide the pace of innovation. Currently the compensation culture may be seen as stifling this. Understandably, insurers will be wary of these new technologies since they are operating at a scale that human biology has not had to deal with before. There is a danger that nano technology could lead to unforeseen and negative impacts but they could also lead to many positive impacts and these should be weighted up in deciding any regulation in future. However, as the insurance industry is often only exposed to the downside, it must protect its long term solvency for the benefit of society as a whole. Our exposure to nanotechnology must therefore be considered and examined very carefully.
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