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Nanotechnology and the Regulatory  
Environment: A Synopsis



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## **Nanotechnology and the Regulatory Environment: A Synopsis**

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### **Abstract**

Even an exact definition for “nanotechnology” is hard to pin down; assessments of its benefits and potential risks are more controversial still. The economic value of the nanotechnology sector is likely to grow exponentially over the next decade or so as the available techniques grow more sophisticated. The use of nanomaterials in electronics, food, medical and environmental applications will become increasingly common. However, a growing body of scientific research indicates that the enhanced and sometimes novel properties associated with nanomaterials may in some cases come with unforeseen health and environmental risks. Further, the impacts of the spread of nanotechnology on both developed and developing societies may be serious and potentially destabilising (e.g. through the effects of nanotechnology patents on intellectual property law regimes).

In this climate, the question of how to develop regulatory approaches that can deal effectively with novel technologies is being asked again with a new urgency. The value of public engagement in shaping an adequate response is being examined, as are the validity of different overarching ethical approaches to the assessment of new technologies. A balance between “soft” and “hard” regulation will need to be struck, and appropriate models of risk assessment and management developed.

This paper presents an overview of the literature relevant to understanding the regulatory environment in which nanotechnology will continue to develop, and includes a summary of reviews undertaken so far in the UK into the adequacy of existing legislation.

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The Centre started work in October 2001 under the leadership of Professor Ken Peattie of the Business School, Professor Terry Marsden of the Department of City and Regional Planning and Professor Bob Lee of the Law School. The Centre exists to understand and promote the vital issues of sustainability, accountability and social responsibility, through research into key business relationships.

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## Introduction

“Nano”, a derivative of the Greek “nanos”, meaning “dwarf” (*Einsiedel and Goldenberg 2006, p. 213*), is used by scientists to denote one billionth of an SI unit (*Kulinowski 2006, p. 14*). However, to define nanotechnology is much more difficult. Many contested definitions exist and there is even much debate over whether the term “nanotechnology” should be replaced by “nanoscience”, “nanoscale science and technology” or something else. UNESCO uses the term “nanotechnology” to denote both basic and applied scientific research, defining it as “research conducted at the nanoscale”, i.e. working with materials sized from 1 to 1000 nanometres (*UNESCO 2006, p. 4*).

A report jointly authored by the UK Royal Society and the Royal Academy of Engineering distinguishes between “nanoscience” and “nanotechnology”, describing the former as the “study and manipulation” of nanoscale particles, and the latter as the “design, characterisation and production” of “structures, devices and systems” at the nanoscale (*RS/RAEng 2004*). The federally-funded US National Nanotechnology Initiative or NNI likewise distinguishes between nanoscience and nanotechnology, defining them as follows:

*“Nanoscience involves research to discover new behaviors and properties of materials with dimensions at the nanoscale which ranges roughly from 1 to 100 nanometers(nm). Nanotechnology is the way discoveries made at the nanoscale are put to work. Nanotechnology is more than throwing together a batch of nanoscale materials—it requires the ability to manipulate and control those materials in a useful way” (NNI 2008).*

Nanotechnology therefore concerns the manipulation of nanoscale particles in order to produce novel material structures and compounds, including for example carbon nanotubes, quantum dots, and nanoscale metal oxides (*Allianz 2007, pp. 28-9*). These materials can possess novel and unexpected properties (such as tensile strength, conductivity and so on) which are not exhibited by “bulk” forms of the same elements, and can be incorporated into bulk products to enhance existing properties or to add new ones. Carbon nanotubes, for example, possess different characteristics to bulk forms of carbon such as graphite (*Uskokovic 2007, p. 46*), and can be used in items such as tennis rackets or ski poles to enhance their strength.

The manipulation of matter at this miniature scale can be done either by “top down” processes, i.e. by etching away material until nano-structures are revealed (*Royal Society and Royal Academy of Engineering 2004, p. 6*), or from the bottom up, i.e. by building materials and larger objects atom by atom or molecule by molecule. This latter possibility is the reason for many of the claims made for the revolutionary potential of nanotechnology, as instead of relying on traditional methods of manufacturing (which employ the manipulation of already-constituted bulk materials), products could potentially be designed and constructed from their basic most basic constituents on up – a kind of molecular engineering (*Drexler 1990, pp. 163-7*).

The inspiration behind nanotechnology lies in Richard Feynman’s 1959 lecture “There’s Plenty of Room at the Bottom” (*Feynman 1960*), where the Nobel Prize-winning theoretical physicist envisioned the development of nanomachines capable of building larger products and other nanomachines with atom-by-atom control:

*“The principles of physics, as far as I can see, do not speak against the possibility of manoeuvring things atom by atom [...] [I]t would be, in principle, possible [...] for a physicist to synthesize any chemical substance that the chemist writes down [...] How? Put the atoms down where the chemist says, and so you can make the substance. The problems of chemistry and biology can be greatly helped if our ability to see what we are doing, and to do things on an atomic level is ultimately developed – a development which I think cannot be avoided”* (*Feynman 1960, pp. 33-4*).

Since the 1980s, when the development of such techniques of manipulation became a possibility with the invention of the scanning tunnelling microscopy (STM) (*Baird and Shew 2004*), there has been much debate over whether the “Feynman vision” can be realised, and if so, how. K. Eric Drexler has been a highly public proponent of the view that nanotechnology could lead to the use of tiny machines known as nanoscale assemblers to manufacture anything simply through processing the constituent atoms of waste materials into desired materials and forms, a form of control which Drexler has written would be “thorough and inexpensive” (*Drexler 1990, pp. 240-2*).

The chemist Richard E. Smalley has argued that Drexler’s interpretation of Feynman’s views is mistaken, and that nano-assemblers are not a possibility, given the physical constraints on the manipulation of matter at the nanoscale (*Smalley*

2001). The uncertainty over the future directions nanotechnology development could eventually take, and how revolutionary future innovations could be, has led to a proliferation of visions of “nanotech futures” as part of the attempts by researchers and industry to attract funding and venture capital. An influential projected four-stage evolution of nanotechnology was provided by Mihail Roco of the NNI (*Roco 2004*). According to Roco, the first stage is the one we are in now, where nanomaterials are largely “passive” and are incorporated into existing objects. The second phase, where nanomaterials become “active” is in its early stages: here, nanotechnology will be used in applications such as the improvement of drug delivery and in electronics. The third, which Roco predicts may begin in another couple of years, will see the development of “nanosystems” in applications such as robotics, leading to the fourth generation in around ten years, in which atomic design and the construction of molecular devices might become a reality. The NNI’s interpretation of the future narrative of nanotech therefore takes its inspiration from the Feynman-Drexler vision of molecular engineering, but adds qualifications.

The NNI’s narrative is one of many future visions. Others have focused on the risks which may accompany the realisation of a Drexlerian vision, even depicting apocalyptic scenarios which may result, such as the transformation of the biosphere by swarms of out-of-control, self-replicating nanobots into “grey goo” (*Joy 2000; ETC Group 2003*), and inspiring popular fiction into the bargain (*Landon 2004*). Some writers have drawn attention to the potential role of nanotechnology in a future revolutionary technological convergence, alongside information technologies and biotechnology (*Anton, Silberglitt et al. 2001; Khushf 2007*), noting that this may mean that the level of control promised by nanotechnology could lead to a redefinition of what it means to be human (*de S. Cameron 2006*). Other influential nanotechnology researchers have challenged the mechanistic visions of control which they see as underlying Drexler’s and Roco’s interpretation of Feynman, arguing instead that “biomimetic” and evolutionary nanotechnology, which aims to produce new structures by triggering nature-mimicking processes of self-assembly, is a more fruitful direction, given the necessary physical limitations on our control over atomic structures (*Jones 2004*). Some commentators have consequently pointed to the existence of “two cultures” within technology, each with its own future narrative and research programme (*Bensaude-Vincent 2004; Kearnes 2006*). Others have noted that

the popularity of future visions among researchers and nanotech enthusiasts risks effacing the boundary between actual developments and science-fiction (*Rip 2006, p. 274*). Warnings from researchers themselves about the “hype” surrounding current and potential nanotechnology applications have also appeared (*Kostarelos, Bianco et al. 2008*). The uncertainty which is produced by conflicting visions of the future has raised fears that policy makers might be prompted by the possibility of a public backlash against the technology to take radical proactive legislative measures which could stifle nanotechnological development (*Rip 2006, p. 274; Monica, Heintz et al. 2007*). The UK Government has recently affirmed, however, that it does not consider moves such as a moratorium on nanotechnology development to be an appropriate response (*UK Government 2008, p. 18*).

### **Current and Near-Term Potential Applications of Nanotechnology**

The commercialisation of nanotechnology currently covers products that come under Roco’s definition of “passive” nanotech. The Woodrow Wilson Institute has listed over 500 products which it assesses as employing nanotechnological innovations (*Woodrow Wilson Institute 2008*). These are still mostly in the established fields of nanotechnological products identified by Theodore and Kunz in 2005, such as coatings for cars and clothing, medicines, cosmetics, agrochemicals, and electronics (*Theodore and Kunz 2005*). The expected marketing value of nanotechnology is evinced by the trend of “relabelling” products which already contain nanoscale particles as “nanotechnology”, even where no specific nanoscientific research has contributed to their production (*Brumfiel 2006*).

UNESCO’s list of recent commercial nanotechnology products comprises, amongst others: Cerax nanowax for skis, Franz Ziener waterproof ski jacket (Nanotex), wrinkle and stain resistant nano-care clothing, L’Oreal deep penetrating skin cream, Kodak’s OLED (organic light-emitting diodes) camera, performance sunglasses, nanofilm antireflective coating, ZCOTE sunscreen, Babolat nanotube tennis racket, InMat’s nanotech tennis balls, Shockjock Aerogel footwarmers (United Nations Educational Scientific and Cultural Organisation (*UNESCO 2006, pp. 1-2*)). Allianz AG identifies the key growth areas of current and near-future nanotechnological innovation as medicine, food and agriculture, semiconductors and computing, textiles and energy (*Allianz 2007, pp. 13-22*). In the near-term future, many

researchers and industry representatives see carbon nanotubes and quantum dots as being the most important nanomaterials in production, with the number of uses for them increasing (*Besley, Kramer et al. 2008*).

Nanotechnology is now a multi-billion dollar industry, and the value of sales of products incorporating nanomaterials is expected to spiral to US\$1 trillion by 2015 (*Lux Research 2004; Allianz 2007, pp. 14-15*). At present, the majority of nanomaterials manufacturing occurs in the United States (49%), with the European Union responsible for 30% and the rest of the world accounting for the remaining 21%. Within the European Union, the UK accounts for nearly one-third of the market (*Aitken, Chaudhry et al. 2006, p. 302*).

In the UK, approximately 50 companies are manufacturing, processing, researching and/or using nanomaterials. Furthermore, there are currently 55 non-commercial entities involved in nanotechnology-related research and development activities (*Aitken, Chaudhry et al. 2006, pp. 302-304*).

### Medical Nanotechnology

One of the widely promoted potential applications of second-phase “active” nanotechnology is the precision delivery of pharmaceutical products and consequent elimination of side-effects (*Langer 2003; Nel, Xia et al. 2006, p. 622; Besley, Kramer et al. 2008, p. 553*). According to Lorraine Sheremata, special nanoscale materials like “liposomes, polymers, silica and hydroxypatite are being used to encapsulate drugs and protect them from biological processes in the body”, thus facilitating their uptake by the body where they are needed (*Sheremata 2006, pp. 249-50*).

The potential of such methods of enabling drug delivery for crossing the blood-brain barrier into the central nervous system has raised the prospect of improved drug delivery to the retina of the eye, as well as improved diagnosis and treatments for conditions such as Parkinson’s disease, Huntingdon’s disease, brain tumours etc. (*RS/RAEng 2004, p. 23; Muldoon, Tratnyek et al. 2006; Sheremata 2006, pp. 249-50; Wickline, Neibauer et al. 2006*). Other near-term potential nanotechnology applications in the medical field include improved surgical robotic tools (*Leary, Liu et*

al. 2006, p. 822), medical imaging (Winter, Chen et al. 2001) and genetic testing (Pilarski, Mehta et al. 2004).

### Environmental Nanotechnology

Two major potential uses of nanotechnology in environmental applications are, on the one hand, improved methods of water purification for human consumption, agriculture and industrial use (Bellobono, Morazzoni et al. 2005; Savage and Diallo 2006) and, on the other, pollution abatement and environmental remediation using e.g. iron nanoparticles (Zhang 2003).

Other potential environmental applications may include sensing of pollutants, pH and chemical warfare agents, ultraviolet light-activated catalysts for treatment of environmental contaminants, oil-water separation, and the destruction of bacteria (including anthrax) (Theodore and Kunz 2005, pp. 3-4).

### Food Processing and Packaging

Nanomaterials are now present in at least 104 food-related products worldwide (mainly in packaging), although the real total may be much higher (Friends of the Earth 2008, p. 11). Their potential uses in food processing may include aiding enzymes used in improving flavour or nutritional value to disperse more quickly through food matrices (Bai, Li et al. 2006).

The use of nanomaterials in packaging is intended to improve characteristics such as strength, barrier properties, antimicrobial properties, and stability to heat and cold. Packaging incorporating nanomaterials could improve the shelf-life of products (Lagaron, Cabdeo et al. 2005). Other potential uses in the food industry include cleansing and disinfection, and improved biosensors to detect the presence of gases (indicating decay) in packaged food. With respect to cleansing and disinfection, it has been shown for example that deposition of silver on nanoparticles of titanium dioxide significantly increases its bacteriocidal effects against *E. coli* (Kim, Han et al. 2006), while titanium dioxide combined with carbon nanotubes can significantly enhance disinfectant properties against *Bacillus cereus* spores (Krishna, Pumprueg et al. 2005).

## Nanoelectronics

The use of nanotechnology in the field of electronics is already established. From the experimental construction of smaller computer chips using self-assembly methods (*Chang 2003*) to the now widespread use of nanoscale materials engineering in computer hard drives and other electronic devices (*Woodrow Wilson Institute 2008*), a number of applications have been developed. In the near term future, it is predicted that microprocessors and memory chips built using new nanoscale processes will continue to be a dominant use of nanotechnology (*Allianz 2007, pp. 3-4*).

The reduction of component scale promised by nanotechnology may lead to more radical innovations in the next ten or so years, such as quantum-switch-based computing (*Anton, Silberglitt et al. 2001, p. 25; Allianz 2007, p. 9*), *molecular electronics* (*Godman 2008, p. 5*) and neuro-electronic interfaces (*Jotterand 2006, p. 663*), although they will have to overcome crucial engineering obstacles. These advances might have the potential to change the way we engineer our environment, construct and control systems, and interact in society. Some future projects which they could facilitate could include so-called “smart clothes” or “wearable electronics”. These could include sensors to monitor body functions or release pharmaceuticals, self-repairing mechanisms or interfaces to access the Internet (*Allianz 2007, pp. 12-13*).

### **Potential Risks of Nanotechnology: From Toxicology to Social Instability**

To be set against the visions of the potential benefits which may flow from nanotechnology development are anticipations of the risks which may have to be weighed alongside them (*Wolfson 2003*). It has been suggested that the relative emphasis given to benefits or risks in a given narrative about the prospect of nanotechnology differs across cultures (for example, between the USA and European countries) (*Gaskell, Ten Eyck et al. 2005*), drawing on cultural theories of risk which suggest that societal assumptions about nature, technology and the limits of scientific certainty affect how technological innovation is evaluated (*Douglas and Wildavsky 1982*).

The extremely high degree of uncertainty over what forms nanotechnology will eventually take on (especially given the physical constraints which may affect nanoscale engineering) means that debate over its possible harms and benefits, and

possible subsequent regulatory action, risks being rendered nugatory in the future (Keiper 2007). Nonetheless, it is arguable that a greater understanding of the potential risks and benefits across a number of “risk sectors”, ranging from the exposure of workers to nanotubes during their manufacture, through accidental environmental release of nanomaterials, to the effects on the economies of developing countries of a widespread adoption of nanoscale manufacturing, can help to focus research here and now. Once focus of comment is proving to be the way in which debates over nanotechnology might transform the way society sees the “contract” between science and civil society (Lee and Jose 2008, pp. 113-15), and how they demonstrate that the research community, industry and government should recognise that technological innovation is shaped by its “social constitution”, the wider needs, assumptions and beliefs about the uses of technology that are prevalent within society (Arnall and Parr 2004, p. 45). As a result, some have called for the ethical, legal and social impacts (ELSI) of nanotechnology to be given much more prominence in debates over risk (ETC Group 2005; ICTA 2008).

### Health and Safety Risks

Although products incorporating “passive” nanomaterials have now been widely commercialised, knowledge about the possibilities of harm resulting from exposure to “free” manufactured nanoparticles, and about the various pathways through which nanoparticles might be transported through the body is still scanty, although absorption through the skin, ingestion, and inhalation are all possible mechanisms of exposure (Hoet, Bruske-Hohfeld et al. 2004, ; Service 2004), although a recent study on dermal absorption claims that it has demonstrated there is no health risk from e.g. use of sunscreens containing nano-TiO<sub>2</sub> (Nohynek, Dufour et al. 2008). The essential problem derives from the same source as the great revolutionary potential of nanotechnology, namely the novel properties substances exhibit at the nanoscale (Nel, Xia et al. 2006, pp. 622-3). There is no way to obtain predictions as to the properties of nanomaterials in general until they are made and employed in specific contexts (Uskokovic 2007, p. 46).

The potential for a lack of firm knowledge about causal factors contributing to health risks to harm investment in nanotechnology has been noted (Davies 2005, p. 22; Gewin 2006). In the absence of such knowledge, and regulations which based upon it,

health scares such as that in Germany surrounding the respiratory symptoms experienced by users of the spray-on ceramic sealant “Magic Nano” (which in fact did not contain nanomaterials) may become more common (*Piller 2006; Wolinsky 2006*).

In the absence of comprehensive data, a risk assessment framework has been proposed to guide the interpretation of research against a background of uncertainty (*Morgan 2006*). Data drawn from studies on animals such as fish has shown that uptake of nanomaterials may be associated with phenomena such as oxidative stress within cells (*Oberdörster, Oberdörster et al. 2005*), with apoptosis or cell death being another risk associated with uptake (*Service 2004; UK Government 2006, pp. 81-2*). A number of long term in vitro and in vivo studies are now underway to test transport mechanisms within the body and to establish likely exposure scenarios (*Thomas and Sayre 2005; IRGC 2006, pp. 22-3*). The main immediate concern is for the exposure of researchers and workers to materials such as carbon nanotubes (*Donaldson, Aitken et al. 2006*), some varieties of which have been recently identified in a pilot study as possibly contributing to mesothelioma in the lungs of mice (*Donaldson, Poland et al. 2008*). So far, major studies of risk factors in workplaces where nanotubes are manufactured (*Robichaud, Tanzil et al. 2005*) have not dealt with specific risks which may arise from the properties of the nanomaterials themselves.

Looking further ahead, the climate of uncertainty and ignorance is one in which many of the potential uses of nanotechnology in fields such as health and medicine will face for a while many unresolved questions about their possible health risks (*Chan 2006*). Calls for more research into nanopathologies, i.e. specific health conditions caused by exposure to free nanomaterials, have been made (*Gatti and Montanari 2008*).

#### Ecological and Environmental Risks

The effects of free nanomaterials on key species such as fish and water fleas is beginning to be documented, as well as on soil micro-organisms (*Oberdorster 2004; Cheng and Cheng 2005; Lovern and Klaper 2006*). Nonetheless, the number of research studies overall on ecotoxicology is still low (*Krug 2005*). Some questions have been raised about the relative priority accorded to ecotoxicology in the investigation of nanotechnology risks. Service (2004, p. 1734) notes that the US National Nanotechnology Initiative claimed in 2004 that 11% of research funding was

spent on environmental studies, but that in fact the majority of this money went on research into potential environmental applications of nanomaterials, not on toxicological studies of existing materials.

The suggestion of potentially very serious harmful effects on key species has prompted calls for precautionary regulatory action. In the UK context, the Government has been advised that use of nanomaterials in environmental remediation should not be pursued in the absence of more evidence of safety, and the presence of nanoparticles in waste streams should be reduced or removed (*RS/RAEng 2004*). The Government subsequently affirmed these recommendations in its response to the 2004 report (*UK Government 2005b, p. 11*), and has detailed how its Nanotechnology Research Co-ordination Group (NRCG) is responding to the need for more research by encouraging work in ecotoxicology (*UK Government 2007, pp. 31-5*). Although the precautionary approach to the environmental release of nanoparticles is absent from the US context (*Kuzma 2005, p. 8*), the Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) have both recently published position papers calling for more research on ecotoxicology (*Kling 2007*).

#### Potential Economic, Legal and Social Impacts

As noted previously, some commentators have called for the social effects of nanotechnology to be given much more prominence in research, noting that studies tend to follow “downstream” once industry has found applications for nanomaterials, rather than forming part of the “upstream” process of development, by informing discussions of social priorities and needs (*Kearnes, Grove-White et al. 2006, p. 294*). A crucial issue in this respect is that of the prospective “nanodivide” (*RS/RAEng 2004, p. 52; Sheremata and Daar 2004, p. 76; Hunt 2006a; Godman 2008, p. 4*) that may arise as a result of the economic advantages conferred on developed countries by early and extensive investment in nanotechnology.

Evidence from published studies suggests that the global North’s priorities in nanomaterials development may be at odds with those identified with experts in the South (*Salamanca-Buentello, Persad et al. 2005*). Some have argued that the possibility of these priorities not being met is made more likely by the evolution of intellectual property rights in relation to nanomaterials. Many of the “building blocks”

of nanotechnological research have already been the subject of extensive patenting (*Lemley 2005, pp. 603-04*), meaning that research in the South may be threatened by what would amount effectively to an extra tax imposed by the North on the South's capacity for nanotechnological development (*Correa 2005*). There is a strong possibility that the rush to patent inventions related to nanotechnology could lead to a patent "arms race", resulting in broad patent claims, extensive litigation and a gradual stultification of nanotechnology development (*Jaffe and Lerner 2004; Vaidhyathan 2006, pp. 232-3*).

The consequences of nanotechnology for civil liability law (*Hannah and Hunt 2006*) and the insurance market (*Wilson 2006*) have also been the object of some comment, given the huge uncertainties over the health and environmental risks of nanomaterials. The Royal Society and Royal Academy of Engineering recommended a strict product liability regime for personal injury from nanotechnological products (*RS/RAEng 2004*). The reinsurer Swiss Re has compared nanotechnologies to asbestos, and points out that the future probabilities and costs of nanotechnology-related risks are impossible to assess and will remain so for some time (*Swiss Re 2004, pp. 42-4*). For its part, Allianz AG has reported that specific issues stemming from nanotechnologies that may affect the scope of product liability and insurance are the likelihood of unforeseeable long-term health and environmental impacts, together with the likely difficulties of establishing causal relationships between nanomaterials and actual effects (*Allianz 2007, pp. 42-3*).

### **"Upstream" Public Participation and the Reception of Nanotechnology**

Recent research suggests that public trust in governmental approaches to regulation will be a key factor in determining whether the risks and uncertainties around nanotechnology will be judged socially acceptable (*Siegrist, Keller et al. 2007*). Following the publication of the RS/RAEng report in 2004, the UK Government affirmed that it was "committed to promoting constructive dialogue on nanotechnologies" (*UK Government 2005b, p. 20*). Nanotechnology has been seen as an ideal opportunity to develop new approaches to engaging the public in science "upstream" of the commercialisation of research (*Wilsdon and Willis 2004*), one motivation being to pre-empt the kind of public scepticism that accompanied the development in the 1990s of genetically modified food (*Barnett, Carr et al. 2006*).

Moving towards such a model of engagement has been prompted by the House of Lords Select Committee on Science and Technology's report *Science in Society* (2000), whose conclusions about public engagement appear to have been accepted by the Government, as evidenced by its latest ten-year innovation strategy document (*HM Treasury 2004*).

A crucial development in this shift has been the explicit determination on the part of government to avoid recourse to the "deficit model" of public understanding of science, in which the role of engagement is seen as communicating "the facts" about the objective risks and benefits of scientific developments to an essentially under-educated and often fearful public. Replacing this model is one which views public engagement as being a process from which science itself can learn. Alongside a major ESRC-funded study of the potential role of upstream public engagement in relation to nanotechnology (*Kearnes, Macnaghten et al. 2006*), the Government's initial response took the form of an outline strategy (*UK Government 2005a*), comprising several public engagement exercises such as SmallTalk, Nanodialogues and NanoJury UK. Government funding was provided for some of these initiatives, along with support for the Nanotechnology Engagement Group (NEG), which undertook to survey the results of the various exercises over the two years in which they would take place.

The NEG's final report set out several outcomes from the engagement exercises. It found that there was public support for nanotechnology, but only so long as it would address clear social priorities, so long as the difference between known risks and scientific uncertainties was acknowledged, and so long as transparency about public funding and responsibility for development was pursued (*Gavelin, Wilson et al. 2007, pp. 92-7*). Other commentators found that engaging the public on technology opened up wider possibilities for the discussion of social priorities, ranging much further than simply issues of risk (*Pidgeon and Rodgers-Hayden 2007*). Nonetheless, these exercises are currently operating against a widespread lack of contact with nanotechnology amongst the public (*Barnett, Carr et al. 2006, pp. 198-99*), which suggests that nanotechnologies are still not a "public issue" in the same sense as GMOs, although this may soon change (*Swiss Re 2004, 44-5*).

Engagement activities are ongoing elsewhere, represented by e.g. the Meridian Institute's work in the USA (Meridian Institute 2008) and the EU-wide Nanologue project (*EU Nanologue Project 2008*).

### **Nanotechnology Regulation**

The difficulties of regulating an emerging technology are well-attested, as success requires striking a balance between precaution and venture, between hasty over-regulation that stifles development (*Monica, Heintz et al. 2007*) and inadequate regulation that leaves risks underdefined, thus scaring away investment (*Gewin 2006*). Further, successful regulation has to be sensitive to the specific nature of a new technology and how it might evolve, rather than "fighting the last war" (*Kearnes, Grove-White et al. 2006, p. 302*) by structuring regulation based on previous experiences with new technologies.

The EU regulatory framework for health and environmental risks mandates a case-by-case precautionary approach, as established in the EU by Directive 90/269/EEC in 1990 (*EU Council 1990*), which was implemented in the UK by the Environmental Protection Act 1992. A general precautionary stance was recommended by the RS/RAEng report (*Royal Society and Royal Academy of Engineering 2004, p. 52*) and affirmed by the Government in its official response (*UK Government 2005b*). But this case-by-case approach would be different from the general precautionary moratorium on nanotechnology products called for by groups such as ETC (*ETC Group 2003*), which has been explicitly ruled out as a possibility by the UK Government (*UK Government 2008, p. 18*).

The role of precaution in regulating nanotechnology, as with GMOs, has to do with the novelty of the technology and the associated lack of relevant past experience of its effects. The question that therefore arises is whether current regulations are sufficient to deal with the uncertainties surrounding nanotechnological products, or whether a specific regulatory regime is required. To date, there is nowhere in the world a nanotechnology-specific system of regulation (*Bowman and Hodge 2006*). Existing legislation in the short-term looks like the only route to regulation, although there are numerous gaps within the existing frameworks which need to be examined. For example, in the USA, the Toxic Substances Control Act would classify carbon

nanotubes as substantially equivalent to graphite (*Service 2004, p. 1734*), the Clean Air and Clean Water Acts would fail to regulate NSPs that could not be detected in real-world situations thanks to their small size (*Davies 2005, p. 14*), and it has been argued that coverage of cosmetics under the Food, Drug and Cosmetics Act is inadequate (*Wilson 2006, p. 708*).

In the UK and EU, the Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH) regulations, which came into effect in June 2007, represent a major new initiative which may have consequences for the regulation of nanotechnologies. However, the fact that REACH assessment is only triggered when a substance is produced in quantities of more than 1 tonne per year may mean that many nanomaterials do not come under the regulations (*Wolinsky 2006, p. 860; Allianz 2007; Kling 2007*). The UK Government has, since 2005, worked using existing regulatory instruments to produce an integrated and interactive approach (*Dorbeck-Jung 2007, p. 267*). This has included a voluntary reporting scheme for companies producing nanomaterials, which has served as a model for the EPA's Stewardship Programme for Nanoscale Materials in the USA and a similar proposed German scheme (*Kling 2007*), although it has to date produced only a limited response due probably to considerations of commercial confidentiality (*Dorbeck-Jung 2007, pp. 264, 268-9*).

### **The Ethics of Nanotechnology**

In reviewing the regulatory state-of-the art, ethical considerations arguably play a key role in pointing up "moral gaps" in current statutes (*Dorbeck-Jung 2007, p. 267*). One question which has already occasioned significant debate is whether there is a "gap" in ethics itself that should be filled by a "nanoethics" dealing with ethical issues raised by the nature of the technology itself. It has been argued that, given the uncertainties surrounding the technology, such a discipline would risk reflecting on issues that may not ever be of any relevance (*Keiper 2007*), and further, that many of the ethical and political issues on which nanotechnology prompts us to reflect are not specific to the technology as such (*Godman 2008*). However, it has been suggested that scientific interventions at the nanoscale may confront us with fundamental questions about the limits of technical control, as well as questions about how far we should intervene within complex natural systems (*Hunt 2006b*).

These issues are often similar to ones which have already been much discussed in relation to biotechnology and genetic engineering, including problems of social justice and global equity. The debates over the “nanodivide” (*Hunt 2006a*) and how public participation should influence the uses of nanotechnology are one example, with another being the problem of how the rapid commercialization of nanotechnologies tends to expose consumers to unknown risks without their having consented to being exposed (*Shrader-Frechette 2007*). The concept of convergence has prompted a number of reflections on the extent to which nanotechnologies could contribute to changing the human condition and our conception of nature (*de S. Cameron 2006; Khushf 2007*) and how they shed light on age-old conundrums about the limits of control and how new technologies give rise to radical uncertainties (*Dupuy 2007*).

### **Nanotechnology, Risk and Precaution**

Closely connected to ethical concerns over nanotech development are debates over the best approach to risk assessment and management for nanotechnologies, particularly given the possibilities of hazards which will take a long time to emerge and may result from interference in complex natural systems (*Hansson 2005*). Given the uncertainties surrounding the possible effects of human and environmental exposure, the EU’s consensus case-by-case precautionary approach (*Commission, 2006*) has been accepted by the UK Government as the most sensible way forward (*UK Government 2005a; UK Government, 2008*). The possibility of a blanket application of the precautionary principle to nanoscale developments has been criticised on the grounds that “nanotechnology” is a generic term which covers an agglomeration of “enabling” technologies rather than a definable set of end products (*Rip 2006, p. 270*).

At the level of government in the EU, there has been explicit acknowledgement that the uncertainties surrounding nanotechnologies are not just a matter of definable risks, but are produced by scientific uncertainty and ignorance too (*UK Government 2008; HSE 2006; UK Government 2005a*). In such a context, a careful use of the precautionary principle appears to be appropriate (*HSE 2006*), and this conclusion is supported by a number of reviews of current regulatory practice. The ways in which such precautionary measures could be implemented now form the focus of much

debate over the respective roles of “soft” versus “hard” regulatory measures (Dorbeck-Jung 2007). Given that it would take a number of years to establish an independent regulatory regime for nanotechnology, it is important to use and extend existing regulatory powers wherever possible, the so-called “incremental approach” which faces specific challenges, particularly given the lack of adequate lifecycle analysis of nanotechnology products (Franco et al. 2007, pp. 280-2). One way in which these could be extended is through more use of voluntary agreements between government and business and the development of good practice regarding “corrigible” procedures and anticipatory risk management in industry and research (Lee and Jose 2008).

Ultimately, issues of risk management point towards the use of transnational institutions as the basis of regulation, which would have to be supported by resources such as an extensive and freely-accessible database containing information on materials and effects (Chan 2006, p. 223). An integrated international risk management framework has been proposed (Tyshenko and Krewski 2008), along with international ethical standards (COMEST 2007). Although the usefulness of many existing institutions may prove to be limited, given their past history (Marchant and Sylvester 2006), framework agreements together with international standards setting as provided by the British Standards Institute (BSI), International Standards Organisation (ISO) and European Committee for Standardization (CEN) will probably prove extremely important in resolving issues of definition and taxonomy, as well as providing arenas for setting future agendas.

**Table 1: Reviews by UK Government bodies of regulations pertaining to nanotechnology**

Report	Key findings in respect of regulation
RS/RAEng (2004) <i>Nanoscience and Nanotechnologies: Opportunities and Uncertainties</i> .	<ul style="list-style-type: none"> <li>▪ Concludes that lack of evidence relating to risks posed by manufactured nanoparticles has resulted in considerable uncertainty.</li> <li>▪ Recommends that relevant regulatory bodies consider whether existing regulations adequately protect human health and the environment from potential risks posed, and address any regulatory gaps arising.</li> </ul>
HM Government (2005) <i>Response to the RS/ RAEng Report</i> .	<ul style="list-style-type: none"> <li>▪ Because of their novel properties, free engineered nanoparticles should be treated as new chemicals under UK and EU legislation in order to trigger safety tests and clear labelling requirements.</li> <li>▪ Safety assessment on the basis of the bulk form of a</li> </ul>

	<p>chemical cannot be used to infer safety of its nanoparticulate counterpart. Regulations must be reviewed to take into account the fact that nanoparticles might have greater toxicity than the bulk form of a chemical.</p> <ul style="list-style-type: none"> <li>▪ The adequacy of current regulatory frameworks will be reviewed to ensure that safeguards to public health are sufficiently robust.</li> <li>▪ Free, engineered nanoparticles used as ingredients in consumer products should undergo thorough safety assessment by the relevant scientific advisory body before being placed on the market.</li> <li>▪ In order to ensure that products of nanotechnologies are properly regulated, sector specific regulations may be required in addition to REACH. This issue is to be addressed through regulatory review.</li> </ul>
<p>Defra (2006), <i>A Scoping Study to Identify Gaps in Environmental Regulation for the Products and Applications of Nanotechnologies</i>.</p>	<ul style="list-style-type: none"> <li>▪ Regulatory gaps identified arise from either exemptions provided for by legislative frameworks or from lack of information relation to: <ul style="list-style-type: none"> <li>○ The scope of definitions;</li> <li>○ Current understanding of risks associated with exposure to nanomaterials;</li> <li>○ Agreed dose units that can be used in assessment of hazard and exposure;</li> <li>○ Methods for risk characterisation and measurement; and</li> <li>○ Potential impacts of nanomaterials on human health and the environment.</li> </ul> </li> </ul>
<p>HSE (2006), <i>Review of the Adequacy of Current Regulatory Regimes to Secure Effective Regulation of Nanoparticles Created by Nanotechnology</i>.</p>	<ul style="list-style-type: none"> <li>▪ The principles of existing regulations are appropriate and applicable to nanomaterials.</li> <li>▪ There is no need to fundamentally change existing regulations, or to introduce new provisions.</li> <li>▪ There are many gaps in knowledge about nanomaterials. These gaps will make it difficult for those involved in the regulatory process to fully discharge their responsibilities within the relevant regulations.</li> <li>▪ By virtue of this lack of information, regulation in some sector areas will require the exercise of judgement. This might lead to different interpretations of the appropriate position within certain regulations.</li> <li>▪ Regulatory issues must be considered on an EU-wide basis.</li> <li>▪ Much of the EU legislation identified in the Report is subject to change under the envisaged REACH system.</li> </ul>
<p>FSA (2006), <i>Draft Report of FSA Regulatory Review</i>.</p>	<ul style="list-style-type: none"> <li>▪ Current information suggests that most potential uses of nanotechnology in relation to food will be subject to an approval process prior to being permitted for use.</li> <li>▪ There are no major regulatory gaps in principle.</li> <li>▪ There is uncertainty as to whether some applications of nanotechnology would be captured by certain existing regulations.</li> <li>▪ The view of independent committees COT, COC, and COM is that existing procedures of risk assessment can apply to nanomaterials.</li> <li>▪ There are no major gaps in information for the identification of hazards associated with</li> </ul>

	<p>nanotechnologies.</p> <ul style="list-style-type: none"> <li>▪ Risk assessment procedures should include mechanisms to facilitate provision of information relating to nanomaterials.</li> <li>▪ Onus should be placed on manufacturers of Nanomaterials.</li> </ul>
<p>DTI/BRASS (2006), <i>An Overview of the Framework of Current Regulation affecting the Development and Marketing of Nanomaterials.</i></p>	<ul style="list-style-type: none"> <li>▪ Potential regulatory gaps arise as a direct result of incomplete information about the implications of human and environmental exposure to nanoparticles, rather than any major regulatory oversight.</li> <li>▪ Where regulation operates by listing substances to be controlled, problems may arise where substances produced through nanotechnology are not covered by such lists.</li> <li>▪ Free, engineered nanomaterials should be classed as ‘hazardous’ substances unless or until there is sufficient evidence of their safety.</li> <li>▪ An examination of the specific properties of free, engineered nanomaterials and an assessment of their associated risks be conducted prior to being placed on the market irrespective of whether those materials are deemed to be ‘new’ or ‘existing’ substances .</li> </ul>
<p>Department for Innovation Universities and Skills (2008), <i>Statement by the UK Government about nanotechnologies.</i></p>	<ul style="list-style-type: none"> <li>▪ There is the potential for engineered nanoscale materials to fall outside regulatory control in certain circumstances, e.g. <ul style="list-style-type: none"> <li>○ there may be a situation where only specified products are covered by the legislation;</li> <li>○ legislation may specify maximum safe concentrations or marketing thresholds which are appropriate to the macroscale material but may not be appropriate for the nanoscale material;</li> <li>○ the possibility that products may evade downstream control.</li> </ul> </li> <li>▪ Nanotechnologies are judged in this regard to be no different from other new products and technologies.</li> <li>▪ All the above are therefore <i>potential</i> regulatory gaps.</li> <li>▪ To decide whether they are <i>real</i> gaps requires better understanding of potential health and environmental risks an adequacy of current risk assessment models.</li> </ul>

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