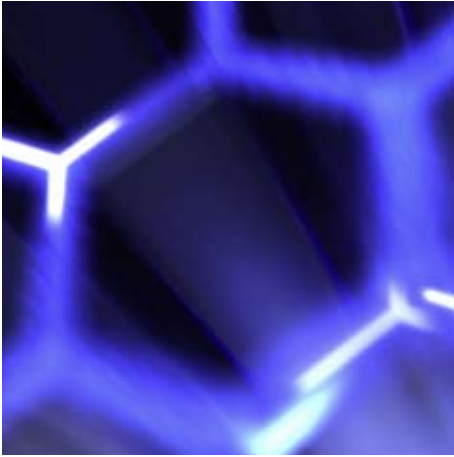




FRESHFIELDS BRUCKHAUS DERINGER

Regulating nanotechnologies



Nanotechnologies may involve the manipulation of materials on a tiny scale, but industry and governments agree that they have the potential to deliver massive economic and social benefits.

The number of potential applications for nanotechnologies has expanded rapidly in recent years:

- they are already in use across a wide range of sectors, including consumer products, healthcare, construction, aerospace, energy, defence and transport;
- there are currently over 1,000 consumer products or product lines on the market globally that are identified by their manufacturers as incorporating nanotechnologies; and
- the value of the global market in nano-enabled products could grow to around \$81bn by 2015.

The challenge now for businesses and regulators alike is to exploit the opportunities presented by these technologies in a way that is both safe and sustainable. This briefing looks at existing regulation and government strategies in the European Union (EU), which aim to shape a nano-enabled future.

‘Technologies of the tiny’: nanotechnologies – a quick guide

The nanoscale is the scale of the very, very small: one nanometre (nm) is one billionth of a metre. By way of comparison, a single human hair is about 80,000nm wide, a red blood cell is approximately 7,000nm wide and a water molecule is about 0.3nm wide.

Nanomaterials are materials with at least one dimension in the nanoscale (ie between one and 100nm). They come in various forms, including particles (eg nano-titanium dioxide), fibres (eg carbon nanotubes) and sheets (eg graphene). When particles of a material are manipulated at the nanoscale, the properties of that material can be affected, making it lighter, harder, more durable or more chemically reactive.

Nanoscience has been defined by the Royal Society as: ‘the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale.’

Nanotechnologies is the broad term used to describe a diverse range of traditional scientific disciplines and activities whose common feature is the tiny dimensions in which they operate.

European regulation of nanotechnologies

The breadth and diversity of nanotechnologies mean that they do not fall neatly into any single regulatory framework.

In 2006, the Centre for Business Relationships Accountability and Sustainability at Cardiff University (BRASS) completed a report for the UK Department of Trade and Industry that mapped then current and potential applications for nanotechnologies against regulations governing controls on marketing, health and safety, consumer and environmental protection, and waste regulation.

BRASS noted that existing regulation was not designed with nanotechnologies in mind, and that the area was governed by multiple, overlapping sets of rules. This meant that there were gaps. For example, core requirements of REACH – Europe’s flagship legislation on the safety of chemicals – may be difficult to apply to nanotechnologies. The requirement on manufacturers and importers of chemicals to assess the risks associated with a substance under conditions of use, and to register data with the European Chemicals Agency, applies only if certain minimum tonnage

thresholds are breached. Because nanoparticles, almost by definition, weigh very little, even large-scale production or importation may not trigger these duties.

Unless a comprehensive regulatory framework is developed – which seems unlikely in the short to medium term – businesses whose products incorporate nanotechnologies will need to assess their compliance with a broad spectrum of regulatory requirements and closely monitor new regulatory developments.

How does sector-specific European legislation apply to nanotechnologies?

Cosmetics

References to nanotechnologies in the context of cosmetic products are usually to the use of insoluble nanoparticles as UV filters in sunscreens. However, other applications may become widespread in future.

Under the EU Cosmetics Directive (76/768/EEC), the manufacturer or importer of a cosmetic product must assess and document its safety before it can be placed on the EU market. This will require an evaluation of the general toxicological profile of the product's ingredients, their chemical structure and the extent to which users of the product will be exposed to them. Certain groups of substances, including UV filters, also need a permit from the European Commission before they can be used in cosmetic products sold in Europe. This will only be granted if the EU's Scientific Committee for Consumer Products (SCCP) gives clearance, based on a review of relevant toxicological data.

The Commission has mandated its independent risk-assessment committees (SCCP and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)) to assess whether existing safety evaluation methodologies are suitable to deal with nanotechnologies and, if so, how.

Currently, titanium dioxide is the only UV filter that is permitted by the Commission to be used at the nanoscale in cosmetic products. Nano-zinc oxide was assessed in 2003, but the SCCP concluded that its safety as a UV filter had not been adequately demonstrated.

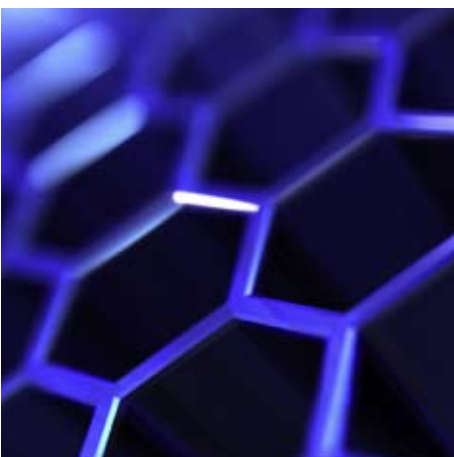
Healthcare

'Nanomedicine' has the potential to lead to significant breakthroughs in the diagnosis, treatment and monitoring of a variety of diseases including cancers, diabetes, Alzheimer's and Parkinson's.

As yet, there are no regulations dealing specifically with medicines or medical devices that incorporate nanotechnologies. According to the UK Medicines and Healthcare Products Regulatory Agency (MHRA), the suitability of existing regulation to cover nanotechnologies in this sector is under continual assessment as the area evolves.

Although reviews of the toxicology of nanoparticles in medicines were carried out in 2006 by the Commission on Human Medicines and the European Medicines Agency, neither identified an immediate need for nano-specific regulation in this field. The MHRA has predicted that nano-regulation will be developed in the future, once there is enough data to allow for the creation of systematic guidance.

As far as medical devices are concerned, the MHRA is of the view that existing regulation is broad enough to cover the risks associated with nanotechnologies.



Food and beverages

The use of nanomaterials in food packaging is already a reality: nanocomposites in drink bottles can minimise carbon dioxide leakage, increasing a product's shelf life; silver nanoparticles embedded in food storage containers can kill harmful bacteria, keeping food fresher for longer.

Legislative proposals to amend the current Novel Foods Regulation (258/97/EC) are currently passing through the EU legislative process. This Regulation requires that all foods not consumed to a significant degree in the EU before May 1997, or produced using new techniques, undergo a safety assessment before being placed on the EU market. Only those products considered to be safe for human consumption are then authorised for marketing.

If the current proposals are adopted, foods produced using processes that incorporate nanotechnologies would remain excluded from the list of authorised novel foods until they have undergone a specific and adequate risk assessment and more is understood about the potential health effects of nanomaterials. Any such foods that were then approved for sale would also be subject to labelling requirements in respect of their nano-content.

EU and national strategies on nanotechnologies

Despite the lack of a coherent regulatory framework, the EU and national governments recognise that society must capitalise on the potential benefits of nanotechnologies.

EU

The EU has long recognised that the potential benefits of nanotechnologies are wide-ranging.

In 2004, the European Commission published a strategy document that proposed an 'integrated, safe and responsible' approach to the development of nanotechnologies. Its four-year nanotechnologies action plan followed in 2005. It identified key policy areas such as research and development; societal expectations and concerns; and health, safety and environmental and consumer protection.

The second implementation report to the action plan, published in October 2009, underlined the Commission's belief that nanotechnologies have the potential to enhance quality of life and environmental protection, and to boost Europe's industrial competitiveness. It concluded that there had been a substantial development of nanotechnologies, supported by growth in research funding and the active development of policy, but that efforts to address societal and safety concerns should continue in order to ensure their safe and sustainable development.

Since then, the Commission has completed a consultation on its Strategic Nanotechnology Action Plan (SNAP), which will run from 2010 to 2015. It sought the views of experts and the public on the benefits, concerns, risks and perceptions of nanotechnologies, and the possibility of policy changes in this area. Suggestions for new EU policy actions included: establishing an inventory of nano-enabled products; the labelling of nano-content on consumer products generally; and the development of new, specifically targeted regulation.

The consultation report has now been published, although the SNAP is not yet available. Broadly speaking, the report concluded that:

- the application of nanotechnologies in the healthcare sector is seen as very promising, but there is a strong perception of potential risks;
- the application of nanotechnologies in agriculture, food and household items is regarded with more scepticism;

- there is the major concern in industry that the rate of nano-innovation in Europe may fall behind other global regions; and
- there is a perceived need to strengthen action in all areas of nanotechnologies strategy.

UK

In March 2010, the then UK government published its nanotechnologies strategy. This explained that nanotechnologies have the potential to deliver benefits to consumers, sustain the recovery and growth of the UK manufacturing industry, and contribute to tackling issues such as global warming and food sustainability.

The strategy focuses on four key areas.

- Business, industry and innovation. Here, the aim is to create a transparent, integrated, responsible and skilled nanotechnologies industry with good links to, and support from, government.
- Environmental, health and safety research. In this respect, the intention is to foster a better understanding of the risks associated with the use of, and exposure to, nanomaterials, and give people the right skills to assess them.
- Regulation. The strategy outlines the need to adopt better-informed policies and regulations relating to nanomaterials and nanotechnologies.
- The wider world. The UK should aspire to having a well-informed public and stakeholders and a leading position on nanotechnologies on the world stage.

The current government has yet to outline its plans in this area, but it seems unlikely that it will ignore the economic and social benefits that nanotechnologies are expected to deliver. There are clear opportunities for businesses seeking to benefit from any support for, and prioritisation of, these technologies.

Germany

In Germany, the Federal Ministry of Education and Research has published its 'Nano Initiative – Action Plan 2010', which sets out the German government's expectation that nanotechnologies will be key to Germany's future competitiveness.

Germany aims to promote a successful and responsible exploitation of the benefits of nanotechnologies by focusing on five key areas.

- Open up future markets and introduce nanotechnologies into new sectors. Here, the aim is to promote the benefits of nanotechnologies to sectors that may still be unaware of them. Dialogue between the automobile, textile, energy and other industrial sectors will be supported.
- Improve general conditions. In this respect, the German government is seeking to co-ordinate its policies regarding environment, health and consumer protection, support young scientists, and foster standardisation on a national and European level – all with the aim of promoting the successful use of nanotechnologies in industry.
- Evaluate the effects of nanomaterials. There will be support for projects investigating the effects of nanomaterials on human health and the environment, and the development of an inter-departmental research strategy.
- Informing the public. The strategy stresses the importance of informing the public about current knowledge and the development of nanotechnologies.
- Identify topics for future investigation. Government, scientists and business are to work together to develop future applications for nanotechnologies.

In short, the German government is aiming to promote the commercialisation of nanotechnologies while identifying and handling their potential risks.

The rest of the world

In 2008, the Organisation for Economic Co-operation and Development (OECD) sought responses from countries around the world on their regulatory regimes for manufactured nanomaterials. Over 20 responses were received from countries such as the US, Canada, Australia, New Zealand, Japan and Switzerland, as well as from EU member states. None reported having legislation specific to nanomaterials, but most indicated that the authority to regulate products incorporating nanotechnologies existed in current legislation.

The OECD believes that the risk-assessment paradigm for nanomaterials will continue to be guided by existing chemicals regimes, although these will need to be re-evaluated as the body of empirical data on nanomaterials develops. The OECD has also recommended that further research be carried out to determine whether any characteristics of nanomaterials may pose unique hazards.

Where next?

Nanotechnologies enjoy strong support among policy chiefs at the EU and member state level, who are keen to encourage private investment in the sector in order to promote innovation and competitiveness.

The next step for regulators will be to work with industry to deepen their understanding of the potential health and environmental risks of nanotechnologies, and to develop effective regulatory frameworks on a sector-by-sector basis. In the meantime, businesses should monitor their products or processes to ensure the continued, responsible roll-out of these technologies and their compliance with existing regulation.

Additional reading

- UK Nanotechnologies Strategy – Small Technologies, Great Opportunities:
<http://bis.gov.uk/assets/biscore/corporate/docs/n/10-825-nanotechnologies-strategy>
- German Federal Ministry of Education and Research: Nano Initiative – Action Plan 2010:
http://www.bmbf.de/pub/nano_initiative_action_plan_2010.pdf?bcsi_scan_5800883AE23650C2=0&bcsi_scan_filename=nano_initiative_action_plan_2010.pdf
- European Commission nanotechnologies pages:
http://ec.europa.eu/nanotechnology/index_en.html

Contacts

For further information please contact



LONDON
Jonathan Isted
T +44 20 7832 7320
E jonathan.isted@freshfields.com



LONDON
Andrew Austin
T +44 20 7716 4048
E andrew.austin@freshfields.com



DÜSSELDORF
Thomas Kreifels
T +49 211 49 79 146
E thomas.kreifels@freshfields.com