Product liability and nanotechnology

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WE ARE NOW SEEING THE USE OF nanoparticles in a multitude of innovative products, including pharmaceuticals, textiles, cosmetics and food additives. As regulators try to keep pace with science, Sarah Croft, of Shook Hardy & Bacon International, assesses the regulatory environment for nanomaterials and considers the product liability implications.

GROWTH IN PRODUCTS AND APPLICATIONS

Nanotechnology describes technologies developed through the manipulation of matter at the atomic and molecular scale. A DNA molecule is 2.5 nanometres wide. At the nanoscale, materials often have different chemical and/or physical properties from materials at the macroscale. Advances in technology have allowed the manipulation of matter at the nanoscale, allowing companies to take advantage of these different properties for industrial purposes.

The Project on Emerging Nanotechnologies keeps track of consumer products containing nanotechnology, and currently lists a total of 1,317 products and applications produced by 587 companies across 30 countries[1].

EMERGING SCIENCE: NEW REGULATION

There are concerns that the risks associated with nanomaterials are not well understood outside specialist sciences. Reviews of existing regulations have concluded that, while regulations do apply to nanotechnology in the EU, there are few that deal with it specifically. Concerns have been voiced that the existing regulations may be inadequate, as they do not address the differences between the properties of nanomaterials and those of materials on the macroscale. A balance is sought between ensuring the safety of products and avoiding stifling technological progress.

In October 2011, the European Commission adopted a recommendation defining nanomaterials as follows[2]:

> 'A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm.'

This definition is applicable to future legislation regulating nanomaterials. The Commission had previously concluded, in 2008, that current legislation largely covered risks in relation to nanomaterials but that the legislation may need to be modified[3].

To date, the only specific requirements in the EU regarding nanomaterials are those found in the Regulation updating the Cosmetics Directive[4]. Pursuant to this, since January 2011, manufacturers have been obliged to notify the Commission of cosmetic products containing nanomaterials. From 11 July 2013, manufacturers must clearly indicate in the list of ingredients all nanomaterials present in the product by inserting the word 'nano' in brackets after the ingredient listing.

The European Commission has asked the Scientific Committee on Consumer Safety to prepare a guidance document on the safety of nanomaterials in cosmetics

NANOTECHNOLOGY IN PRACTICE

- Self-cleaning glass: windows coated with titanium dioxide nanoparticles react with dirt when exposed to sunlight, allowing it to be easily washed off by rainwater.
- Mould resistant paint: silver nanoparticles that help prevent mould developing.
- Sports equipment: carbon nanotubes are used to strengthen equipment such as tennis racquets while keeping them light.
- Healthcare: the antimicrobial properties of silver nanoparticles are used in some wound dressings.

to assist in the implementation of the Cosmetics Regulation. It is anticipated that this guidance document will be presented at the next meeting of the Committee at the end of April 2012.

The European Commission is conducting a review of REACH (Registration, Evaluation, Authorisation and restriction of Chemicals, the regulatory framework for chemicals), the results of which are expected in June 2012. The Commission has previously indicated that it considers nanomaterials to be covered by these regulations[5]. Concerns exist, however, that nanomaterials are in danger of slipping through the net, as REACH applies only to chemicals produced in quantities of more than a tonne per year, whereas nanomaterials may well be produced in smaller quantities. In contrast, the Canadian government has set the lower limit at 1kg for its safety reporting scheme.

At national level, the French government has recently published a decree that will introduce the first mandatory reporting scheme for nanomaterials in Europe. From January 2013, French companies that manufacture, import or distribute nanomaterials in quantities greater than 100g will be required to submit an annual declaration to the Ministry of the Environment providing information on the quantity and use of the materials.

In March 2010, the UK government published *Nanotechnologies Strategy: Small Technologies, Great Opportunities*, which included proposals such as appointing chief scientific advisers to review co-ordination of nanotechnology research, creating a new website to keep the public informed about government work on nanotechnologies and creating a new nanotechnologies collaboration group to facilitate ongoing communication and collaboration between government, academia, industry and other interested parties.

There has been little sign of the implementation of any of these strategies in the UK, although in January 2011, the Nanomaterial Bioavailability and Environmental Exposure Consortia (Nano-BEE) was established. This is a scientific collaboration between US and UK scientists, jointly funded by the governments of the two countries, established to carry out risk assessment for nanomaterials used in consumer goods and provide scientific evidence to inform the policies of government and industry.

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FUTURE LIABILITY RISKS

Manufacturers still have the same responsibilities to ensure that any product they put on the market is safe, as defined by legislative and common law standards. The fact that a manufacturing process may involve nanotechnology or a product may contain nanoparticles does not change this position. What is different, however, is the way nanotechnology works. The size of the particles means easy absorption by tissues, organs and into the bloodstream. Also the potential for reactivity may be higher compared with materials on the macroscale. It is this different mechanism of action that must be understood and that has an impact on risk assessments.

The science examining the potential unwanted health effects of nanoparticles is still young, but developing all the time. Active areas of study into the possible impact on human health include research into the effects of zinc oxide and titanium dioxide nanoparticles (used to make sunscreen clear rather than white on the skin) and into silver nanoparticles, sometimes used in clothing as an antimicrobial agent[6, 7].

In June 2011, as part of its announcement regarding new regulations for sunscreen products, the US Food and Drug Administration (FDA) issued an advanced notice of proposed rulemaking requesting comments on a proposal for warning labels advising consumers to avoid inhaling sunscreen sprays, in order to 'address the possibility that inhalation of aerosolized particulates could cause adverse health effects'. The results of this consultation

NOTES

1) www.nanotechproject.org.
2) Commission recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU).
3) Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Regulatory Aspects of Nanomaterials. COM (2008) 366.
4) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products.
5) COM (2008) 366, p4.
6) Ng et al 'The role of the tumor suppressor p53 pathway in the cellular DNA damage response to zinc oxide nanoparticles', *Biomaterials* Vol 32, issue 32, p8218, Nov 2011.
7) For example, P V Asharani et al 'Toxicity of silver nanoparticles in zebrafish models', *Nanotechnology* Vol 19, No 25, 2008.
8) Memorandum from John P Holdren, assistant to the president for science and technology, Office of Science and Technology Policy, Cass R Sunstein, Administrator, Office of Management and Budget, Islam A Siddiqui, Chief Agricultural Negotiator, Office of the US Trade Representative 1-2 (9 June 2011), www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf.

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have not yet been published. Earlier this year, the White House released a memorandum establishing principles for regulating nanotechnology[8]. In the US, in early 2012, a coalition of consumer groups filed a lawsuit against the FDA seeking to force the agency to regulate products containing nanotechnology due to safety concerns (*Int'l Ctr For Tech Assessment v Hamburg* [2011]).

While the science on possible health effects is still in its early days, in-house counsel should bear in mind that, particularly in some jurisdictions, there is the potential for claims where no personal injury has occurred. If it transpires that there is an increased risk of injury or disease from using a particular product, regardless of whether an individual or a workforce has suffered physical injury, a claim might be made for medical monitoring for a potential future risk. In the US in particular, plaintiffs may also seek to base a claim on anti-fraud legislation, asserting that they would not have purchased a product had they known what it contained.

CONCLUSION

The science of nanotechnology presents many exciting possibilities but it should be firmly on the radar of in-house counsel in terms of ongoing risk assessments. As the scientific research into the possible health effects of nanoparticles evolves, there are also many regulatory changes on the horizon, both at EU and national level.

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Int'l Ctr For Tech Assessment v Hamburg, No 3:11-cv-06592-MEJ (ND Cal Filed 21 Dec 2011)