Product liability briefing from Shook, Hardy & Bacon published in the July/August 2014 issue of *The In-House Lawyer*:

Product liability and nanotechnology: an update

Product liability and nanotechnology: an update

WHILE THE USE OF NANOMATERIALS continues to grow, for some, concerns remain regarding the potential risks of using these materials and whether there is an adequate regulatory framework. Following up on an article published in *The In-House Lawyer* in May 2012, Sarah Croft, of Shook Hardy & Bacon International, assesses developments in the regulatory environment for nanomaterials and considers the product liability implications for manufacturers using them.

EVER INCREASING USE OF NANOMATERIALS

The Project on Emerging Nanotechnologies, which keeps track of consumer products containing nanotechnology, now lists a total of 1,628 products and applications which have been introduced to the market since 2005 – this represents an increase of 24% since 2010.[1] Manufacturers have continued to make use of the different properties of nanomaterials in textiles, cosmetics and food products. Recent reports have indicated an increased use of nanomaterials in medical applications too. In February 2014, for example, it was reported that researchers from the Universities of Surrey and California had developed a way of growing human embryonic stem cells using a carbon nanotube substrate.[2] Scottish scientists have been working on a process to make hip replacements more durable using 'nanopatterns'.[3]

As the use of nanomaterials grows, so do the concerns of some commentators, worried that these materials are becoming more and more widely used in products without users being fully informed. Some argue that there is a perception that a lack of information is being provided on the likely impact of nanomaterials on health and the environment. Also they suggest that regulators have failed to respond effectively. In the US, in May 2014, concern was expressed over revelations that 96 food products were on sale containing unlabelled nano ingredients, such as titanium dioxide nanoparticles, which are used as a colour enhancer to make dairy products such as yogurt or soy milk appear whiter.[4] There are currently no requirements for such products to be labelled as containing nanomaterials in the US.

Australia is often seen as a country which takes the lead in the field of consumer safety regulation. In May 2014, however, the environmental group Friends of the Earth Australia issued a report which was critical of the regulatory response there to the increased use of nanomaterials.[5] The report calls for a ban on the sale of all products, including cosmetics that contain nanomaterials until:

> '... adequate regulation is in place to manage the health and environmental risks of nanotoxicity'.

Further the authors of the report note that while there is a 'rapidly increasing number of commercial products containing nanomaterials', there is also an 'increasingly large body of peer reviewed evidence that certain nanomaterials may cause harm to human health or the environment', yet Australian companies have 'virtually no restrictions' on the import of nanomaterials or the products containing them. The authors call for a mandatory public register of all nanomaterials and all products containing them, plus a 'comprehensive and precautionary regulatory regime' under which all nanomaterials are subject to environmental health and safety assessments as new substances combine with a requirement that all products containing nanomaterials carry a disclosure label.

RESEARCH INTO HEALTH RISKS

Key to this debate is scientific research into the possible effects of nanomaterials on health. There has been further research into the use of titanium dioxide nanoparticles in food and personal care products.[6] Such research includes attempts to quantify the

'As the use of nanomaterials grows, so do the concerns of some commentators, worried that these materials are becoming more and more widely used in products without users being fully informed.'

Sarah Croft, partner, Shook, Hardy & Bacon International LLP

amount of nanoparticles such as titanium dioxide in food (including sweets), toiletries, and other household consumer items such as paint. The underlying issue is the extent to which nanoscale titanium oxide could result in human exposure and also whether it could enter the environment. In 2012, the European Commission's Scientific Committee on Consumer Safety (SCCS) published its opinion on the nano form of zinc oxide, which is used in many cosmetic products.[7] It concluded that, while tests had indicated some potential for risks to human health, there remained work to be done in ensuring that adequate testing and risk assessment methods are used, as there are still knowledge gaps regarding the behaviour of nanomaterials.

These gaps in the understanding of nanomaterials were also highlighted in a report published by the Organisation for Economic Co-operation and Development (OECD) in August 2013.[8] The report likewise mentions 'major gaps' in knowledge of 'how traditional physico-chemical approaches can be used to assess the behaviour of nanomaterials'.

REGULATORY DEVELOPMENTS

In the European Union, due to recent legislation, there are now some sectoral regulations specific to nanomaterials. Since July 2013, under the revised Cosmetics Directive, manufacturers have been obliged to list as ingredients all nanomaterials present in a cosmetic product. Similar requirements came into force in September 2013 for biocidal products – typically used to protect humans, animals, or materials against harmful organisms, disinfectants for example.[9] From December 2014, food manufacturers will be obliged to indicate the presence of nanomaterials in the ingredients lists for all food products.[10] The names of such ingredients must be followed by the word 'nano' in brackets.

The European Commission published its Second Regulatory Review on Nanomaterials in October 2012. It provided an assessment of the adequacy and implementation of EU legislation relating to nanomaterials and indicated follow-up actions. It concluded that REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) and the General Product Safety Directive set the best framework for the risk management of nanomaterials. REACH is the European regulatory framework for chemicals and, while it does not mention nanomaterials explicitly, the Commission had previously indicated that it considers nanomaterials to be covered by these regulations.

'In the absence of regulation, manufacturers will seek to minimise any potential liability risk through diligent testing, risk assessment and monitoring of the evolving scientific picture.'

In spite of the Commission having reached this conclusion, in 2012, the European parliament and several EU countries (The Netherlands, Austria, the Czech Republic, Denmark, France, Italy, Luxembourg, Spain, Sweden and Croatia) notified the Commission that they considered the current regulatory framework to be inadequate. They called for more transparency, traceability and improved levels of information through the introduction of legislation introducing registers and the mandatory labelling of all consumer products containing nanomaterials. In response to these concerns, the Commission is carrying out an impact assessment of relevant regulatory options, to ensure further clarity on how nanomaterials are addressed. As part of this impact assessment, the Commission is currently carrying out a public consultation on transparency measures which is open until August 2014. In 2013, the Commission also carried out a consultation on policy options for the modification of technical provisions of the REACH Annexes. Also, in April 2014, the Commission's Joint Research Centre published a report outlining concerns and recommendations related to labelling and reporting regulations for nanomaterials in consumer products in the EU.[11] The results of the

NOTES

1) Woodrow Wilson International Center for Scholars, www.nanotechproject.org.
2) Eric W Brunner, et al, 'Growth and Proliferation of Human Embryonic Stem Cells on Fully Synthetic Scaffolds Based on Carbon Nanotubes', *Applied Materials & Interfaces* (6 February 2014).
3) http://www.bbc.com/news/uk-scotland-19431643
4) http://www.motherjones.com/tom-philpott/2014/05/nanotech-food-safety-fda-nano-material.
5) http://nano.foe.org.au/sites/default/files/FOE_nanotech_food_report_low_res.pdf.
6) Weir, A et al (2012) 'Titanium dioxide nanoparticles in food and personal care products', *Environmental Science and Technology* 46:2242-2250.
7) http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_103.pdf.
8) *Co-operation on Risk Assessment: Prioritization of Important Issues on Risk Assessment of Manufactured Nanomaterials – Final Report*, www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2013)18&doclanguage=en.
9) Under Regulation 528/2012.
10) Under Regulation 1169/2011.
11) http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/31575/1/reqno_jrc88931_considerations_information_needs_nm_consumer_products_online.pdf.
12) Gary E Marchant, '"Soft Law" Mechanisms for Nanotechnology: Liability and Insurance Drivers', *Journal of Risk Research* (2014).
13) http://ec.europa.eu/research/science-society/document_library/pdf_06/nanocode-apr09_en.pdf.

‘Several voluntary programs for risk management of nanomaterials have been implemented or proposed, such as the framework prepared by the partnership of the Environmental Defense Fund and DuPont in the US.’

impact assessment are expected by autumn 2014.

As well as notifying the Commission that they view the current regulations as inadequate, at national level, several European countries have independently chosen to take measures to track the use of nanomaterials in consumer products. From January 2013, French companies which manufacture, import or distribute nanomaterials in quantities greater than 100g have been required to submit an annual declaration to the Ministry of the Environment providing information on the quantity and use of the materials. A Belgian decree establishing a notification scheme for nanomaterials was signed into law on 7 February 2014 and will commence on 1 January 2016. As in France, notification will be required for quantities greater than 100g. A Danish proposal for a similar system was notified to the European Commission in November 2013.

Several voluntary programs for risk management of nanomaterials have been implemented or proposed, such as the framework prepared by the partnership of the Environmental Defense Fund and DuPont in the US but participation in such programs has been reportedly limited to date.[12] In 2008, the European Commission issued a non-binding recommendation containing a ‘code of conduct for responsible nanosciences and nanotechnologies research’.[13] It is not clear the extent to which this code of conduct has been adopted.

FUTURE LIABILITY RISKS

Manufacturers have a responsibility to ensure that any product they put on the market is safe as defined by legislative and common law standards. In the absence of regulation, manufacturers will seek to minimise any potential liability risk through diligent testing, risk assessment and monitoring of the evolving scientific picture. We have seen a trend in recent years towards legislation and regulation which is aimed at improving the ability to track and trace consumer goods. It may be that, absent a further understanding of the way nanomaterials may have an impact (if indeed they do at all), perhaps the minimum we can expect is regulation from Europe harmonising the requirement on manufacturers to track the use of nanomaterials in consumer products and in the workplace.

By Sarah Croft, partner, Shook, Hardy & Bacon International LLP.
E-mail: scroft@shb.com.