

Small can be dangerous

Manufacturers and insurers need to be alert to the legal risks when developing nanotechnologies.

The first episode of the American hit sitcom Mork and Mindy was broadcast on 14 September 1978. Soon after, “Nanoo Nanoo” (Orkan for “Goodbye”) became a household alien catchphrase. Twenty-nine years on, it seems that a new catchphrase is emerging: “Nano Nano” – humanoid for a whole new range of exciting technologies. But with these new technologies comes risk as well as opportunity.

What is nanotechnology?

Nanotechnology is a field of science generally associated with the manipulation of matter on an atom-by-atom or molecule-by-molecule basis to construct a certain atomic or molecular configuration so as to create computer chips and other devices that are thousands of times smaller than current technologies permit. These miniaturised configurations are able to undertake highly complex work by performing operations in parallel.

The result is the widespread development and production of nanotechnology-related products and applications in many sectors, such as aerospace, car manufacturing, chemicals, biotechnology, medicine and food. Helmut Kaiser Consultancy Group estimates that the global nano-food market was worth US\$5.3bn in 2005 and will rise to US\$20.4bn by 2010. It further predicts that nanotechnology will be used in 40% of the food industries by 2015. An iconic example of nano-based “future food” was Kraft’s clear, tasteless nano-drink that contained hundreds of flavours in invisible nanocapsules. The idea was that a microwave transmitter could be used to trigger release of the flavour, colour, texture and concentration of the individual’s choice. This “smart” drink received international attention and remains the most widely cited example of potential nano-food.

Major advantages

As the world population continues to explode, it is hoped that nanotechnology will help solve the dilemma of limited planetary resources through more efficient generation, storage and distribution of energy. It is also envisaged that nanotechnology will enhance the quality of life for human beings through medical diagnostics, drug delivery and customised therapy. It could also benefit the environment through, for example, the development of stronger, lighter-weight materials in transportation that reduce fuel use. Furthermore, it is hoped that nanotechnology applications in electronics will increase access to technology through reduced cost and higher performance of memory, networks, processors and components.

Inherent risks

Reducing bulk material to the size of nanoparticles may cause it to behave differently and to display completely new and unexpected properties. Some studies indicate that certain nanoparticles may cause adverse effects due to their small size and specifically manufactured properties. Initially, it is easy to identify the risk posed to those involved in the electronics industry and particularly to employees dealing with the production instruments using nanotechnology. But there is also fear of the unknown consequences of digesting minute particles which are designed to behave in a specific way in the body, and which could arise in any number of diverse circumstances.

Consequently, in order to determine effectively both the long-term properties and the general reliability of nanoproducts – as well as their effects on human health and the environment – it has been suggested that all involved parties (including scientists, businesses, regulatory authorities, consumers and the insurance industry) start an open “risk dialogue”.

EU action plan

On the 7 June 2005, the European Commission adopted the action plan “Nanosciences and nanotechnologies: An action plan for Europe 2005-2009”, the text of which was adopted by the European parliament on 28 September 2006. This action plan defines a series of actions for the immediate implementation of a safe, integrated and responsible strategy for nanosciences and nanotechnologies. Elements of the nanotechnology action plan include research, development and innovation, public health and safety, together with environmental and consumer protection.

UK law and regulation

One example of the gaps in the UK regulation of nanotechnology is the use of nano versions of already approved ingredients in food products. Currently, each additive used in food products must comply with specific purity criteria laid down in related European Commission directives. So any new nanomaterials would need to undergo safety assessments by the European Food Safety Authority before they were included on the relevant positive list and so be permitted in foods. These risks are taken very seriously by the EU. As a result, the Food Safety Agency (FSA) has called for research proposals to assess the potential applications of nanotechnology for food additives and other novel ingredients, and to consider consumer safety and the regulatory implications of their possible use.

The FSA has also suggested an amendment to the legislation to require that all nanocomponents be subject to their own risk assessment. Alternatively, it might be

possible to base future law dealing with nanotechnology on established rules concerning analogous products or processes, such as biotechnology. It may well be that a co-ordinated regulatory approach of both nanotechnology and biotechnology will develop. Either way, it is arguable that laws will have to be made to ensure limits on research of particularly dangerous nanodevices, so as to ensure adequate safety monitoring of nanotech products in use and to make certain that sufficient procedures are in place to compensate those who may be adversely affected by them.

Risk of liability

There are risks and challenges facing manufacturers and insurers in relation to the development of these new technologies. For example, manufacturing companies will have to be responsible for ensuring that nanotech products do not pose a danger to their users or others passively. Furthermore, as the nanotech market expands, and law and regulation evolve, manufacturers will have to conduct safety trials to show product safety and quality. This is cutting-edge technology and problems are bound to arise.

UK manufacturing companies must seek ways to develop a regulatory system, as well as prepare for potential product liability claims arising out of exposure to these new technologies both during manufacture and after the goods have entered the public domain. Although the products may be nano, the claims against those manufacturing them could be mega, and insurers of relevant manufacturers involved in this field should be aware of the potential risk.

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