



REACH and the regulation of nanotechnology

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The implementation of the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation, represents a fundamental shift in the regulation of manufactured and imported chemicals in the EU. Having entered 'into force' on 1 June 2007 and 'into operation' on 1 June 2008, the new regime's overriding objective is 'to ensure a high level of protection of human health and the environment' and is heavily underpinned by the precautionary principle. Furthermore, the uncertainty associated with nanotechnologies under the new regulation creates an interesting dilemma: ensuring a high level of protection of public and environmental health and safety must be weighed up against the capacity implications for industry, both large and small. REACH also seeks to enhance competitiveness and innovation in the chemical industry, and the regulation of chemical substances under REACH is likely to present a significant challenge in resolving the conflict between progress and protection for nanomaterials.

To adequately control any risk arising from chemical substances, REACH is based on the principle that 'it is for manufacturers, importers and downstream users to ensure they manufacture, place on the market or use such substances that do not adversely affect human health or the environment.'

Therefore, REACH effectively shifts responsibility from authorities to industry to gather information on chemical substances and assess their safety. The Regulation prohibits the manufacture or sale of any substance in the EU that has not been registered with the European Chemical Agency (ECHA). It is a volume-triggered system, with registration requirements depending on the tonnage of the substance manufactured or imported per year, per legal entity, and the hazard class. Registration of substances produced in quantities of more than 1 tonne per year requires a technical dossier to be filed with information on the properties of the substance, its use, classification and labelling. For substances produced over 10 tonnes per year, additional physicochemical, toxicological and ecotoxicological information and a Chemical Safety Report is required.

There is however, uncertainty over the adequacy of the provisions in regulating the quickly developing nanotechnology industry. In 2004 The Royal Society and Royal Academy of Engineering published a report which identified and highlighted gaps in regulations relating to the manufacture and use of nanoscale substances within the UK (RS/RAEng, 2004).

Since then, commentators such as Friends of the Earth have stressed their hope for implementation of the new regulation to fill this gap and ensure a framework for appropriate testing and market placement of nanomaterials. (Friends of the Earth, 2006).

During the second reading of REACH in 2006, the Committee on the Environment, Public Health and Food Safety of the European Parliament proposed a number of amendments during its second reading of REACH, to specifically relate to engineered nanoparticles (Bowman and Calster, 2007). Amendment 325 proposed that the one tonne per year manufacturer or importer threshold and information requirements for registration be revised to consider engineered nanoparticles. Despite this, nano-specific provisions were not included in the final REACH regulation document; however the registration requirements of nanomaterials will have to be considered as for any other substance.

As the regulation stands, a manufacturer or importer of any nanoscale substances or producer or importer of nanoscale substances contained in articles, in volumes of one tonne or more per year, will be obligated under the REACH regulation to register the substance with the ECHA and provide at minimum a technical dossier on the nanoscale substance.



However, with current production volumes typically being relatively low for nanoscale substances, only a few manufacturers, importers or producers will actually exceed the tonnage threshold for registration. Therefore, many will be exempt from the general obligation to register the substance with ECHA.

Nonetheless, the European Commission have stated that the restriction and authorisation processes can be applied to substances that are of very high concern, produced or imported in volumes below 1 tonne per year. This in effect means that risks from certain nanoscale substances would be addressed through the Regulation if they were identified as being 'substances of very high concern' as defined in Article 57, for example being persistent, bioaccumulative and toxic (PBT). The EC are funding research to address methodologies for identifying the hazards of nanoscale substances through the 7th Research Framework Programme (FP7) and point out 'it will also be necessary to carefully monitor over the next few years whether the [1 tonne per year] threshold for registration and the information requirements under REACH are adequate to address potential risks from particles on a nanoscale.'

Whilst there is the potential for nanoscale substances to be addressed distinctly under REACH, the regulation does not currently distinguish between nanoscale substances and their bulk equivalent at the micro or macro scale. With nanoparticles considered to have new and different properties, which may imply increased toxicity, this lack of distinction may limit the assessment of novel properties posed by nanomaterials.

A particularly relevant example for consideration is that of carbon nanotubes (CNTs). 'Carbon' (EINECS number 231-153-3) has recently been removed from the list of exempt substances under REACH (Annex IV). If upon registration under REACH, CNTs are deemed to be the chemical equivalent of carbon or carbon black (and thus registered using the EINECS / CAS numbers for carbon or carbon black), a registrant of carbon nanotubes would need only to supply the same technical information as they would for carbon or carbon black. However, if carbon nanotubes and carbon / carbon black are deemed to be different chemical substances for the purpose of registration, then before the carbon nanotubes were permitted entry into the market, the registrant would be required to submit a technical dossier to include guidance on their safe use, as specified by Article 10 of the REACH Regulation.

At this time, it is still unclear if the EC will consider nanoscale substances as equivalent to their bulk counterparts. Fullerenes have been recently assigned CAS numbers, so there does seem to be scope for ECHA to consider nanoscale substances as separate entities. However, if nanoscale substances are treated as 'existing' chemicals due to their chemical composition being comparable to their micro or macro counterpart under REACH, there is the danger that the regulation may fail to adequately control nanoscale materials in the presence of scientific uncertainty regarding their toxicity.

The European Trade Union Confederation (ETUC) is calling for REACH to give better and wider coverage to engineered nanomaterials, particularly to cover those manufactured or imported below the threshold of one tonne per year. The opinion of the EC's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), which is shared by the ETUC, is that REACH's 'no data, no market' principle should apply to nanoscale forms of chemicals as well. (SCENIHR, 2006; ETUC, 2008) Current REACH policy states that materials of a very high concern will require authorisation for their use and their placing on the market. The opinions of SCENIHR, ETUC and other concerned bodies, coupled with the little knowledge associated with nanomaterials, could influence the decision to place further restrictions on nanomaterials until sufficient data is provided to show that nanomaterials have no negative effect on human health or the environment.

Despite concern over adequate restrictions, the REACH regulation as it stands is still likely to present substantial new hurdles to industry. The EC has estimated the compliance cost at 2.3 billion euros



over the next eleven years, although other estimates may vary (Commission of the European Communities, 2003). To alleviate this expense, the ETUC has suggested that 15% of public nanotechnology research budgets be earmarked for safety research. However, this may not suffice as the implications of the REACH regulations will not only affect the current EU chemical industry but also independent parties specializing in nanomaterial synthesis wishing to gain access to the world's largest chemical market.

The impact of this on the EU chemical industry is likely to be amplified further should ECHA determine that nanoscale materials are different from micro scale materials and even more so if they are considered to be 'substances of very high concern'. It is possible that the potential introduction of very strict regulations may deter investment. Moreover, industry is likely to respond by slowing nano-development to ensure their output of nanoscale substances falls short of the production volume triggers. This could mean a slow down in both innovation and realisation of the potential benefits promised by nanotechnology.

In 2012, a general review regarding the scope of REACH will be carried out including a review of the specific information requirements for substances at the various quantity triggers. Hence there remains an opportunity for improvements to be made to the legislation in terms of nanomaterials.

What is apparent is that ECHA should address as a priority the adequacy of REACH for determining the potential risks of nanoscale substances. Only then will the full implications, impact and subsequent cost of REACH to the nanotechnology industry become clear.

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