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Nanotechnology and REACH

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One Bird with Two Stones — International Regulation of Carbon Nanotubes

Carbon Nanotubes (“CNT”) are allotropes of carbon whose cylindrical shape results in novel properties that appear to be useful in numerous applications, including medicine delivery, electronics, optics and the structural strength of materials. The diameter of CNTs is typically only a few nanometers, though its length may be as much as a million times greater. In the past, there has been some uncertainty whether CNTs would be regulated as carbon or graphite or whether, due to their unique structure, they would be treated as a new material. Recent pronouncements from the US Environmental Protection Agency (“EPA”) and the European Commission (“EU”) make it clear that CNTs will be regulated as a new material in the United States and the European Union.

On Friday, October 31, 2008, the EPA published a notice regarding the regulation of CNTs under the Toxic Substances Control Act (“TSCA”). The EPA stated that it “generally considers CNTs to be chemical substances distinct from graphite or other allotropes of carbon” and, therefore, may be new chemicals subject to the premanufacture notice requirements of TSCA. Under this interpretation, any person manufacturing or importing CNTs must file appropriate documentation with the EPA at least 90 days prior to manufacture or import. Though the EPA has attempted to make this interpretation known to the industry in the past, the notice states the agency’s concern that some in the industry still misunderstand its approach to CNTs under TSCA. The EPA further stated that, at some time after March 1, 2009, it will focus its compliance efforts on TSCA

requirements regarding CNTs — a clear signal of future enforcement actions by the agency.

On October 8, 2008, the European Commission adopted an amendment to its REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) Regulation to remove the exemption from REACH’s registration, downstream user and evaluation requirements for carbon and graphite. REACH requires companies manufacturing or importing chemical substances into the European Union or European Economic Area to identify the properties, hazards and uses of their substances and to assess their risks to human health and the environment as part of its registration regime. Carbon and graphite had been excluded from these requirements on the grounds that sufficient information was known about these substances and they were considered to cause minimum risk, based on their intrinsic properties; however, the Commission determined that insufficient information was known about carbon and graphite, in particular at the nano-scale, noting that the EINECS and/or CAS numbers for carbon and graphite are often used to identify forms of carbon or graphite at the nano-scale.

CNTs already constitute a significant item in international commerce. Companies manufacturing, importing or using CNTs should be careful to assure compliance with TSCA and/or REACH, and may need to assess whether their suppliers or customers comply with one or both of these regulatory programs, as appropriate.