

Annex 6

The Regulatory Challenge of 'new' nano-materials

- 1) One of the novel features of nanotechnology is that in many cases the physic/chemical characteristics of a material can be altered by choice. This is achieved not by a change in its chemical formulation but by a change in its physical structure.
- 2) Currently the placing of new substances on the market is regulated under the Notification of New Substances Regulations 1993 (NONS). Changes in physical structure are not currently interpreted as a new substance. Thus a 'nano' version of an existing material, which may have different characteristics, would not have to submit a new set of data for assessment prior to its being placed on the market.
- 3) However the requirements of Chemicals (Hazard Identification and Packaging) Regulations 1993 requires suppliers of chemicals to identify if they are dangerous to human and/or the environment and for suppliers of dangerous chemicals to give adequate information to help those who may use the chemicals to do so safely. Thus there is still a requirement to provide necessary safety information down the supply chain.
- 4) Both of these regulations are the UK implementation of the Dangerous Substances Directive (seventh amendment) and are primarily aimed at ensuring that the risks posed by chemicals are identified and communicated in a systematic way. Ideally the situation regarding nano-materials and NONS should be resolved but this would have to be undertaken in the European forum. It currently would be difficult to justify the resource required to get agreement across Europe to change the interpretation of what is a new substance, as NONS will be replaced. The Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (REACH), which would replace the Dangerous Substances Directive is in negotiation and it may be more suitable to input such issues in to that process. DEFRA is the lead department for REACH with HSE inputting into the process.