

DEFRA March 2006 and August 2006.

Consultation on a proposed 'Voluntary Reporting Scheme' for engineered nanoscale materials

Certainty on the potential harm from nanotechnology is still some years away. There are no immediate plans to define new statutory duties but there are plans to produce good practice guidance; which could be influential in civil cases. The government is hoping that information provided by industry will help define regulatory and guidance needs. Information is to be provided on a voluntary basis.

In recognising that toxicity of engineered nanoparticle is unpredictable, the government seek to gain more information on the properties and uses of these products. Once enough information is analysed it is hoped that patterns of toxicities can be related to measurable physical and chemical properties. If and when these are established it ought to be possible to identify appropriate regulation to protect human and environmental health.

The voluntary scheme will also help identify which areas are most likely to be exploited commercially and therefore the areas where regulation should be prioritised.

Several advantages to the developers of nano products are suggested:

- 1) Regulators will be using real data to inform their activities. Inaccurate regulation would be avoided.
- 2) Participation would be taken as a sign that the developer was being cooperative. [there is no amnesty from prosecution being offered here, in any case, there is no consensus on what evidence would be viewed as sufficient to bring a successful prosecution]
- 3) Good practice would be established more readily by pooling such views.

Consultees were asked to respond on issues such as scope of reporting, confidentiality and compulsion.

Thirty six firms responded to the consultation and the Government published its response in August 2006. There were no responses from liability insurers or reinsurers, unless these were made by proxy.

Civil society organisations indicated that waiting until evidence had accumulated was not a sufficiently precautionary approach as it implied that market exploitation could continue until there was evidence that it should be regulated. The position is understandable if releases of nanomaterials could not be remediated before any resulting harm was done. No evidence to support that concern was reported on in the government response. In response, the government said it would engage in information gathering primarily through research, supported by the voluntary [definitely not mandatory] reporting scheme.

Information provided to the scheme would be kept confidential.

The initial focus of the Voluntary Reporting Scheme will be all free engineered nanoscale materials with two or more dimensions up to 200nm.

There was strong support for the development of 'good practice' guidance.

Comment

In effect the voluntary scheme will operate for two years before it is fully evaluated. It seems unlikely that regulatory measures would be taken before then except to deal with very specific high hazard issues. Good practice guidance would probably also be delayed for two years. The scheme will commence as soon as possible after the publication of this response.

Volunteering information would assist in the development of an appropriate standard of care. It being voluntary, there would be very little scope to conclude that anyone who did not take part had breached a duty of care.