

WATCH COMMITTEE PAPER		WATCH/2008/10	
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Exemptions:			

WATCH COMMITTEE

BSI Published Document PD 6699-2:2007 Guide to safe handling and disposal of manufactured nanomaterials

Issue

1. The Committee's views are sought on BSI PD 6699-2 (Annex 1) and particularly the acceptability of the benchmark exposure levels included in Part 8.3 of the document.

Timing Considerations

2. Routine

Recommendation

3. WATCH is invited to consider the issues noted in this cover paper and to respond to the actions in paragraph 14.

Background

4. BSI PD 6699-2 is one of a suite of guides prepared by BSI Standards Committee NTI/1 in support of standardisation in the field of nanotechnology. It is available free of charge from the BSI website. The document was drafted by the Institute of Occupational Medicine (IOM), Edinburgh on behalf of the committee and was widely consulted on. The benchmark exposure levels, however, were a late addition, included in response to comments from consultees, but not seen by the HSE representatives on the committee.

Argument

5. The advice in the guide on the identification and management of risks associated with manufactured nanomaterials is generally sound and usefully elaborates on the brief advice HSE published a few years ago. However, the benchmark exposure levels go considerably further than the precautionary approach adopted by HSE and if applied would impose a very precautionary standard, one that is not supported by current research on the toxicology of nanomaterials. It is also not known if control to these levels is achievable in practice. The proposed exposure levels represent the considered judgement of individuals with substantial experience in the fields of toxicology and occupational exposure control; but the consideration of the benchmark levels by WATCH will be the first formal committee appraisal.

6. The two main problems for monitoring exposure to engineered nanoparticles (ENP) are:

- i. Which measurement metric or metrics do we use to measure exposure to ENP that best connects with the assessment of potential health consequences? Current research indicates that surface area and number /size, rather than mass, should be measured for nanoparticles. Nanoparticles have far more surface area for the equivalent mass of larger particles, which increases the chance they may react with biological systems.
- ii. How do we discriminate between exposure to ENP and ambient nanoparticles that may be present in the workplace from other workplace sources, from vehicle emissions or other combustion sources? Real-time particle measurements are non-discriminative and all particles are counted / measured regardless of being engineered or ambient environmental nanoparticles. The background levels in workplaces may be higher than the level of engineered nanoparticles generated from

a handling or process activity and often fluctuate with time. Discrimination from ambient environmental nanoparticles is very complex and sometimes impossible. Physico-chemical methods of measurements for nanoparticles are limited.

7. Currently, these questions cannot be answered and considerable effort is being expended worldwide to provide a way forward. Without reasonably reliable exposure measurement methods the purpose of even pragmatic guidance levels must be questioned. One also needs to recognise the different meanings and regulatory significance of different types of exposure level guides and limits, ie whether or not they are targets to be aimed for or maximum levels to be beneath; whether or not they have regulatory/legal standing; and what degree of associated reassurance of avoidance of ill-health consequences are attached to them.

8. For example, whilst it may appear to be reasonable to use asbestos-derived exposure limits as the basis for fibrous nanomaterials, the logic behind the proposed benchmark of 0.01 fibres/ml (UK asbestos clearance indicator) as assessed by TEM or SEM is questionable. Experience shows that analysis of typical airborne chrysotile distributions by TEM (counting fibres of all lengths) will give about 100 times the number of fibres recorded by phase contrast optical microscopy (PCM). In addition, there is no mention as how fibrous agglomerates or very long fibres should be counted. The current wording suggests a benchmark exposure level that may be orders of magnitude below the current EU control limit for asbestos (0.1 PCM fibres/ml). This proposed benchmark level of 0.01 fibres/ml might be judged over-precautionary for the current level of knowledge even taking into account the recently published work on carbon nanotubes by Poland and al. (2008).

9. The limits for non-fibrous nanomaterials, are also doubtful with questions against the science behind the NIOSH proposed exposure limit of 0.1 mg/m^3 for TiO_2 , the use of mass as a metric and the multipliers for CMAR and soluble materials. In addition, nothing is said about discrimination from the ambient environmental particles, which maybe many times higher and the rationale for choosing 20,000 particles/ml (e.g. for 10nm particles at a density of 1g/cm^3 it would correspond to $\sim 0.00001 \text{ mg/m}^3$)?

10. When this document was first mooted we thought to endorse it and withdraw HSE's earlier guidance note that is in need of updating. However, the presence of these exposure benchmarks, which could unnecessarily constrain the development of technologies and products that could benefit the UK population and economy, place that proposal at risk. Even more important is the issue of having a scientific consensus on exactly what sizes of fibres and particles should be measured (agglomerates or single particles) and any agreed method, which can reliably and reproducibly give these measurements.

Link to HSC Strategy

11. This is part of a cross-cutting programme of "Futures" work being undertaken to ensure that HSE understands the issues relating to the regulation of the nanotechnologies and that the health and safety regulatory framework is sufficient for the task.

Consultation

12. There has been no wider consultation on the content of this cover paper beyond HSE at this stage.

European Context

13. There are no specific links to EU procedures or activities but the document will inform the development of international standards and the work of the REACH working group on nanotechnology in due course.

Action

14. WATCH is asked to consider the issues described in this paper and to:

- i. provide views on whether the benchmark exposure levels in Part 8.3 have a sufficient scientific basis;
- ii. provide views on the document as a whole;
- iii. decide whether it can recommend that HSE endorses this document.

Contact:

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References / Attachments

Annex 1 **PD 6699-2:2007** Nanotechnologies –Part 2: Guide to safe handling and disposal of manufactured nanomaterials

Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study. Craig A. Poland, Rodger Duffin, Ian Kinloch, Andrew Maynard, William A. H. Wallace, Anthony Seaton, Vicki Stone, Simon Brown, William MacNee & Ken Donaldson. Nature Nanotechnology 3, 423 - 428 (2008).