



Chartered
Institute of
Environmental
Health

Working safely with engineered nanomaterials and nanoproducts – a guide for employers

CIEH comments on a draft guidance note being produced for the European Commission Directorate General for Employment, Social Affairs and Inclusion by a consortium led by Risk and Policy Analysts Ltd and IVAM University of Amsterdam.

September 2012

The Chartered Institute of Environmental Health

As a **professional body**, we set standards and accredit courses and qualifications for the education of our professional members and other environmental health practitioners.

As a **knowledge centre**, we provide information, evidence and policy advice to local and national government, environmental and public health practitioners, industry and other stakeholders. We publish books and magazines; run educational events and commission research.

As an **awarding body**, we provide qualifications, events, and trainer and candidate support materials on topics relevant to health, wellbeing and safety to develop workplace skills and best practice in volunteers, employees, business managers and business owners.

As a **campaigning organisation**, we work to push environmental health further up the public agenda and to promote improvements in environmental and public health policy.

We are a **registered charity** with over 10,500 members across England, Wales and Northern Ireland.

Any enquiries about this response should be directed in the first instance to:

David Kidney
Head of Policy
Chartered Institute of Environmental Health
Chadwick Court
15 Hatfields
London
SE1 8DJ

Introduction

There is a great detail of uncertainty concerning the hazards and risks that may be posed by engineered nanomaterials and their products. A fundamental concern is that they are likely to be new substances with significant unknowns in terms of their characterisation and their exposure limits. There is little or no historical evidence or experience on which to base risk assessment and risk management decisions. The Organisation of Economic Co-operation and Development published, on 11 September 2012, its view that the current approaches for the testing and assessment of traditional chemicals are, in general appropriate, for assessing the safety of nanomaterials, with some exceptions¹. However, this does not accelerate our knowledge of the many unknowns that are facing us regarding the properties of manufactured nanomaterials and their products.

There are a number of issues relating to the technical guidance and the assumptions regarding the toxicological matters to comment on in the draft guidance.

Technical Content

It is sometimes the case that ineffective health and safety guidance is due to the convoluted application of the controls, rather than poor identification of the technical hazards. I would therefore offer comments regarding:

1. The ease of application of the Guide for employers and employees and;
2. The need for regular updating due to the rapid advances in this scientific field and the development of the next generation(s) of Manufactured Nanomaterials and their products.

Application of the guide

a). General Comments

The format proposed follows a standard approach to the production of risk assessments, albeit more complex. Since many managers (who have to apply the contents) are not as skilled technically as their employees, the *system* for applying controls needs to be as straightforward as possible. *Technical* accuracy is the province of suppliers and competent employees (rather than managers) who will follow the system and apply the guidance.

For example, simply transferring information already available from a supplier's materials safety data sheet (MSDS) to Table 1, for each nanoproduct, introduces an additional opportunity for error and an extra step which must be included in updating activities. T.1 is likely to be consulted very rarely, except for changes in the materials in use and the latest MSDS would be the preferred source of information.

It may also be possible to combine some of the tables such as T.3 and T.15, since a smaller business, with few employees, may have extensive entries in T.15 and their ID could be logged in T.3 instead.

The Introduction refers to Annexe 1 and the "...*provision of examples of the application of the Guide to real workplaces...*" which will be identified during consultation and previous experience. This is absolutely essential for those involved in managing the risks for their

technical staff, since it gives an idea of the functions which must be controlled to comply with the requirements of Risk Assessments and how they might be implemented.

The field of manufactured nanomaterials is developing at such a rate that any new safety discoveries which appear will need to be incorporated into risk assessments as soon as possible for health & safety and legal reasons.

The Guide should be available online if a host site is available, and it could then be updated as frequently as resources allow. That would allow case studies in particular to be continually improved and there may even be scope for a Wiki or blog of best practice on which users can upload their latest scenarios for comment or adoption by others if appropriate or similar.

On the positive side, therefore, this draft guidance is a reasonable starting point. The tiered approach makes sense, as does the separation of MNMs from incidental NPs.

An online resource could, therefore, also provide the means for employers to safeguard their civil liabilities by remaining aware of the dates on which a 'prudent employer' should have been aware of improved controls or changed hazard information.

b). Specific Comments

- The guide provides largely a qualitative generic approach which is easy to follow but the information required on MNM to complete the different stages may be not be easily accessible/ available in particular small and medium manufacturing companies.
- The guide makes a distinction between MNM and PGNPs but in practice this may be difficult. It is also not clear why this distinction is important when we should be evaluating the effect of total exposure arising from the workplace.
- A main concern is that the guidance provides methods for assessing exposure but there is little information on the type of health effects associated with nano-particles. In the absence of defined effects may be difficult to justify control measures and management systems derived from the proposed methodology.
- Little information is provided on methods for measuring exposures (particle number, diameter and concentration), the reliability of sampling and analysis methods and appropriate sampling strategies for nano-particles. There is a need to also include suppliers of equipment and typical costs.
- A worked examples (qualitative and quantitative) would be very helpful based on an actual scenario for (a) MNM (b) MNM and co exposure to PGNPs
- Step 1 recommends default assumption of the presence of MNM in all substances which may result in unnecessary effort and costs in conducting the assessment and implementing RMM.
- The document needs consider the constraints (resources and expertise) for SMEs for each stage of the proposed methodology

Toxicology

On the less positive side, the groupings (Table 2) look somewhat arbitrary. More specifically:

1. There is too much focus on the asbestos-paradigm, which:
 - 1.1 is not really widely demonstrated/accepted and:
 - 1.2 misses other potentially uniquely nano effects, perhaps not yet discovered or fully understood.
2. The CIEH is not convinced of the argument for separating categories 2a and 2b on density:
 - 2.1 There is data to indicate that Zinc Oxide located in Table 2.(2b) should be grouped with the more toxic biopersistent nano-granular materials in 2a, and ;
 - 2.2 Is there sufficient evidence to justify Fe/Fe oxides being sufficiently toxic to justify the grouping in 2a despite their density?
3. Solubility is not considered sufficiently.

Conclusion

Overall, this draft guidance is welcomed as a first step in providing information and guidance to both employers and their employees on how to organise a safe place of work in a climate of such uncertainty.

It is essential that this is a "living" document which is readily available and updated regularly.

The CIEH trusts that these comments are of some assistance in the development of the proposed new guidance.

Reference:

1. OECD (2012), *Six years of OECD work on the safety of manufactured nanomaterials*
<http://www.oecd.org/chemicalsafety/safetyofmanufacturednanomaterials/Nano%20Brochure%20Sept%202012%20for%20Website%20%20%282%29.pdf>