Deliverables

- Tools for performing regulatory risk assessment, including: adequate methods for nanomaterial toxicological endpoint testing, intelligent testing strategies to predict the toxicological effects of new nanomaterials and reduce the need of testing; occupational scenarios for workers exposed covering the life cycle of nanomaterials; risk characterisation guidance. Reducing the level of uncertainty about the risks should enable the EU to regulate nanomaterials.
- Instrumentation and strategies for measuring occupational exposure to nanoparticles at the workplace.
- Generation of high quality, systematic exposure data enabling modelling exposure.
- Guidance and standards that enable companies, regulators and other stakeholders to responsibly deal with uncertain risks during the production and use of ENMs.
- Methodologies for risk assessment and management for workers exposed to ENMs.
- Innovative safe-by-design approach for the scientific community and industry.

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[5] *K. Savolainen, H. Alenius, H. Norppa, L. Pylkkänen, G. Kasper, Risk assessment of engineered and nanotechnologies – a review; Toxicology, 2010, 269, 92-104.*

[6] *G. Ramachandran, M. Ostraat, D.E. Evans, M.M. Methner, P. O'Shaughnessy, J. D'Arcy, C.L. Geraci, E. Stevenson, A. Maynard, K. Rickabaugh. A strategy for assessing worplace exposures to nanomaterials, Journal of Occupational and Environmental Hygiene, 2011, 8:11, 673-685.*

Further information:
This research challenge is part of the PEROSH report "Sustainable workplaces of the future – European research challenges for Occupational Safety and Health". The full report, as well as each of the research challenges separately, can be downloaded in pdf-format from the PEROSH website: http://www.perosh.eu/p/OSHresearch2020

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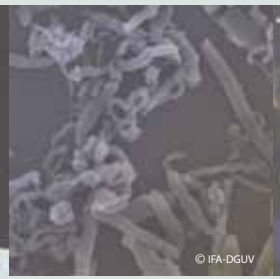
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Occupational risks related to engineered nanomaterials (ENMs)

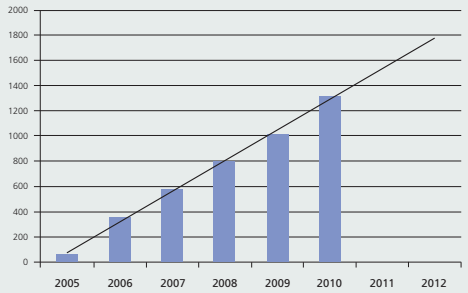
Summary

Engineered nanomaterials present new challenges to understanding, predicting and managing health risks to workers. As nanotechnology applications and uses expand, safety of these emerging materials is identified as one of the research priorities. It has been shown that the physical characteristics of nanoparticles can influence their effects in biological systems, but results from available studies are insufficient to elucidate the potential health concerns. Research efforts have to address knowledge gaps in potential toxicity of nanomaterials, occupational exposure measurement and effective risk management procedures. In this area, European level collaboration is an obvious choice due to the complexity of the issues.

1. Description of the priority. What is at stake? Why is it a priority?

Since the beginning of the 21st century, nanotechnologies have developed enormously, judging simply by the number of products now on the market and the funds dedicated to research and development (R&D) in this area[1]. The direct employment generation impact of nanotechnologies is estimated to be around 2.3 million jobs worldwide by 2015, of which 0.9 million in USA and 0.4 in Europe. Nanotechnology-based applications will substantially improve the performance of many products through the unique properties of ENMs[2].

Figure 1: Progression of products listed in the Consumer Products Inventory.



Source: http://www.nanotechproject.org/inventories/consumer

At the same time however, the nanoscale size of ENMs generates concerns with regard to the potential health and safety risks. The earliest and most extensive exposure to nanomaterials is most likely to occur in the workplace. Therefore the health and safety of workers exposed to ENMs and products containing ENMs are a key issue. Significant research has been performed to assess occupational exposure and the impact of nanomaterials on health and safety. However, occupational risks associated with manufacturing and the use of ENMs are not yet clearly understood and there is still a great considerable lack of knowledge[3].

Additional research is needed to address the gaps. The main goals of this research are to assure safe handling of ENMs while attaining the societal benefits of nanotechnology. Regarding the complexity of knowledge gaps, there is a clear need to join forces and to coordinate ongoing efforts for research in this domain at European level. The results of the research will then be translated in various forms which are understandable to stakeholders: workers, enterprises, regulators and the society at large[4].

2. Research needs at European level

The potential risks of ENMs must be managed through identification of hazards, measurement and control of exposure. The research needs include the following:

2.1 Research in toxicology to understand the specific biological properties of ENMs and identify their potential adverse effects

Specific goals in this area should focus on exploring the material characteristics that contribute to biological effects (e.g. size, shape, surface area, surface activity, solubility, trace components and surface coating) and investigating effects and mechanisms of effects of different types of ENM on biological systems (in vivo, in vitro)[5]. The ultimate aim of the research is to reduce the need for testing and provide a foundation for a safety classification of ENMs based on their physical and chemical characteristics.
Another key issue is the adaptation of the existing methods of testing for toxicity of nanomaterials and the development of new screening methods. These methods should be suitable for predicting the potential effects: short and long-term pulmonary and systemic effects of inhalation exposure to nanomaterials, genotoxicity, reproductive toxicity and immunological responses. They should be relevant in terms of determination of dose-response relationships between deposited dose and the adverse effects. New intelligent testing strategies adapted to a high number of ENMs are required to be applied for future testing.
There is also a need to address the criteria for a proper description of the dose in relation with the adverse effects. Overall, increasing the knowledge with respect to hazards of ENMs will contribute to the setting of occupational limit values.

2.2 Research in ENM characterisation and metrology

The overarching goal in this research area is the development of harmonised reliable methods to assess occupational exposure to ENMs and to produce preliminary work for standardisation. The predominant route of occupational exposure is inhalation.
There is a need to test the effectiveness of instruments and to develop improved measurement tools (affordable and portable devices which allow personal and on-line detection of ENMs and their distinction from nanoparticles originating from sources other than industrial processes). In addition, from a workplace monitoring perspective there is a need to define which significant characteristics of ENMs should be measured and how. Common measurement strategies should be defined and field-tested.[6]
The research needs also to include an understanding of the potential release and the fate of ENMs after emission. One promising approach is to benchmark (and if possible harmonise) dustiness testing. Exposure should be assessed for all stages of the ENM life cycle. However current knowledge is mainly from primary production with very limited data for applications. Research about release of nanomaterials during the use of ENMs in liquids or embedded in matrices is needed.
Exposure modelling is used in regulatory risk assessment. Extensive work is still required for validation of existing exposure models when applied for ENM and for new model approaches to be developed.

2.3 Research on exposure control and risk management

There is a need to conduct quantitative evaluation of efficiency of ventilation and capture devices at workstations producing or handling ENMs.
The following issues should be investigated: containment efficiency of ventilation devices, robustness of the containment with respect with to disturbances, influences of the ENM source and surface contamination.
Another key research area relates to the effectiveness of respiratory protective devices. Face seal leakage and protection factors against nanoparticles have to be studied in laboratory and in the workplace.
The result of the research will be translated into risk management guidance. Risk management has to be integrated in the early stages of the development of new substances and technologies. In this context, research is needed to validate appropriate control banding techniques.

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