

the effectiveness of respiratory and dermal protection equipment, and local exhaustive ventilation (LEV) systems to control the exposure to ENMs in occupational settings. New experimental data on the protection factors achieved under representative exposure scenarios, as well as recommendations for the design of PPE and ECs will be presented.

The testing activities were conducted after the validation of a set of standardized procedures, including the evaluation of the permeation to ENMs for dermal protective equipment, total inward leakage (TIL) inward leakage for respirators and filters, and capture efficiency for ventilation systems. The experimental work was conducted in a dedicated nano-aerosol exposure chamber where several exposure scenarios can be reproduced. The results from the test suggest that the control of exposure via inhalation is a key priority. Respirators provided medium performance levels of filtration efficiency against NMs. The performance levels determined suggest that face seal leakage, and not filter penetration, is a key parameter to be considered when working with NMs. The evaluation of dermal protective equipment showed very low permeation levels, meaning that common measures are effective.

The capture efficiency of the LEV systems was demonstrated to be adequate. The data are compiled in a library of nano-specific RMMs developed using Microsoft Excel®. The library helps stakeholders to select proper measures depending of the type of ENM and process, guiding the user in the selection of proven risk management measures. The research leading to these results has received funding from the European Union's FP7 Grant Agreement n. 310584 (NanoReg project), and the LIFE project NanoRISK (LIFE ENV/ES/000178).

## **An analysis of the OECD WPMN dossier regarding the availability of data for risk assessment**

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The OECD Working Party on Manufactured Nanomaterials (WPMN) recently published dossiers of their Sponsorship Programme for testing 11 important Manufactured Nanomaterials (MNM). Our study aimed to assess its usefulness for regulatory risk management of MNM.

We first identified information available in the dossiers on Test guidelines used; Environmental fate and pathways; Ecotoxicological/Toxicological information; Manufacture, use and exposure of nanomaterials; and Human exposure scenarios. In a refined analysis we assessed the Endpoint Study Records (ESR) of three types of nanomaterials (fullerenes, SWCNT and zinc oxide) regarding availability of characteristics recommended by nanosafety experts: chemistry, nanoscale descriptors and circumstances of the (eco)tox experiments.

All 6075 dossier pages were thoroughly reviewed and 5279 annex pages were referred to when necessary. The testing programme adopted 131 test guidelines, 65 from OECD. Good overall coverage of endpoints was seen for aquatic, acute and geno-toxicity; Moderate coverage for terrestrial systems; and poor coverage for long-term effects and human toxicity. No ESR were identified for carcinogenicity and almost no data was available about the manufacture, use and exposure of nanomaterials. Most ESR (> 96%) provided only chemical description and circumstances of the experiments, while only very few study records provide nanospecific characteristics of actually delivered preparations.

The dossiers represent an enormous chemical testing effort. However, the data provided is mostly insufficient to make statements regarding the nanospecificity of observed hazard data, and to what nano-scale properties they may be linked. The dossiers also do not allow conclusions on the appropriateness of current Testing Guidelines for assessing ENM hazards. Finally, the possibility of artefacts and thus the potential for false negative toxicity results cannot be assessed on basis of reported data.

The first version of the software was realised and has been tested by PEROSH members and three external partners. It is planned to offer the software to organisations, which perform exposure measurements for nanomaterials, and companies that produce or use nanomaterials. Aim is to enlarge the number of users and datasets and thus enhance the benefit for the users. Participating companies e.g. can benchmark themselves amongst their peer group. Scientific users can enlarge data pools to strengthen statistical conclusions or validate their measurement results with reference data. Finally public access shall be enabled to publish consolidated and anonymised information.

**Conclusion:**

Due to the limited amount of data in the field of exposure to nanomaterials, a harmonised exposure database linked to other databases, e. g. on material or toxicological properties, is able to accelerate the improvement in occupational safety.

## **A critical and in-depth analysis of the environmental aspect of the OECD SP dossiers**

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In 2015, the OECD finally published the findings of its seven-year testing programme for manufactured nanomaterials. Here, we present the first in-depth analysis of the published OECD dossiers with regards to data on physical and chemical properties, environmental fate and ecotoxicology. Each individual study in the dossiers was reviewed with regard to, among other, which OECD Test Guidelines (TG) were used, and the reliability assigned to the study. We furthermore analyzed in detail the suspension methods used, how media quality was quantified and physical and chemical characterization performed prior, during and/or at the end of the study. We find that the information in the dossiers present an incomplete portfolio of nanomaterial ecotoxicological evaluations that are difficult to draw substantive conclusions from and that most of the studies were not designed to investigate the validity of the OECD test guidelines. We acknowledge the effort of the OECD WPMN and recommend that a follow-on program is established with well-defined goals, end-points and direct funding to qualified research laboratories to ensure valid, rigorous, reproducible and efficient research.