NANORISK

LAYMAN´S REPORT

Best practices effectiveness, prevention and protection measures for control of risk posed by engineered nanomaterials

LIFE12 ENV/ES/178

With the contribution of the LIFE financial instrument of the European Commission

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DATA PROJECT

Project location	Valencia (Spain)
Project start date	01/10/2013
Project end date	30/09/2016
Total budget	1,165.973 Euro
EC contribution	582.893 Euro
(%) of eligible costs	50%

DATA BENEFICIARY

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PROBLEM TARGETED

Nanotechnology is a widely applied cross-sectional technology with innovations in almost all industry sectors, with potential applications in a wide range of sectors, from energy (production, catalysis, storage), materials (lubricants, abrasives, paints, tires, and sportswear), electronics (chips and screens), optics, and remediation (pollution absorption, water filtering and disinfection), to food (additives and packaging), cosmetics (skin lotions and sun screens), medicine (diagnostics and drug delivery), and numerous other industrial sectors.

Due to its potential to develop new added value products, the use of engineered nanomaterials (ENMs) is growing continuously, with a staggering number of ENMs on the market. However, along with the benefits, there is an **on-going debate about their potential effects on the human health or the environment**.

As nanotechnology applications move from research laboratories to industrial and commercial settings, the likelihood of workplace exposure and industrial releases of ENMs will tend to increase, and therefore, producers and users of engineered nanomaterials should take appropriate measures to ensure a safe and healthy work environment, and prevent release of ENMs into the environment.

Recent publications have demonstrated that ENMs can be released to the environment during production, further processing, use and disposal life cycle stages. Recent reports from different EU research projects as well as other peer reviewed publications have demonstrated the release of ENMs to the environment, with concentrations up to micrograms level in rivers, which produces adverse effects in sensitive species.

Within this context, the scheduled actions and tasks are aimed to define proven Risk Management Measures (RMMs) to prevent or minimize exposure to ENMs during the specific workplace situations of the polymer nanocomposite industry, as well as to develop a

functional test chamber prototype to support a standardized evaluation of the adequacy of Personal Protective Equipment (PPE) and Engineering Controls (ECs) to protect workers from the risk posed by use of ENMs.

From a regulatory point of view, and considering the LIFE + priorities, the project supports the implementation of the **EC regulation 1907/2006 REACH**, which plays a central role to ensure the protection of environment and health from risk posed by emerging chemicals such as ENMs to the extent that the responsible of the commercialization of substances, in whatever size, shape or physical state, must evaluate the environmental, health and safety (EHS) risk across the product life-cycle, reporting to the European Chemicals Agency (ECHA), the necessary measures to achieve an acceptable level of risk on the basis of the risk characterization process.

It has been acknowledged that the existing REACH based risk assessment paradigm developed for traditional chemicals should also be applied to ENMs (OECD, 2012). Nevertheless, these steps need specific considerations in practice when applied to NMs (e.g. metric to use, exposure assessment methodology etc.), introducing new challenges for regulators, as well as all other stakeholders. Moreover, current knowledge on the effectiveness of personal protective equipment and technical measures against nanomaterials is still scarce.

NanoRISK focuses on the generation of knowledge on the exposure potential to ENMs in workplaces, as well as on the development of guidance documents and tools to assist companies and stakeholders on the selection of proper risk management measures to control and reduce the potential exposure to ENMs in workplaces.

NanoRisk SOLUTION

The goal of the LIFE NanoRisk project is to provide the industry and regulators with a list of **robust testing methods** and **reliable data** on the effectiveness of common risk management measures, including local exhaustive ventilation (LEV) systems, respiratory, dermal and eye protective equipment.

In particular, the objective of the activities conducted under the project are oriented to provide the industry with reliable methodologies and tools to obtain quantitative data on the effectiveness of personal protective equipment (PPE) and engineering controls (ECs) when dealing with NMs in dry form and/or dispersed in liquid.

The tools developed within NanoRISK take into account the needs of the industry and regulatory bodies, including advanced functionalities and data to assist small and medium sized enterprises (SMEs) and large companies to fulfil their main duties under REACH and currently applicable safety regulations. In detail, key stakeholders are:

- Health and safety advisors and occupational hygienists from private companies, universities and/or research organizations working with ENMs
- Workers and professional users who use ENMs as such, in mixtures or incorporated into articles in research or production processes
- Researchers from academia, non-profit research organizations and private research institutions

- External Occupational Safety and Health Consultants working with companies dealing with ENMs
- Experts from industry associations and other stakeholder organizations informing companies about the requirements for the safe handling and use of ENMs on a regulatory basis, especially for risk control purposes
- Experts from standardization (i.e. ISO committees) and/or regulatory bodies (i.e. ECHA).

The tools and solutions developed included:

A user-friendly library of risk management measures, developed and programmed using Microsoft EXCEL, and oriented to assists companies in the selection of adequate and experience based personal protective equipment (PPE) and engineering controls (EC) for preventing exposure to nanomaterials and release in the workplace.

A **multimedia guidance on recommended measures to reduce and control the exposure nanomaterials to in the workplace**. The on-line version contains interactive figures, downloadable videos and links specifically designed to support the achievement of the main objective of the guide, the selection of adequate measures to control the exposure to ENMs and prevent release into the environment.

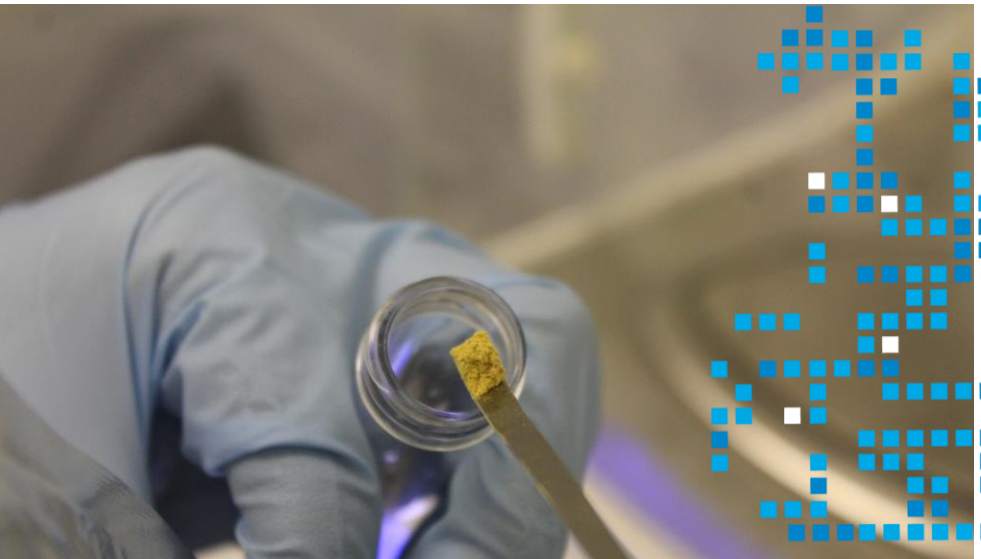
A functional and validated **exposure chamber prototype**, developed by the members of the consortium and designed to guarantee the performance of reproducible experimental activities and the generation of reliable data on the effectiveness of personal protective equipment and technical measures.

The NanoRISK guidance and RMM library are permanently accessible and free of charge via the World Wide Web through the URL: **http://www.lifenanorisk.eu** . These tools are continuously updated by the nanosafety research group of the project coordinator, ITENE, including relevant news, documents and links directly related with the implementation of REACH.

PROJECT DEVELOPMENT

The project has been coordinated by ITENE, a technological institute located in Valencia (Spain), with wide experience in nanotechnology and safety issues. The scheduled actions are supported by: VITO, a research organization which is involved in several projects related with the nano safety field; Avanzare, a company supplier of high-performance nanomaterials and nanotechnology based solutions, located in Zaragoza (Spain); CRP, a company which activities address the application of micro and nanotechnologies for photonics and lighting devices in the automotive and civil sectors; INVASSAT, a public body in charge of the promotion of the implementation of occupational healthy and REACH at regional scale (Comunidad Valenciana – Spain); and INSHT, a public body in charge of the promotion of occupational health and safety at national level (Spain).

The NanoRISK project is structured in 5 main actions on the basis of the type of eligible actions under the framework of the LIFE + call, including preparatory (A1 to A4), implementation (B1 to B7), monitoring (C1 to C5), communication (D1 to D4) and management (E1 to E4).



The specific actions conducted are depicted in the table:

Action nº	Action Title	Action Leader
	Preparatory Actions	
A.1.	Selection and description of the types of nanomaterials	ITENE
A.2.	Information gathering on the conditions of use, risk management measures and exposure data across nanomaterials life cycle	ITENE
A.3.	Compilation of data regarding the efficiency of risk management measures for occupational and environmental exposures	VITO
A.4.	Identification of the test chamber prototype requirements for standardized testing	VITO
	Implementation Actions	
B.1.	Compilation and critical evaluation of the published standards for determining the protection efficiency	VITO
B.2.	Design and construction of the test chamber prototype for demonstration activities	ITENE
B.3.	Development of the testing activities according to the selected approaches	ITENE
B.4.	Development of a Risk Management Measures (RMM) library tool	ITENE
B.5.	Scaling up to industrial case studies	CRP

B.6.	Guidance on the required measures and controls for mitigating and control the risk posed by the target nanomaterials during its entire life cycle	INSHT
B.7.	Training activities for end users and stakeholders	INVASSAT
Monitioring Action		
C.1.	Definition of the starting situation – baseline	ITENE
C.2.	Quantitative Assessment and monitoring of the protection factors achieved under controlled conditions	ITENE
C.3.	Evaluation of the improvements achieved in industrial conditions	CRP
C.4.	Promotion of REACH fulfilment by implementing the LIFE nanoRISK project	ITENE
C.5.	Assessment of the socio-economic impact of the project actions	ITENE
Communication and dissemination actions		
Project management and monitoring of the project actions		

Considering the objectives of the project and in view of the project scheduled actions, the activities conducted has been focussed on the selection of the design and development of the nanoaerosol testing chamber, the experimental evaluation of the effectiveness of conventional risk management measures against ENMs under controlled conditions and following new testing protocols defined and developed under the scope of the project, and the design and development of the NanoRISK RMM library and multimedia guidance.

In detail, the most relevant tasks and activities conducted can be summarized as follows:

1. Selection of the most relevant ENMs in the context of REACH, including carbon-based materials, metal and metal oxide nanoparticles, layered nanoclays and nanocellulose whiskers;
2. Characterization and description of the main activities and processes that are conducted across the life cycle stages of the target ENMs and polymer nanocomposites, describing in detail those processes that affect exposure and release in the workplace;
3. Definition of the specific types of Personnel Protective Equipment (PPE), ventilation, filtration and other workplace controls used to prevent, control or reduce the exposure at industrial level;
4. Definition of priority performance factors based on ISO standards, including total inward leakage (TIL) and average penetration factor (APF) for respiratory protection equipment, permeation and penetration factor for dermal protection equipment, capture efficiency for ventilation systems, as well as splash protection against ENMs in solution, among others;
5. Construction and validation of the nanoaerosol testing chamber prototype, being installed at ITENE facilities;
6. Definition and validation of a compendium of 10 full described protocols based on current ISO / ASTM standards commonly applied to evaluate the effectiveness of respiratory and dermal protective equipment, and engineering controls;
7. Development and validation of the experimental activities scheduled to evaluate the effectiveness of respiratory, dermal and body protective equipment, Exhaustive Ventilation (LEV) systems, and administrative controls.
8. Development and validation the Risk Management Measures (RMM) library;
9. Design and development of the guidance on the required measures and controls for mitigating and control the risk posed by the target NMs;
10. Definition of a priority list of actions to comply with REACH regulation according with the information generated on the levels of exposure and effectiveness RMMs studied;
11. Dissemination of the main outcomes of the project to the target audience by means of dedicated materials, workshops and REACH relevant events.

RESULTS

Following results were accomplished:

- A functional and newly developed aerosol testing chamber for the standardized evaluation of the effectiveness of the working procedures, prevention and protection measures to control the risk posed by ENMs.
- An interactive library of proven, technically feasible and economically viable organizational measures, personal protective equipment and engineering techniques to control and reduce the risk of exposure to ENMs.
- A multimedia guidance on recommended measures for mitigating and control the risk posed by nanomaterials.
- A compendium of 10 standardised protocols to evaluate the effectiveness of the work place controls against NMs.
- Enhancement on the knowledge base on the potential releases of ENMs to air, soil and water from industrial facilities on a life cycle basis; and on the parameters that determine the exposure to ENMs at industrial scale
- A support to the hazard and exposure characterization for ENMs with the aim to help the industry in carrying out their Chemical Safety Assessment (CSA) as stated by REACH
- A structured compendium of free webinars and workshops to support the training of end users and stakeholders in the use and implementation of the RMM.
- A set of informative material to disseminate the project actions at a Regional, National and European level.

Considering the data on the effectiveness of RMMs, special emphasis on the enhancement of the face seal during normal conditions of use shall be considered as key priorities to reduce the levels of exposure in occupational settings.

Results concerning protective gloves and clothes showed that common protective equipment offered a proper protection against ENMs, being similar to the efficiency of this type of protective clothes against chemicals, including vapour, gas, liquid jet, sprayed liquid, small splashes or dust and particles.

Finally, local exhaustive ventilation (LEV) systems, primary engineering control for controlling occupational exposures to nanoparticles, has been demonstrated to be effective at removing ENMs at their source, limiting or eliminating worker exposures altogether

In the long term, the improvement on the REACH implementation will enable the mitigation of risk posed by chemicals in general and engineering nanomaterials in particular, reducing the health and environmental impacts of substances at the nanoscale due to a better knowledge on the risk management measures.

CONCLUSIONS

The results of the project revealed that an adequate protection of the human health and the environment can be achieved by means of the combination of administrative controls, engineering controls and personal protective equipment. Notwithstanding, a proper risk evaluation by expertise staff should be conducted to evaluate the risk in the workplace. Moreover, as in the case of larger-scale chemical sub-stances, employers should arrange to review regularly the adequacy of the precautions taken, particularly if the circumstances of use change or in the light of new technical developments or information on the nanomaterials.

This project reflects that there is an urgent need to continue working in new designs and innovations to increase the performance levels of respiratory protective equipment (RPE), dermal protection equipment (DPE) and engineering controls (EC) against nanomaterials, with special emphasis on the need for considering realistic condition of use.

It shall be noted that the set of tools developed within the project are designed to guarantee a safe working environment when dealing with nanomaterials. The use and implementation of the tools developed are expected to support an overall reduction of unintentional emissions of nanomaterials into the workplace and the environment.

Further information of specific topics of the project and details on project outcomes can be requested directly contacting the project coordinator.

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CONSORTIUM

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