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

Publicly Available Report

Coordinator of the Project
ITENE

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Executive Summary

The LIFE NanoRISK project is focused on the **evaluation of the effectiveness of common risk management measures to prevent or minimize exposure to Engineered Nanomaterials (ENMs)** during the specific workplace situations of the polymer nanocomposite industry, including data on the efficacy of Engineering Controls (ECs), Personal Protective Equipment (PPE) and Administrative Controls (ACs).

To this end, the project focuses attention on the definition of the most relevant types of ENMs on the basis of market penetration and potential Environmental, Health And Safety (EHS) risks, the characterization of the main activities conducted at the workplace to improve the current knowledge on the exposure and release potential, and finally, the development of an aerosol testing chamber to conduct the evaluation of the risk management measures in controlled and reproducible conditions, ensuring the reliability of the data generated within the project.

The main goals of the project involve the d**efinition of a specific compendium of proven Risk Management Measures** (RMMs, i.e. personal protective equipment and engineering controls) **to mitigate and control the exposure to ENMs in occupational settings and the reduction of the amount of ENMs released into the environment**, to support the RMM library developed within the REACH Implementation Projects, with experimental data on the effectiveness of PPE, engineering techniques and organizational measures against NMs, and to develop an aerosol testing chamber prototype able to evaluate and demonstrate the performance of the RMM at laboratory scale.

The achievement of these objectives will promote the protection of environment and health from risks posed by ENMs, providing new data on exposure patterns and the inputs for the chemical safety assessment process in the context of REACH regulation (Exposure estimation and RMMs efficiency), both relevant aspects to consider evaluating the safety use of the nanomaterials in a regulatory context.

In addition, it´s expected an overall reduction between 5 and 10 % of unintentional emissions to the air, water and / or soil compartment from production processes, depending on the specific risk management procedures and measures implemented by the industry.

The abovementioned results will promote the protection of environment and health from risks posed by nanomaterials, providing new data on exposure patters and the inputs for the chemical safety assessment process in the context of REACH regulation of exposure estimation and risk management measures efficiency, both relevant aspects to consider evaluating the safety use of the nanomaterials in a regulatory context.

The present document contains a complete description of the activities conducted within the NanoRISK project, including detailed information of the progress so far and results encountered in each of the actions conducted up to date.

Introduction to the NanoRisk Project

As above mentioned (*cf*. Executive Summary), the project rises from the need to ensure a high level of protection of human health and the environment from the risks that can be posed by the use of ENMs.

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 PPE and ECs to protect workers from the risk posed by use of ENMs.

The concept of the project is depicted in the Fig. 1, where the scheduled actions and their interdependence are shown schematically, highlighting the need for reducing the current lack of data on the potential hazards of common ENMs, exposure levels in occupational settings and effectiveness of risks controls, key barriers that constrain the commercialization and use of ENMs.

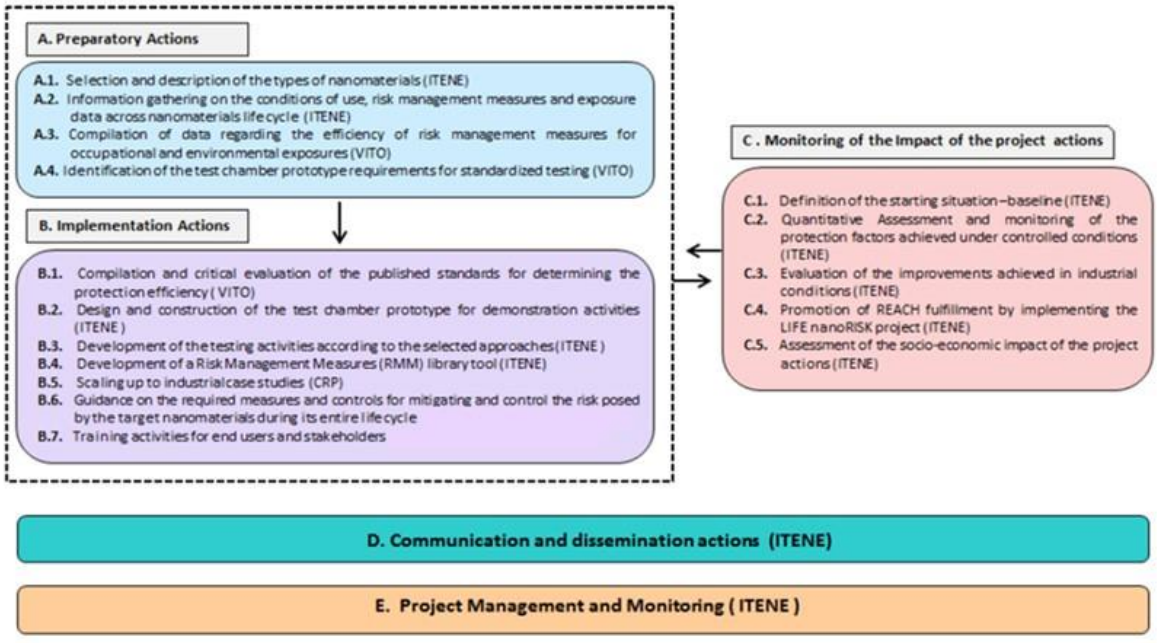

Figure 1. Concept of the NanoRISK project

In this document, the activities undertaken and outputs achieved so far in quantifiable terms conducted since the beginning of the project are summarized. A more detailed description of the results is provided in the deliverables developed according with the work plan.

Action A1. Selection of representative ENMs

The main objective of the action is to define a set of representative ENMs in the context of REACH, taking into account the scope and exemption of REACH provisions. To this end, a set of specific activities were conducted, including the establishment of selection criteria, the compilation of relevant information on the use and forms of ENMs placed on the market and the selection of target ENMs according with their industrial relevance and potential risks.

The analysis of the information gathered resulted in a list of 12 ENMs depicted in Table, 2, considering different forms and different chemical composition and main sector application.

Table 1. Target Engineered Nanomaterials

GROUP	NANOMATERIAL	Sector
INORGANIC NON-METALLIC	Silicon dioxide	Packaging & building
	Titanium dioxide	
	Zinc oxide	
	Cerium dioxide	
	Iron oxide (Fe_3O_4)	Automotive & electronics
	Silver	Packaging, building,Automotive & electronics
CARBON-BASED	CNTs	Automotive & electronics
	Graphene	
	Carbon black	
	Fullerenes	Electronics
Natural NMS	NanoClays	Packaging, building, Automotive & electronics
	Nanocellulose	

Action A2. Information gathering on the conditions of use, risk management measures and exposure data across nanomaterials life cycle

Within this action was intended to gather information related to the operative conditions and RMMs commonly employed across the ENMs and nanocomposites life cycle, including activities such as the synthesis at laboratory scale, manufacturing at industrial scale, nanocomposites production at industrial sites and waste management.

As a result, 30 Exposure Scenarios (ES) grouped in four main Generic Exposure Scenarios (GES) were defined, considering all life cycle stages of a nanoparticle used for developing nanocomposites materials within the studied sectors.

Action A3. Compilation of data regarding the efficiency of Risk Management Measures for occupational and environmental exposures

The aim of this action is to collect information on the effectiveness of the RMMs, including the definition of the performance factors of the RMMs selected, the identification of reliable information on the efficacy of ECs, PPE and ACs and the critical evaluation of the experimental approaches retrieved from the literature.

A compendium of 15 performance factors have been defined and additionally, a list of 29 priority references containing reliable data on the RMMs efficiency have been included into and excel spreadsheet.

Action A4. Identification of the test chamber prototype requirements for standardized testing

During this action the technical requirements of the test chamber prototype were clearly defined, such as equipment needed to perform the experiments, spatial dimensions, volume (m^3), number of sampling points (aerosol inlets), number of aerosol outlets, proposed building materials, range of environmental conditions and air flow rates, characteristics necessary to conduct standardized testing activities.

The design of the chamber considered as key issue the maintenance of a safe environment inside. To this end, there was established a pressure drop between the outside air and the air inside the room, forcing the airborne materials to remain in the room with negative pressure, being very unlikely a release of the nanomaterials outside the chamber.

The activities conducted within the action are reported in deliverables A4a and A4b, this last focused on the description of the chamber requirements.

Action B1. Compilation and critical evaluation of the published standards for determining the protection efficiency

The compilation and identification of the current standards and guidelines on testing RMMs effectiveness was the main purpose of the action B1. The applicability of the experimental set up was evaluated to subsequently develop adequate protocols based on the specific characteristics of the ENMs, including low solubility, aggregation/agglomeration patters or airborne behavior among others, as well as the specific measurement instruments and analytical techniques needed to evaluate the performance factors defined by each standard.

A total of 10 protocols have been developed, including 3 for respiratory protection (masks, filters), 3 for protective clothing (coats, gloves), 2 for engineering controls (LEVs) and another 2 for administrative controls (maintenance, cleaning). These protocols are listed below.

1. Determination of inward leakage of nanoparticles
2. Determination of total inward leakage of nanoparticles
3. Determination of particle filter penetration by nanoparticles
4. Determination of inward leakage of aerosols of nanoparticles into suits
5. Determination of resistance to penetration by spraying a liquid solution of nanoparticles
6. Determination of permeation to nanoparticles in gloves
7. Determination of particle filter penetration in local exhaust ventilation
8. Determination of fume hood effectiveness
9. Determination effectiveness of RMMs during maintenance operations
10. Determination effectiveness of RMMs during cleaning operations

Action B2. Design and construction of the test chamber prototype

The aim of this action was to design and construct the test chamber prototype on the basis of the requirements defined in action A4, including the definition of the structure and spatial dimensions, the development and building, conditioning and validation of the chamber.

The chamber has been designed by ITENE and VITO on the basis of the requirements of the testing protocols detailed into relevant standards. The validation activities were conducted after the construction of the chamber in ITENE, including the evaluation of the adequacy of the functioning parameters to develop the experimental set up defined under relevant standards. The validation was conducted following a phased approach, considering in a first stage the evaluation of the compliance with the specifications defined by ITENE and VITO and in a second stage, the operating range of the chamber in term of airflows, illumination, pressure, temperature and humidity.

The following figure includes images of the nanoaerosol testing chamber.

Figure 2. External views of the testing chamber

Action B3. Development of the testing activities according to the selected approaches

The main aim of the action is to design a series of experimental set ups to conduct the testing activities and the execution of the experiments according to the specifications of the standardized approaches evaluated within action B1, including when needed modifications of the methods due to the special characteristics of the nanoparticles. Some of these experiments are shown in Fig. 3.

Figure 3. Samples of some experimental set ups for RMMs testing: masks (upper left), LEVs (upper right), suits (down left) and gloves (down right).

Although the action is currently on going (it is expected to finish it by July 2015), some preliminary results can be found in deliverables B3a and B3b, and a summary of the effectiveness factors defined so far are included in table 2.

Table 2. Effectiveness levels under static and simulated conditions

			Av Protection	
RMMs	**Specifications**	**Performacen factos**	**Static**	**Simulated**
Disposable filtering half mask	Filter type P2L	Total inward leakage	79 ± 3 %	69 ± 9 %
	Filter type P3L		84 ± 3 %	73 ± 5 %
Unpowered Half mask	Filter type P2L		89 ± 5 %	81 ± 5 %
	Filter type P3L		91 ± 3 %	86 ± 8 %
Unpowered Full face mask	Filter type P2L		93 ± 3 %	90 ± 3 %
	Filter type P3L		95 ± 2 %	92 ± 6 %
Chemical protective gloves	Nitrile	Permeation	98 ± 1 %	91 ± 4 %
	Butyl		99 ± 1 %	96 ± 3 %

RMMs	Specifications	Performacen factos	Av Protection	
			Static	Simulated
Body protection	Laboratory Coats / Pants	Particle penetration	80 ± 1 %	70 ± 4 %
	Full Body Suit (Tyvek / Saranex)		98 ± 1 %	89 ± 6 %
	Chemical Splash Suit		91 ± 5 %	85 ± 5 %
Eyes protection	Safety glasses	Total inward leakage	91 ± 5 %	86 ± 5 %
Receiving hoods (LEV Systems)	Canopy hoods	Capture efficiency	65 ± 5 %	60 ± 7%
Capturing hoods (LEV Systems)	Movable capturing hoods	Capture efficiency	70 + 5 %	64 ± 5 %

Some conclusions which arise from the experimental results so far suggest that the control of exposure via inhalation is a key priority when dealing with ENMs. However, conventional chemical protective gloves and protective suits are effective against ENMs, being the use of butyl or nitrile gloves recommended. it shall be noticed as well the reduction on the average protection factor under simulated conditions of the personal protective equipment tested, which is mainly due to the effects of the body movements on the fitting.

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