NanoRISK

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

Contract Agreement: LIFE12 ENV/ES/178 Website: http://www.lifenanorisk.eu
Coordinator: Carlos Fito, Packaging, Transport and Logistics Research Center , Valencia, Spain

No.	Beneficiary name	Short name	Country
1	PACKAGING, TRANSPORT AND LOGISTICS RESEARCH CENTER	ITENE	Spain
2	VITO NV- VLAAMSE INSTELLING VOOR TECHNOLOGISCH ONDERZOEK N.V.	VITO	Belgium
3	AVANZARE INNOVACION TECNOLOGICA S.L.	AIT	Spain
4	CENTRO RICERCHE PLAST-OPTICA S.P.A	CRP	Italy
5	INSTITUTO VALENCIANO DE SEGURIDAD Y SALUD EN EL TRABAJO	INVASSAT	Spain

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Project Duration: 1 October 2013 – 30 June 2016
Project Budget: 1,165,973EUR

1 Summary

The nanotechnology came out as a key enabling technology (KET) to contribute to a sustainable development of "High-Tech" applications under several industrial sectors such as packaging, building, cosmetics, health care, textiles, waste management, household, detergents, electronics, ceramics or painting.

Along with the benefits, **there is an on-going debate about their potential effects on human health or the environment**, considering as a key issue the potential adverse effects of ENPs on workers upon inhalation.

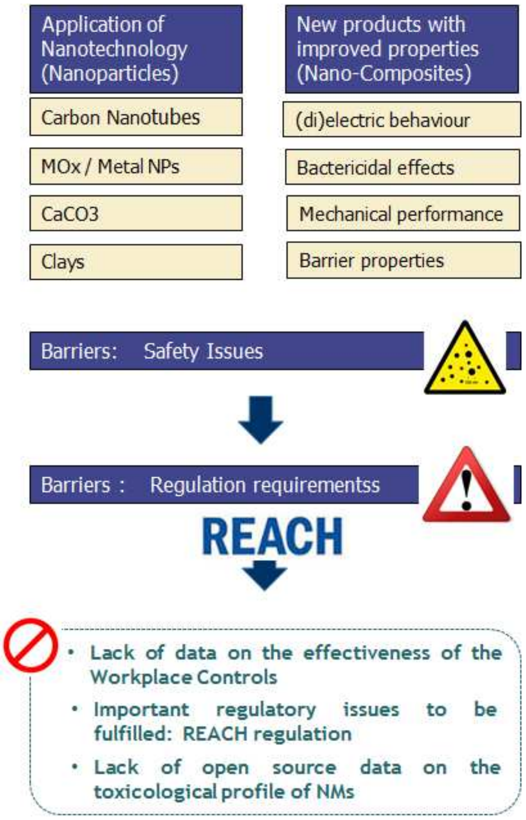
Moreover, recent publications have demonstrated that ENPs can be released to the environment during production, further processing, use and disposal. Recent reports from EU research project as well as other peer reviewed publications have demonstrated the release of nanomaterials to the environment, showing concentrations up to micrograms in rivers, which involves adverse effects in sensitive species. Similarly, studies focused on the release of ENMs from the production sites have found concentrations up to 4.6x 106 pt/cm3, which depending of the type NMs could exceed the current Occupational Exposure Limits (OELs).

In order to address these major concerns , the **main objective of the project is to define proven Risk Management Measures** (RMMs) to prevent or minimize exposure to engineered nanomaterials (ENMs)during the specific workplace situations of the polymer nanocomposite industry, as well as to **support standardization activities concerning the certification of the adequacy of Personal Protective Equipment** (PPE) and **Engineering Controls** (ECs) to protect workers from the risk posed by use of ENMs.

Within this context, the **concept of the project in to ensure a high level of protection of human health and the environment** from the risks that can be posed by the use engineering nanomaterials.

On the other hand, considering the LIFE + programme priorities, the implementation of chemical legislation, and in particular REACH regulation, **plays a central role to ensure the protection of environment and health** from risks posed by chemicals by 2020, meaning that an investigation of proven strategies for controlling existing worker exposures and reduce release in the workplace is therefore not just interesting, but also necessary to provide the political decision-makers and stakeholders with solutions to ensure the sustainable development of the nanotechnology.

In view of the above, and considering the growing production of nanoparticles to develop high-tech applications, the project and its action stems from the need of supporting the mitigation and control of the emerging risk posed by the use of engineering nanomaterials.



2 Background

The use of nanomaterials is steadily increasing daily due to the new properties addressed by the nanotechnology based products. The data published show a significant increase in the production rates of the most representative nanomaterials with growth expected to achieve 2 billion jobs by 2015, being the European Union responsible for 30 % of nanomaterials manufacturing and use.

In this respect, the main materials and substances at the nanometer scale currently produced in the Europe include nanopowders (metals, metal oxides, alloys), magnetic nanomaterials, carbon nanotubes (single, multi-walled), nanoceramics, nano-silica (fumed, colloidal), quantum dots (metal and semi-conducting nanocrystals) and polymer composites containing nanoreinforcements.

Such rapid proliferation results in a key environmental problem due to the fragmentary scientific knowledge of their health and environmental impacts and subsequent effects on ecosystem health.

Taking into account the current situation, the rising production and use of ENMs is generating both environmental and human health impacts. To overcome the adverse effects of the nanotechnology development in the environment, REACH regulation will play a central role to the extent that the responsible of the commercialization must evaluate the environmental exposure across the product life-cycle, reporting to the European Chemicals Agency (ECHA), the necessary measures to achieve an acceptable level of exposure on the basis of the risk characterization process.

Taking into account the current situation, the **project deals with the characterization of highly-efficient work place controls to reduce and control the risk posed by the use of ENMs**.

The project is focused on the polymer nanocomposites industry, where several studies show a substantial release of engineering nanomaterials during the production process. In addition, recent estimations of the levels of release performed by within the FP7 project NanoSafePack show that the current production of nanocomposites will result in a release of 4,895 metric tons of engineering nanomaterials to the environment, where the release via air is the main source of environmental pollutions (71 %), followed by water and soil.

Regarding the levels of exposure, data retrieved from the literature shows levels of exposure up to 4,6x105 pt/cm3 and mass concentrations up to 53 µg/m3. In the specific case of the nanocomposite industry, recent studies demonstrate that the weighing and sanding processes of 600 mg of NMs is able to generate a respirable mass concentration up to 2.68 µg/m3. In addition, measurements in the breathing zone results in mass concentrations up to 31.5 µg/m3. In view of such data, the production of 1 tonne of nanomaterial can generates a mass concentration of airborne NMs up to 4.5 mg/cm3, which depending of the type NMs could cause adverse effects upon exposure via inhalation or dermal exposure.

In view of such data there is an urgent need to provide the industry with proven, technically feasible and economically viable organizational measures, Personal Protective Equipment (PPE) and engineering techniques to control and reduce the risk of exposure to engineering nanomaterials.

Scientists agree that if engineering controls are well designed they will be effective in limiting nanomaterials exposure. However engineering controls need to be supplemented by good work practices and the use of appropriate PPE (Tsai & Hallock 2007), which are especially relevant where other approaches such as elimination, substitution or modification of nanomaterials is not possible.

3 Concept and Objectives

3.1 Project Concept

The **NanoRISK project deals** with the characterization of highly-efficient work place controls to reduce and control the risk posed by the use of ENMs in the nanocomposite industry, as well as with the development of standardized approaches to support the testing and demonstration activities.

The overall aim of NanoRISK project is to improve the protection of environment and health from risk posed by chemicals by supporting the implementation of the REACH regulation with regard to nanomaterials, whose use raise many questions and generate concerns due to their potential health and environmental risks. On the basis of this concept, the following activities will be conducted:

a- Generation of practical information to be used in the context of REACH, including the selection of representative nanoscale materials , the identification of reliable information to evaluate hazard and exposure, as well as the identification of information sources regarding the effectiveness of common Risk Management Measures against nanomaterials , all of them key aspects fort risk assessment purposes on a regulatory basis.

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b- Characterization of standard protocols to support the quantitative evaluation of the effectiveness of workplace controls

c- Design and development of an aerosol testing chamber prototype for the for the standardized evaluation of the effectiveness of the working procedures, prevention and protection measures to control the risk posed by engineered nanomaterials.

d- Generation of reliable data on the airborne behaviour and release ratios of relevant engineered nanomaterials, including new data on their aggregation/agglomeration patterns and deposition factors under the specific operative and environmental conditions of use presented in the nanocomposites production facilities

e- Promotion of REACH fulfilment by implementing a RMM library containing reliable information on the protection factors of common risk controls against nanomaterials.

3.2 *Project Objetives*

The main objective of the project is to **define proven Risk Management Measures (RMMs) to prevent or minimize exposure to engineered nanomaterials (ENMs) during the specific workplace situations of the polymer nanocomposite industry**, as well as to support standardization activities concerning the certification of the adequacy of Personal Protective Equipment (PPE) and Engineering Controls (ECs) to protect workers from the risk posed by use of ENMs. In detail, and considering the role of REACH regulation and the LIFE+ priorities, the specific objectives of the project are:

- To support the Library on RMM (RMM library) developed within the REACH Implementation Projects with quantified data on the effectiveness of personal protective equipment (PPE), engineering techniques and organizational measures;
- To develop an aerosol testing chamber prototype to evaluate and demonstrate the performance of the RMM at laboratory scale;
- To improve the knowledge base on the parameters that determine the exposure to ENMs at industrial scale;
- To enhance the knowledge base on the potential releases of ENMs to air, soil and water from industrial facilities on a life cycle basis;
- To analyze the adequacy of current international standards (ISO /CEN /ASTM) to evaluate the effectiveness of PPE and collective protection measures;
- To improve the knowledge on the likely Exposure Scenarios in the nanocomposite industry;
- To support the hazard and exposure characterization for ENMs with the aim to support the industry in carrying out their Chemical Safety Assessment (CSA) as stated by REACH;
- To disseminate the project results for a large community of SMEs and potential stakeholders;
- To support the monitoring of REACH compliment and its impact on risk mitigation and prevention of pollution posed by NMs.

4 Overall view of the Workplan

The NanoRISK project is structured in 5 main actions on the basis of the types of eligible actions under the framework of the LIFE + call.

The scheduled actions and the responsible partner are included in the following table:

Table 1: Scheduled Actions of NanoRISK

WP nº	WP 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 and risk management measures 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 pilot plant 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	INVASSAT
B.7.	Training activities for end users and stakeholders	INSHT
Monitoring 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	ITENE
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

As can be derived from the table, the work plan has been split into 3 types of activities or actions and based. The overall objectives of each activity are explained below:

1. Preparatory Actions

A set of four preparatory actions will be conducted aiming at clearly define a set of representative NMs in the context of REACH, identify the specific exposure scenarios across their life-cycle, evaluate the feasibility and accuracy of the current approaches for testing and define in detail the technical requirements of the test chamber.

2. Implementation Actions

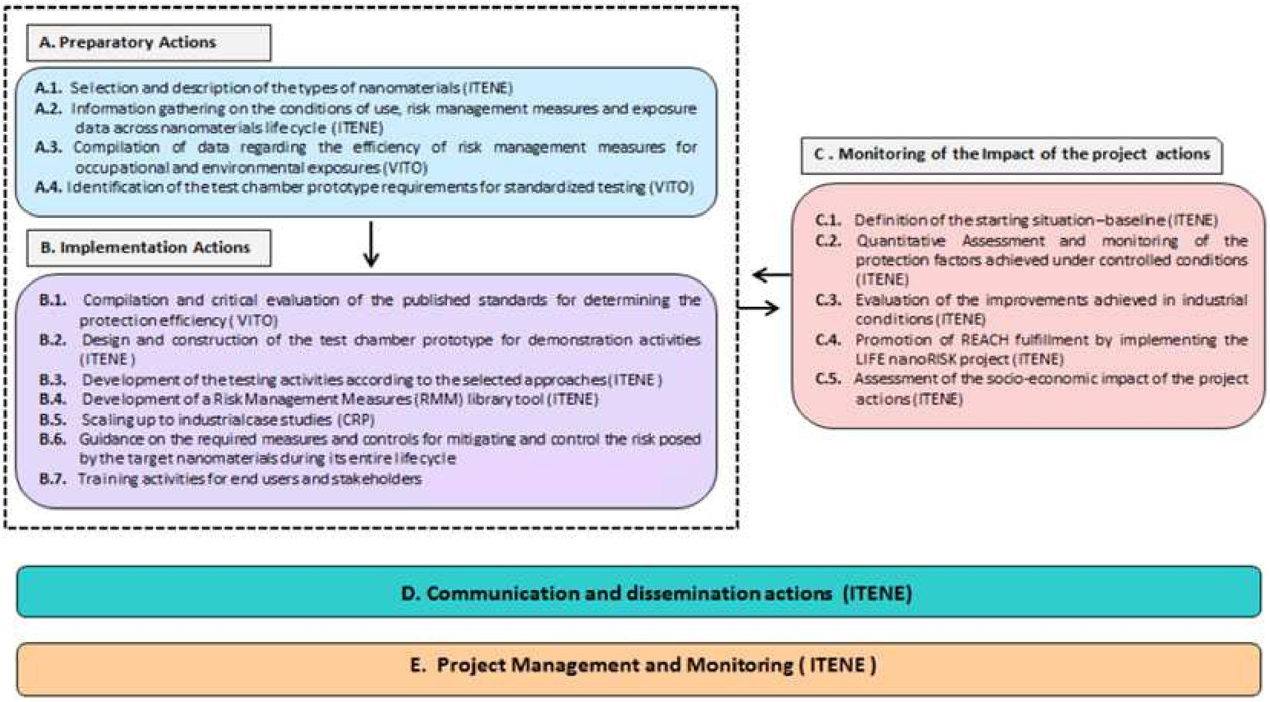
The implementation actions will work on the validation of the workplace controls to prevent or minimise exposure to ENMs including the design of a test chamber prototype for harmonized testing , the development of tools to support the decision making process for selecting control approaches for NMs and Scale up studies.

3. Monitoring Actions

These actions will be focussed on the monitoring of the improvements addressed by means of the project actions, as well as the adequacy of the developed means to address the specific problems and threats.

Besides the above, in order to achieve an optimal management and use of the Project across the EU, management and dissemination actions are also essential to the success of the NanoRISK project.

The scheduled actions and their interdependence are shown schematically below:



5 Added value to EU policies and regualtions

The project will explore legal and policy issues, as well as scientific and technical issues, that might arise in the application of the regulatory process related to the use of NMs at the workplace. At this stage, the project results will increase the knowledge about the risk to the human health and the environment, supporting the regulatory activities with scientific data to establish new legal requirements to the use of NMs in the nanocomposite industry in particular and other nanotechnology fields in general.

The project is aligned with the considerations expressed by the European Parliament resolution of 24 April 2009 on regulatory aspects of NMs, which explains that the use of NMs should respond to the real needs of citizens and that their benefits should be realized in a safe and responsible manner, considering the potential EHS problems.

Research activities are ongoing under the Research Framework Programmes and the Joint ResearchCentre, as well as in EU Member States and internationally within the OECD Working Party on MNMs and the International Organization for Standardisation. According to the Europe 2020 strategy, one of the strategic goals will be ensuring the safe development and application of nanotechnologies by advancing scientific knowledge of the potential impact of nanotechnologies on health or on the environment, and providing tools for risk assessment and management along the entire life cycle. In this sense, the future needs may include identifying and demonstrating the effectiveness of containment technologies for safe handling of NMs through the life cycle, investigating the effectiveness of different work practices for human and environmental exposure mitigation, and strengthening current research on RMM including process enclosure, ventilation and PPE.

Therefore the nanoRISK project is in line with the research areas underpinning risk assessments and management in which new knowledge is more needed, bringing value to the European development of risk management knowledge by the identification of proven measures and controls to reduce exposure to NMs during its entire life cycle.

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6 Expected Results

The main outcomes of the project will be a **library of proven and technically feasible prevention and protection measures** for mitigating and control the environmental, health and safety (EHS) risks posed by nanomaterials during the nanocomposites production, use and release, as well as a set of standardized testing protocols based on the application of a newly designed test chamber to support the quantitative evaluation of the effectiveness of the workplace controls.

In detail, It´s expected to produce the following results:

- A library of proven, technically feasible and economically viable organizational measures, PPE and engineering techniques to control and reduce the risk of exposure to ENMs.
- A functional and newly developed testing chamber prototype for the standardized evaluation of the effectiveness of the working procedures, prevention and protection measures to control the risk
- A compendium of at least 10 well defined and standardized protocols to evaluate the effectiveness of the work place controls against NMs.
- A complete assessment report of the ISO standards for PPE testing
- A complete description of the current ES across the nanocomposites life cycle, including an in depth description of the existing OC, efficient RMMs and measured exposure levels.
- New information on the release rates to air, surface fresh and marine water, waste water and soil for each relevant stage on the life cycle
- New knowledge on the airborne behaviour of the target NMs, including new data on their aggregation/agglomeration patterns and deposition factors under the specific conditions of use presented in the nanocomposites production facilities.
- 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.
- A network platform to close the knowledge gaps about nanomaterials impact and to develop and implement, in collaboration with scientific committees

7 Progress to date

The project started officially on October 1st 2012, and had the project had its kick-off meeting at the coordinator facilities on October 23th.

Considering the concept of the project, expected outcomes, and in view of the project timetable and scheduled actions with the project, much of the activities since the beginning of the project have been focused on the definition of the ENMs to be studied within the project, the definition of the nature and extent of processes and activities conducted during the ENMs and nanocomposites (PNCs) production, use and disposal, as well as the determination of the minimum set of information to be generated during the effectiveness testing assays.

On the other hand, several meetings have taken place between partners to define the task under each action, especially between the technical partners ITENE and VITO, both involved in the characterization of harmonized approaches to evaluate the effectiveness of risk management measures against NMs and the design of the aerosol testing chamber prototype.

Finally, ITENE, in charge of the dissemination activities has prepared the first brochure of the project, which will be available in the project web site.

8 Directory

Table 2. Directory of people involved in this project.

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