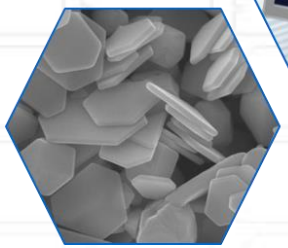
Best practices in NMs Risk Assessment

Demonstration actions under REACHnano and LIFE-NanoRISK Projects

PACKAGING, TRANSPORT & LOGISTICS RESEARCH CENTER

ITENE



REACHnan

REACHnano HELPDESK

NANORISK

Life

George Boulougouris R&D- NanoSafety and environmental modelling
ITENE - Packaging, Transport and Logistics Research Center
George.Boulougouris@itene.com

Wednesday, 21th of May, 2014

NANOSTRUC International Conference of Structural Nanocomposites – Madrid - 2014

SIRENA First International workshop of the SIRENA-Life Project

Best practices in NMs Risk Assessment: Demonstration actions under REACHnano and LIFE-NanoRISK Projects

Index

1. Overview of the REACHnano and Life NanoRISK projects
2. Risk Assessment approaches: REACHnano Toolkit & Nanoaerosol testing chamber

REACHnano HELPDESK

REACHnano and LIFE NanoRISK are funded by DG Environment under the LIFE+ Programme Environmental Policy and Governance (LIFE11 ENV/ES/000549) and ((LIFE12 ENV/ES/000168) respectively

Best practices in NMs Risk Assessment: Demonstration actions under REACHnano and LIFE-NanoRISK Projects

1. Overview of the REACHnano and Life NanoRISK projects

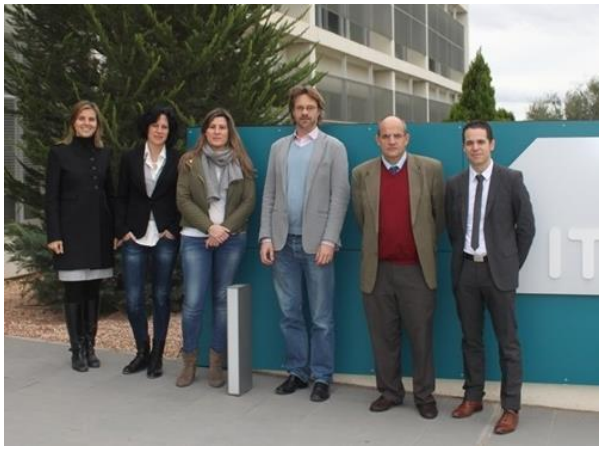
REACHnano and LIFE NanoRISK are funded by DG Environment under the LIFE+ Programme Environmental Policy and Governance (LIFE11 ENV/ES/000549) and ((LIFE12 ENV/ES/000168) respectively

1. Overview of the REACHnano and Life NanoRISK projects

REACHnano Presentation

- **Project Title:** Development of a web based REACH Toolkit to support the chemical safety assessment of nanomaterials
- **Theme:** Chemicals – Nanomaterials Risk Assessment
- **Call Identifier:** LIFE+ Programme Environmental Policy and Governance - 2011
- **Grant Agreement nº:** LIFE11 ENV/ES/000549

Official starting date: 1rst of October 2012
Duration of the project: 36 months
Ending date: 31th of September 2015



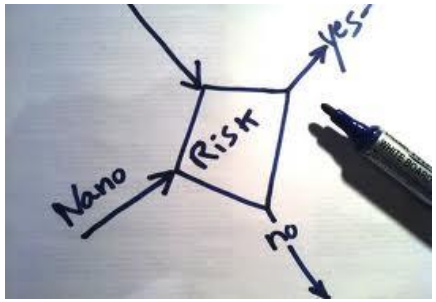
- Coordinator: Carlos Fito (ITENE)

1. Overview of the REACHnano and Life NanoRISK projects

❑ Motivation

REACH regulation establish a registration process for substances manufactured or imported in quantities of 1 tonne or more per year, where reliable information on the physicochemical, toxicological, and ecotoxicological properties, use and exposure shall be provided to the European Chemicals Agency (ECHA), however:

- There is an evident lack of knowledge regarding the PC and (eco)toxicological properties of ENMs
- There is no scientific agreement on the adequacy of the current methods for risk assessment, including test guidelines for hazard characterization and tools for exposure characterization
- A limited number of resources such as databases or guidelines are in place to support the implementation of REACH for substances at the nanometer scale

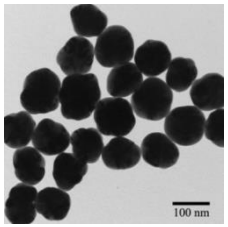


What can we do to change this situation?

1. Overview of the REACHnano and Life NanoRISK projects

❑ Objectives

The overall aim of REACHnano 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.



Use and Commercialization of Substances in Nanoform

REGULATION REQUERIMENTS

REACH

Health / Safety at Work

Environmental regulation

Technical Dossier - REACH regulation requirements for NMs

Physicochemical Properties

(Eco)Toxicological Properties

Exposure & Risk

REACH

- Lack of data on relevant properties
- Lack of information on ES
- Lack of Standards for testing
- Application of IUCLID 5
- Application of Chesar
- QSAR data
- Exposure Dosis / Metrics
- Risk Management Measures

REACHnano

REACHnano HELPDESK

1. Overview of the REACHnano and Life NanoRISK projects

Objectives

In detail, the key objectives are:

- To promote the enhancement of knowledge on the hazards posed by nanomaterials in their specific condition of use.
- To improve the access to information regarding physicochemical, toxicological and ecotoxicological properties of substances at the nanometer scale.
- To support the search for safer alternatives to potentially harmful nanomaterials
- To promote and support the implementation of environmental legislation, in particular REACH regulation as a key node to improve the protection of the environment
- To develop cost effective solutions to implement REACH properly, with special emphasis in the information exchange and the management of risk.

1. Overview of the REACHnano and Life NanoRISK projects

Scope

Considering the current situation, REACHnano project deals with:

- The **enhancement of knowledge base on risk assessment of ENMs** through the identification and evaluation of available information on the physicochemical, toxicological, ecotoxicological properties of the ENMs on the basis of the requirements laid down on REACH regulation

- The **development of a web based Help Desk tool** to support the risk assessment and promote the safety use of NMs along their life cycle, providing the industry and stakeholders with easy to use tools to support the implementation of REACH regulation.

1. Overview of the REACHnano and Life NanoRISK projects

Expected Results

- Development of a **web based toolkit for decision making support** on risk assessment and REACH compliment (REACHNano Toolkit), when manufacturing or handling substances at nanoscale,
- Development of a set of **3 complementary tools to support the risk assessment** process, information exchange and the information search process.
- A structured **compendium of free Webinars and workshops** to support the training of end users and stakeholders in the use of the REACHnano help desk to promote the implementation of REACH
- A set of **informative material** to disseminate the project actions at a Regional, National and European level.
- A **structured compendium of reliable information** to be include into the chemical safety assessment report-CSR.
- A complete **selection of standard testing models** to be used in the risk characterization process

REACHnan

Online support for nanomaterials under REACH

Best practices in NMs Risk Assessment: Demonstration actions under REACHnano and LIFE-NanoRISK Projects

1. Overview of the REACHnano and Life NanoRISK projects

A. Preparatory Actions

- **A.1.** Selection of representative nanomaterials (NIA)
- **A.2.** Identification of information requirements to complete the chemical safety assessment of substances at nanoscale under REACH requirements (ITENE)
- **A.3.** Identification of information sources (LEITAT)
- **A.4.** Identification of REACHNano Help Desk functionalities (ITENE)

B. Implementation Actions

- **B.1.** Compilation, analysis and evaluation of data (ITENE)
- **B.2.** Characterization of possible approaches to assess the risk posed by nanomaterials (LEITAT)
- **B.3.** Characterization of current lack of data to prepare the REACH registration dossier by means of authorized reporting tools (ITENE)
- **B.4.** Recommendations regarding the registration for substances at nanoscale to increase effectiveness and/or efficiency (LEITAT)
- **B.5.** Design and Development of the web based REACH Help Desk (ITENE)
- **B.6.** Development of complementary tools and plugins of the REACHNano Help Desk (ITENE)
- **B.7.** Validation by application end users (ITENE)
- **B.8.** Training and demonstration activities (INVASSAT)

C . Monitoring of the Impact of the project actions

- **C.1.** Definition of the starting situation (NIA)
- **C.2.** Strengthening of the knowledge base on nanomaterials properties and risk assessment (ITENE)
- **C.3.** Promotion of REACH compliance by implementing REACHnano Help Desk (LEITAT)
- **C.4.** Integrative assessment of risk characterization ratios when implementing risk management measures functionalities (ITENE)
- **C.5.** Assessment of the socio-economic impact of the project actions (NIA)

D. Communication and dissemination actions (NIA)

E. Project Management and Monitoring (ITENE)

1. Overview of the REACHnano and Life NanoRISK projects

Members of the Consortium

The consortium of the REACHnano project consists of 2 RTDs, 1 EU Association and 1 Public Body, representing 3 main areas: Spain, Belgium and United Kingdom.

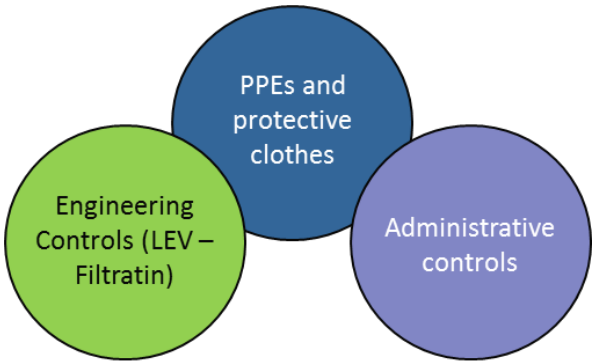
Participants		Contact
Instituto Tecnológico del Embalaje, Transporte y Logística	ITENE	Mr. Carlos Fito cfito@itene.com
ACONDICIONAMIENTO TARRASENSE - LEITAT	LEITAT Technological Center	Dr. Socorro Vazquez Email: svazquez@leitat.org
Instituto Valenciano De Seguridad Y Salud en el Trabajo	INVASSAT	Mr. Juan Uriol Batuecas uriol_jua@gva.es
Nanotechnology Industries Association AISBL - NIA	NIA	Mr. David Carlander Email: david.carlander@nanotechia.org

1. Overview of the REACHnano and Life NanoRISK projects

LIFE NanoRISK Presentation

- **Project Title:** Best practices effectiveness, prevention and protection measures for control of risk posed by ENMs
- **Theme:** Chemicals – Nanomaterials Risk Assessment
- **Call Identifier:** LIFE+ Programme Environmental Policy and Governance - 2012
- **Grant Agreement nº:** LIFE12 ENV/ES/000178

Official starting date: 1rst of October 2013
Duration of the project: 36 months
Ending date: 31th of September 2016



- Coordinator: Carlos Fito (ITENE)

1. Overview of the REACHnano and Life NanoRISK projects

❑ Origin of the Idea

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.

It has been demonstrated that **ENPs can become airborne during common industrial activities**, some of them related with the production of nanocomposites for packaging and/or automotive applications. These airborne particles, including nanoparticles and ultrafine particles may enter into the human respiratory tract via inhalation.

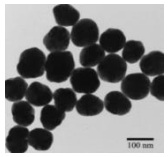
Best practices in NMs Risk Assessment: Demonstration actions under REACHnano and LIFE-NanoRISK Projects

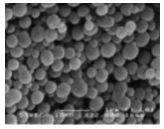
1. Overview of the REACHnano and Life NanoRISK projects

❑ Motivation

It has been demonstrated that ENPs can become airborne during common industrial activities, some of them related with the production of nanocomposites for packaging and/or automotive applications. These airborne particles, including nanoparticles and ultrafine particles may enter into the human respiratory tract via inhalation

Application of Nanotechnology (Nanoparticles)	New products with improved properties (Nano-Composites)
Carbon Nanotubes	(di)electric behaviour
MOx / Metal NPs	Bactericidal effects
CaCO3	Mechanical performance
Clays	Barrier properties





Problems: Safety Issues

- ❑ Several studies have indicated that **exposure to specific nanomaterials can lead to a gamut of adverse effects** in humans and environment
- ❑ A limited amount of data exits regarding the effectiveness of PPEs for controlling workplace exposures

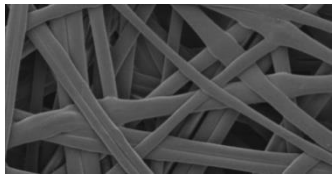
- **Lack of data on the effectiveness of the Workplace Controls**
- **Important regulatory issues to be fulfilled: REACH regulation**
- **Lack of open source data on the toxicological profile of NMs**

1. Overview of the REACHnano and Life NanoRISK projects

Project Objectives

The overall aim of nanoRISK 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

1. Overview of the REACHnano and Life NanoRISK projects

Project Objectives

- 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.

Best practices in NMs Risk Assessment: Demonstration actions under REACHnano and LIFE-NanoRISK Projects

1. Overview of the REACHnano and Life NanoRISK projects

A. 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)

B. 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 [redacted] sk posed by the target nanomaterials during its entire [redacted]
- **B.7.** Training activities for end users and stakeholders (ISTAS)

C . Monitoring of the Impact of the project actions

- **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 fulfillment by implementing the LIFE nanoRISK project (ITENE)
- **C.5.** Assessment of the socio-economic impact of the project actions (ITENE)

D. Communication and dissemination actions (ITENE)

E. Project Management and Monitoring (ITENE)

1. Overview of the REACHnano and Life NanoRISK projects

Members of the Consortium

The consortium of the NanoRISK project consists of 2 RTDs, 2 Industrial companies and 2 Public Body, representing 3 main areas: Spain, Belgium and Italy.

Coordinating Beneficiary

Instituto tecnológico del embalaje, transporte y Logística (ITENE)

Associated Beneficiaries:

- Vlaamse Instelling voor Technologisch Onderzoek n.v (VITO) - Belgium
- Centro Ricerche Plast-Optica (CRP) – Italy
- Avanzare Innovación Tecnológica S.L. (AVANZARE) Spain
- Instituto Valenciano de Seguridad y Salud en el Trabajo (INVASSAT)
- Instituto Nacional de Seguridad e Higiene en el Trabajo (INSHT)

Best practices in NMs Risk Assessment: Demonstration actions under REACHnano and LIFE-NanoRISK Projects

2. Risk Assessment approaches: REACHnano Toolkit & Nanoaerosol testing chamber

REACHnano and LIFE NanoRISK are funded by DG Environment under the LIFE+ Programme Environmental Policy and Governance (LIFE11 ENV/ES/000549) and ((LIFE12 ENV/ES/000168) respectively

1. REACHnano Toolkit & Nanoaerosol testing chamber

❑ Risk Assessment under REACH regulation

Under REACHnano project, several approaches to evaluate the human, environmental and safety (EHS) risks of ENMs are currently being studied, including modelling and grouping "in silico" approaches for hazard and risk prediction, experimental methodologies for hazard evaluation, including in vitro and in vivo methods, as well as qualitative, semi-quantitative and quantitative approaches for exposure assessment.

According to ECHA, the main requirements under REACH regarding the Chemical Safety Assessment are: :

- To perform a complete Hazard assessment based on the physicochemical, toxicological and ecotoxicological properties of the substance
- To define the levels of exposure under reasonable conditions of use
- To characterize the risk by comparing the levels of exposure and threshold levels below which risks for human health and for the environment are considered to be controlled.

$$RCR\ human\ health = \frac{Exposure}{DNEL} \qquad RCR\ enviroment = \frac{PEC}{PNEC}$$

1. REACHnano Toolkit & Nanoaerosol testing chamber

❑ Risk Assessment under REACH regulation

Under REACHnano project, several approaches to evaluate the human, environmental and safety (EHS) risks of ENMs are currently being studied, including modelling and grouping "in silico" approaches for hazard and risk prediction, experimental methodologies for hazard evaluation, including in vitro and in vivo methods, as well as qualitative, semi-quantitative and quantitative approaches for exposure assessment.

According to ECHA, the main requirements under REACH regarding the Chemical Safety Assessment are: :

- To perform a complete Hazard assessment based on the physicochemical, toxicological and ecotoxicological properties of the substance
- To define the levels of exposure under reasonable conditions of use
- To characterize the risk by comparing the levels of exposure and threshold levels below which risks for human health and for the environment are considered to be controlled.

Best practices in NMs Risk Assessment: Demonstration actions under REACHnano and LIFE-NanoRISK Projects

1. REACHnano Toolkit & Nanoaerosol testing chamber

❑ Proposed Tools

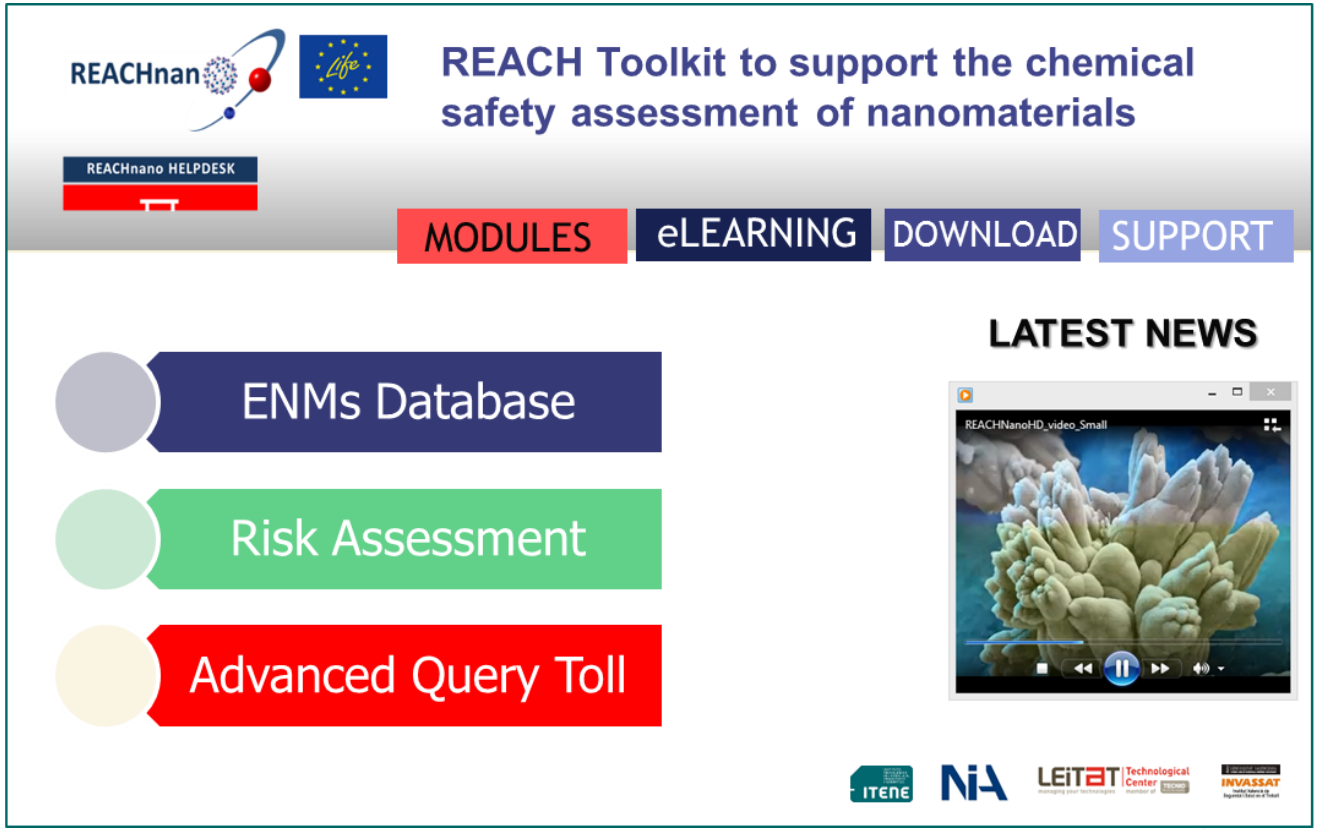
Under REACHnano project, we propose to develop a REACHnano Toolkit baased on the integration of reliable information on the hazardous properties of 30 NMs + 2 dedicated tools for Risk Characterization

TRANSLATE

ACCESS TO REACH TOOLKIT

REACHnano HELPDESK

IN PROGRESS: The main outcome of the project will be a web-based toolkit, available for free to all European stakeholders.



1. REACHnano Toolkit & Nanoaerosol testing chamber

- REACHnano toolkit

❑ Module I: BDD

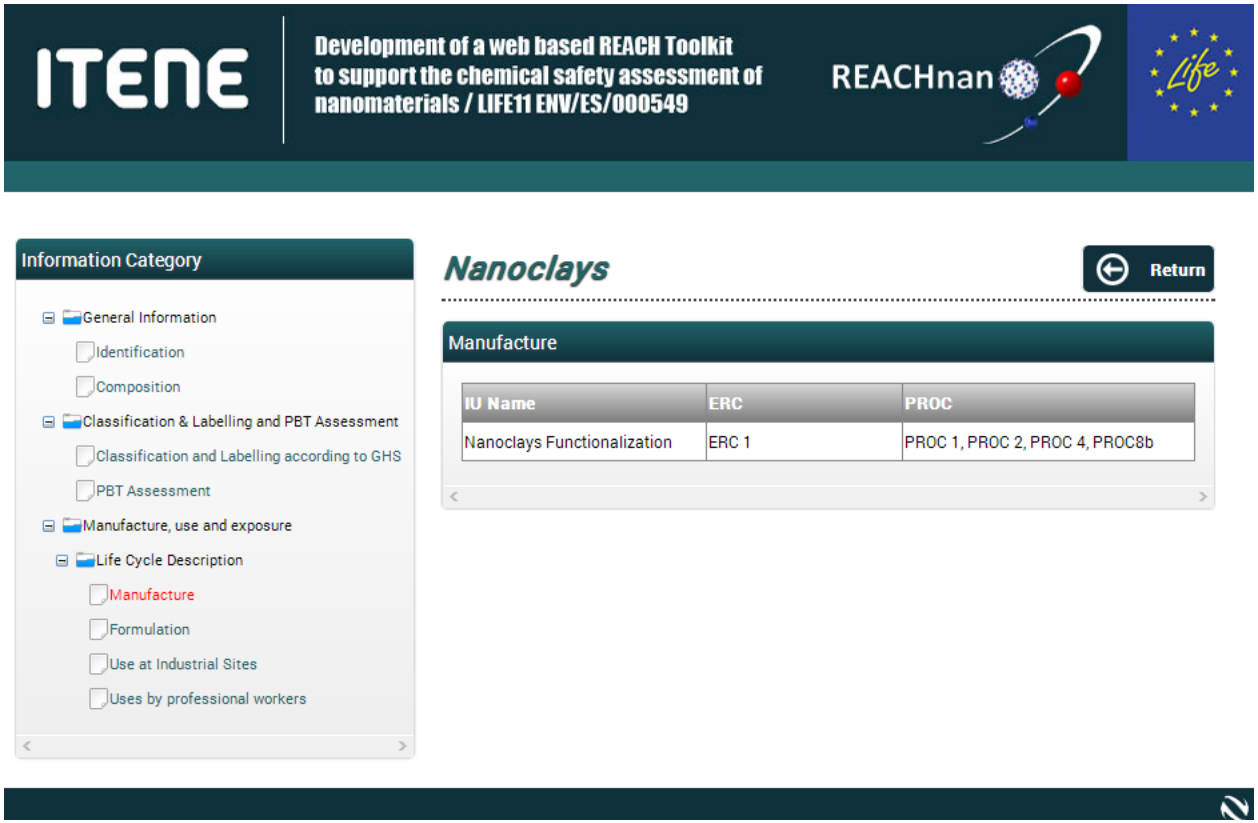
- Web based
- Data visualization
- Download options
- Browser .
- BackOffice managed by ITENE

1. REACHnano Toolkit & Nanoaerosol testing chamber

- REACHnano toolkit

❑ Module I: BDD

- Web based
- Data visualization
- Download options
- Browser
- BackOffice



1. REACHnano Toolkit & Nanoaerosol testing chamber

❑ Module II - Risk Assessment based on exposure determinants and release factors

Human Health	Exposure estimation (Inhalation)						
General conditions		TRA Predicted Exposure (mg/m3)	Concentration factor	Duration factor	RPE factor	Probability index (CB)	Predicted Exposure (mg/m3)
CS (n)	PROC/FORM/LEV/DISPERSION						
CS(1)	PROC5/S/YES/MEDIUM	0,5	1-5%	1-4 hours	Efectiveness 90%	Likely	0,009
CS (2)	PROC9/L/NO/HIGH	250	>25%	>4 hours	None		25,000

Human Health	Exposure estimation (Dermal)					
General conditions		TRA Predicted exposure (mg/kg/dia)	Concentration factor	PPE used	Probability index (CB)	Predicted dermal exposure (mg/kg/dia)
CS (n)	PROC/LEV					
CS(1)	PROC6/YES	1,37	1-5%	Gloves-intensive training	Less likely	0,007

Environment	Exposure Estimated						
Release times per year	225	Industrial use of process regulators for polymerisa-tion processes in produc-tion of resins, rubbers,					
General consitions		Release fraction to air	Release fraction to water	Release fraction to soil	Amount used	Water	Waste water	Soil
CS(n)	SP ERC/No ERC/ releases times per year							
CS(1)	TEGEWA 3/5/220	0,001	0,2	0	5	0,005	1	0

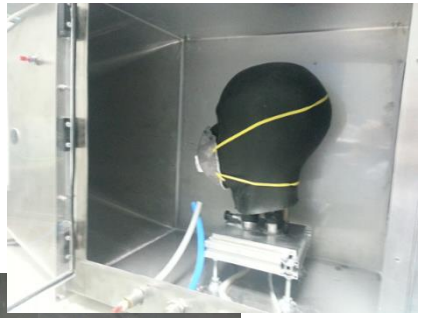
1. REACHnano Toolkit & Nanoaerosol testing chamber

❑ Quantitative Risk Assessment under NanoRISK

The NanoRISK project focuses on the characterization of the exposure to ENMs at industrial level and the definition of proven risk management measures to control and mitigate the exposure and release, including PPE and Engineering controls

The risk assessment process within NanoRISK includes :

- Simulation of common industrial processes under controlled conditions in a **nanoaerol testing chamber** developed as part of the project
- **Measurement campaigns** on site
- Evaluation of the **effectiveness of common RMMs to define a list a proven strategies**, including dermal and respiratory protection, ventilation systems and administrative controls

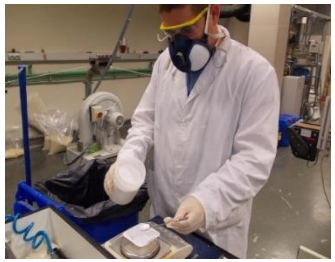


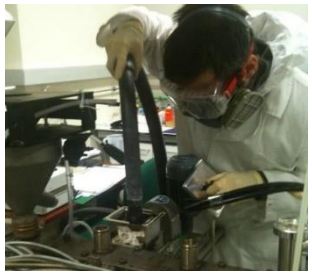
1. REACHnano Toolkit & Nanoaerosol testing chamber

❑ Quantitative Risk Assessment under NanoRISK - Simulation Studies

The chamber will be used to evaluate the airborne behavior of a list of 12 ENMs under different conditions, supporting the understanding of the exposure potential and release patters at industrial level. Common processes within the Polymer nanocomposite industry will be simulated

	OPERATIVE CONDITIONS							
	Process	PROC	Physical form	Conc.	Applied amount	Duration and frequency	Tª	Process Type
Synthesis	Handling	PROC 15 PROC 19	OC6 - Solid, high dustiness	AgNO3 solution (1,0 to 6,0 mM) and 8% (w/w) SDS	G13 - Small Amounts (up to 500 mg)	G5 – 2-4 h/day 2-3 days/week	50°-70°C	Manual
	Weighing	PROC 26					25 °C	Manual
	Bagging	PROC 8a PROC 8b PROC 9		G13 - % substance in the product up to 100 %	G13 - Small Amounts (up to 500 mg)		25 °C	Manual
	Cleaning and maintenance	PROC 0			G13 - Small Amounts (up to 500 mg)	G5 -0.5- 2h /day 2-3 days/week	25 °C	Manual



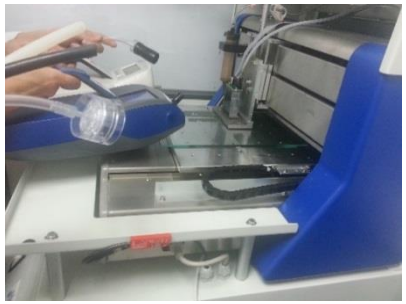


1. REACHnano Toolkit & Nanoaerosol testing chamber

❑ Quantitative Risk Assessment under NanoRISK - Measurement Strategies

The characterization of the levels of exposure to ENMs is key to understand the potential environmental, health and safety (EHS) derived from the application nanotechnology, however, **monitoring the exposure levels of ENMs at the workplace or study the fate and transport of ENM in complex environmental matrices is complicated** due to the lack of detection techniques and the lack of a defined set of standardized metrics to be consistently measured

On the basis recent studies, within NanoRISK the following steps will be conducted to obtain reliable data on the levels of exposure:

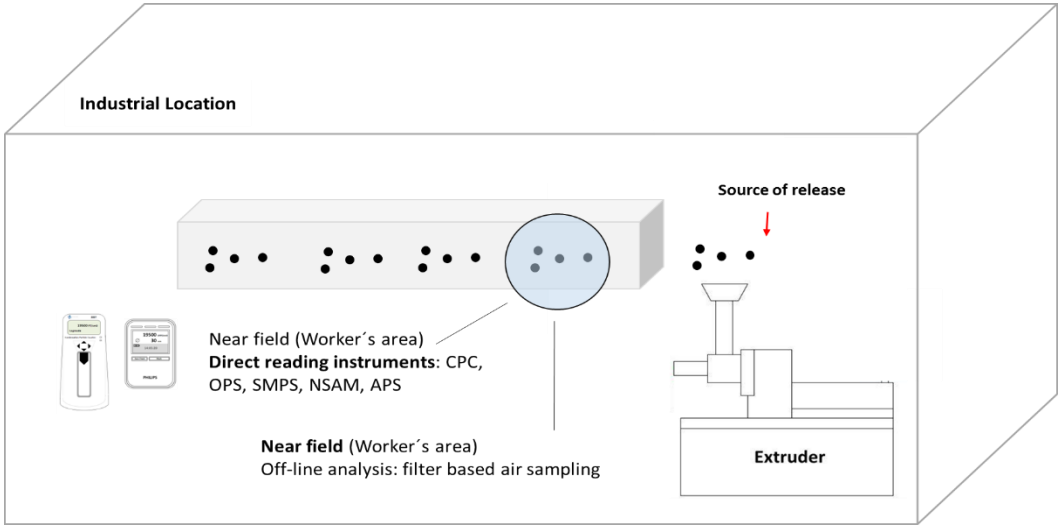


- Identify the potential sources of emission (e.g. Dedicated questionnaires)
- Define the measurement strategy, including instrumentation and metrics
- Consider background distinction, describing sources of ENMs and characteristics
- Data processing methods to analyse, evaluate and report of exposure data

1. REACHnano Toolkit & Nanoaerosol testing chamber

- Quantitative Risk Assessment under NanoRISK - Measurement Strategies

Targeted Measurement Campaign(s) Assessing Releases and Potential Exposure, by Process & Substance



1. REACHnano Toolkit & Nanoaerosol testing chamber

❑ Quantitative Risk Assessment under NanoRISK - Effectiveness Testing

Within LIFE NanoRISK, the following performance factors will be characterized:

- Barrier efficiency for skin protective equipment
- Particle penetration potential for protective clothing and filtration
- Assigned Protection factor (APF) and leakage efficacy for respirators
- Percentage reduction in emissions for Ventilation, including fume hoods, cabinets and other extraction methods.
- Leakage efficacy for protective goggles.

Aim: **Define Safe Exposure Scenarios**

PACKAGING, TRANSPORT & LOGISTICS RESEARCH CENTER

ITENE

¡THANK YOU FOR YOUR ATTENTION!

NANORISK

REACHnan

REACHnano HELPDESK

Fedit
Centros Tecnológicos de España

iVACE
INSTITUTO VALENCIANO DE COMPETITIVIDAD EMPRESARIAL

RED IT
RED DE INSTITUTOS TECNOLÓGICOS DE LA COMUNIDAD VALENCIANA

REACHnano and LIFE NanoRISK are funded by DG Environment under the LIFE+ Programme Environmental Policy and Governance (LIFE11 ENV/ES/000549) and ((LIFE12 ENV/ES/000168) respectively

1992-2012 20 YEARS Life

EUROPEAN COMMISSION