LIFE Project Number

LIFE12 ENV/ES/000178

FINAL Report

Covering the project activities from 01/10/2013 to 30/09/2016

Reporting Date

23/02/2017

LIFE+ PROJECT NAME

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

(LIFE NanoRISK)

Project Data

Project location	Valencia (Spain)
Project start date:	01/10/2013
Project end date:	30/09/2016 **Extension date:** non-applicable
Total Project duration (in months)	18 months
Total budget	1,165,973 €
Total eligible budget	1,165,973 €
EU contribution:	582,893 €
(%) of total costs	50 %
(%) of eligible costs	50 %

Beneficiary Data

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2. Executive Summary

2.1. Project objectives and key messages

The **LIFE NanoRISK** project is focused on the **evaluation of the effectiveness of common risk management measures (RMMs) 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 technical measures, personal protective equipment and administrative control.

The term “nanomaterials” used under this report refers to materials with basic structural units, grains, particles, fibres or other constituent components smaller than 100 nm in at least one dimension.

The project focuses attention on the definition of proper measures to assist companies on the control of the exposure to ENMs in the workplace, as well as to reduce the release of pollutants in the nanometer range into the environment. To this end, 4 key activities were scheduled, including: 1) the selection of relevant types of ENMs considering data on market penetration, exposure potential, and effects on human health and the environment, 2) design, development and validation of a testing chamber prototype to conduct experimental activities under controlled conditions, 3) development and validation of standardized procedures (SOPs) to conduct the experimental evaluation of selected RMMs, and 4) development of easy-to-use tools to support the selection of recommended RMMs when handling ENMs under common industrial processes.

On the basis of the overall aim goal of the project, and target activities schedule, key aims of the project are:

- To **evaluate the effectiveness** “performance” of common personal protective equipment (PPE), including respiratory and eye protective equipment, chemical protective gloves, as well as technical measures, to control the exposure to ENMs during the manufacturing and downstream use processes;
- To develop an **aerosol testing chamber prototype** to evaluate and demonstrate the performance of the RMM at laboratory scale;
- To define a compendium of **standardized protocols** based on international standards to evaluate the effectiveness of PPE and collective protection measures.
- To **develop a set of tools** to assist companies on the selection of proper measures to guarantee a safe working environment and reduce the release of ENMs into the environment, considering: a computerized library on risk management measures (**RMM library**) and a multimedia guidance on recommend RMMs against ENMs.
- To improve the **knowledge base on the parameters** that determine the exposure to ENMs in workplaces, considering common condition of use 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** involving the production and downstream use of NMs in the nanocomposite industry;
- To support the industry and target stakeholders in **the hazard and exposure characterization** of ENMs for regulatory purposes, especially the EC regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
- To **disseminate the project results** for a large community of SMEs and potential stakeholders.
- To support the **monitoring of REACH compliance** and its impact on risk mitigation and prevention of pollution posed by NMs.

The achievement of these objectives **will promote the protection of environment and health from risks posed by ENMs**, providing regulators and the industry with new and reliable data to complete the chemical safety assessment as defined by REACH regulation, where information on the levels of the exposure and efficiency of RMMs is of prime importance to determine if the use of a substance, in this case ENMs, is safe.

The expected outputs and key deliverables of the project are aligned with the abovementioned objectives. The results achieved are listed below:

1. A functional and validated **testing chamber prototype** designed to support the evaluation of the effectiveness of RMMs against ENMs under controlled conditions, and provide stakeholders with a proper space to simulate operative conditions involving the use of ENMs as such, in a preparation or in articles (i.e. polymers).
2. A compendium of **10 well defined and standardized protocols (SOPs)** to evaluate the effectiveness of local executive ventilation systems and personal protective equipment against particles and aerosols below 100 nm.
3. Reliable data on the **performance of common risk management measures against NMs**, including information on the protection factor (PF) for respiratory and eye protection equipment, permeation and penetration factor for protective gloves and suits, capture efficiency for ventilation systems (LEVs), and removal efficiency of emission control technologies.
4. Implementation and validation of recommended RMMs in **5 case studies** covering the life cycle of relevant ENMs.
5. An innovative Microsoft excel® based **risk management measures library** containing information of the effectiveness against target ENMs and critical operative conditions.
6. A **multimedia guidance** to assist companies on the selection of recommended measures to control the exposure in workplaces and reduce release of ENMs to the environment.
7. A complete **assessment report of current ISO and ASTM standards** for personal protective equipment (PPE) testing, including an in depth critical analysis of the application of current experimental protocols;
8. A complete **description of the current Exposure Scenarios across the nanocomposites life cycle**, including an in depth description of the existing operative conditions, efficient risk management measures and measured exposure levels (ELs)
9. 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.

10. 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
11. 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.
12. A set of **informative material to disseminate the project actions** at a Regional, National and European level, including a functional project web-site, brochures, newsletters, and informative videos.
13. A network platform to close the knowledge gaps about nanomaterials impact and to develop and implement, in collaboration with scientific committees

In addition, an **overall reduction of unintentional emissions of ENMs** to the air, water and / or soil compartment from the production process by a 15 % has been estimated, considering both experimental data on the efficiency of the risk management measures and results of the implementation phase.

As key result, NanoRISK provides stakeholders with scientific based tools and data to guarantee a safe working environment, promoting the implementation of REACH provisions, in particular the chemical safety assessment process. It shall be noted a direct contribution of the project to **decrease the exposure of a man and environment to dangerous substances**, and to increase the transparency on hazard and exposure related data, promoting the concepts of responsible care, sustainability and green economies. Finally, the key deliverables developed within the project are described in the table below:

Table 1. Key Deliverable products of the project

Name	Act.	Description	Achieved
Report on regulatory requirements of NMs under REACH	A1	Complete description of the requirements established by REACH, including information, classification and labelling.	13/01/2014
Report on operative conditions and RMMs in different processes of the nanomaterials life cycle	A2	Report on the specific uses, operative conditions and RMMs applied under several processes identified across the life cycle of target ENMs and sectors.	10/01/2014
Data on exposure levels to ENMs over the NMs life cycle	A2	Report on the current levels of exposure to NMs on the basis of peer reviewed publications.	27/02/2014
Report on effectiveness of RMM based on published information	A3	Report on the current knowledge on the performance levels of common risk controls against NMs.	27/03/2014
Report on the effectiveness of RMM testing methods against NMs	B1	In depth description of the adequacy of common standards to support the certification of personal protective equipment against NMs.	24/04/2014
Operation manual of the test chamber	B2	Technical manual of the aerosol testing chamber, including instructions, functions and troubleshooting.	05/09/2014
Report on the experimental set up for testing	B3	Detailed description of the set up designed for testing the effectiveness of RMMs.	14/05/2014
Report on the quantitative evaluation of the effectiveness of the RMM	B3	Analysis of the performance of RMMs, including protection factor for respirators, penetration / permeation for dermal protection, and capture efficiency for ventilation.	27/03/2015
Guidance on using the RMM Library Tool	B4	Step-by-step manual to assist end users. A Detailed description of the layout, structure and functions of the computerize library is also included.	05/09/2016

Name	Act.	Description	Achieved
Final Version of the Guidance in pdf	B6	Guidance on recommended measures developed. Available:www.lifenanorisk.eu/index.php/interactive/multimedia-guideline	15/09/2016
Training manuals	B7	Compilation of the presentations and practical exercises used during the workshops organized.	18/06/2016
Project Web Site	D2	Web site available on - line	27/12/2013
Project Leaflet	D3	3-fold brochure for dissemination purposes. Three versions available in the project web site.	20/12/2013 17/09/2016
Project Factsheet	D3	Detailed description of the project, including concept, objectives, expected results, work plan and progress.	14/02/2014
Project Newsletter	D3	Newsletter published containing relevant results and progress of the project. Three newsletter available.	31/03/2014 06/09/2016
Notice Boards	D3	Roll-up of the project, including an overview of the main objectives and results. Two versions available	30/04/2014 06/09/2016
Report on the Socioeconomic impact of the project	C5	Report containing data on the socio-economic benefits of the project at regional, national and EU scale.	27/09/2016

2.2. Summary of the report

The final report contains a complete description of the activities conducted within the NanoRISK project, including detailed information of the activities conducted and results encountered.

The project has been coordinated by ITENE (Spain), a technological institute with wide experience in nanotechnology and safety issues. The scheduled actions were supported by VITO (Belgium), with wide experience in exposure assessment and REACH implementation, INVASSAT (Spain), a public body in charge of the promotion of REACH at regional scale, and the Spanish National Institute for Occupational Safety and Health (INSHT), public body in charge of the certification of personal protective equipment and technical measures. In addition, two SMEs were involved in the project, including AVANZARE, a Spanish manufacturer of ENMs, and Centro Ricerche Plast-Optica S.p.A (CRP), an Italian company manufacturing polymer based nanocomposites.

The LIFE NanoRISK project was structured in 5 main actions on the basis of the types 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 E5) actions.

The project started officially in October, 2013 and was completed last September, 2016. All the activities conducted were performed with the support of the consortium partners, and relevant stakeholders and industries representatives.

The work performed since the beginning of the project focused on, 1) the selection of relevant ENMs, the considering those ENMs that are currently on the market, 2) the compilation of existing data on the effectiveness of RMMs and measured concentration of ENMs in workplaces

and the environment, 3) the collation and analysis of currents standards applied to support the certification of the effectiveness of PPE and technical measures, 4) the design, development and validation of a exposure chamber prototype, 5) the experimental evaluation of representative models of PPE and LEV systems, 6) the design and development of the computerized RMM library and the multimedia guidance on recommended measures, and 7) the dissemination of the main outcomes of the project to the target audience by means of dedicated materials, workshops and relevant events.

The scheduled milestones of the project have been achieved, including:

- The selection of a list of 30 representative ENMs
- The definition of the condition of use and risk management measures implemented at companies manufacturing or using ENMs;
- The development of the exposure chamber prototype;
- The experimental evaluation of existing PPEs and technical measures;
- Delivery of the RMM library and edition of the guidance on recommended measures to control the exposure to ENMs;
- Demonstration / validation activities completed

Concerning dissemination activities, the target audience of the project includes mainly producers and downstream users of ENMs, industry associations, policy makers with an interest in REACH and nanomaterials, competent authorities for REACH implementation, academic researchers and other stakeholders especially the OECD Working Party on Manufactured Nanomaterials (WPMN).

Fig. 1. Nanoaerosol testing chamber and home page of the NanoRISK web site.

Dissemination materials, including the Layman Report, leaflets, project video, and roll up (notice board) are available on http://www.lifenanorisk.eu/index.php/dissemination.

A continuous update of the project web site, including publication of relevant events concerning REACH and nanomaterials, news, REACH relevant updates, as well any other information considered relevant to support the implementation of REACH when dealing with ENMS has been considered in the after-life plan.

3. Introduction

3.1. Background, problem and objectives

Along with the benefits of nanotechnology, there is an on-going debate about the potential effects of ENMs on the human health or the environment. At the same time, the **increase of the production of ENMs raise concerns about their environmental impact** at all stages of the value chain, considering that ENMs can be released to the air, soil or water in common industrial processes and/or accidental events, and ultimately accumulate in the soil, water or biota, endangering the health of living organisms and ecosystems.

Within this context, and considering the priority areas of LIFE + call, the main objective of the project is to **define proven RMMs to prevent or minimize the release of ENMs** during the specific workplace situations industry. To this end, a dedicated **nanoaerosol testing chamber** was developed to evaluate the effectiveness of conventional RMMs against ENMs, following standard testing protocols, and considering critical activities in occupational environments.

The results of the project have been outlined in the previous chapter. Key outcomes from the project are: the testing chamber developed, standard operation procedures (SOPs) designed to evaluate the effectiveness of common RMMs, as well the **library of RMMs** and the **guidance on recommended controls**, both of prime importance to support the implementation of REACH.

Fig.2. key outcomes of the project

The project provides stakeholders with **innovative tools to support new studies to elucidate the specific risks derived from the use of ENMs** under realistic exposure scenarios. In addition, the RMM library will enhance the science-policy integration in support of REACH legislation.

3.2. Expected long term results

NanoRISK explored 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..

The benefits of the project related to the environment include: 1) less actual damage to the environment, 2) lower spending to remediate or compensate for environmental damage and, 3) lower risks of damage to the environment. Concerning long term results, an overall reduction of unintentional emissions to the air, water and / or soil compartment from the production process by at least a 5 % has been defined based on the characterization and implementation of proven risk management procedures and measures capable to reduce the release of ENMs to the environment.

4. Administrative Part

4.1. Description of the management system

4.1.1. Project phases, activities and planning

The work plan has been split into 3 types of actions based on the specific eligible actions under LIFE financial rules. The actions completed and their interdependence are shown below:

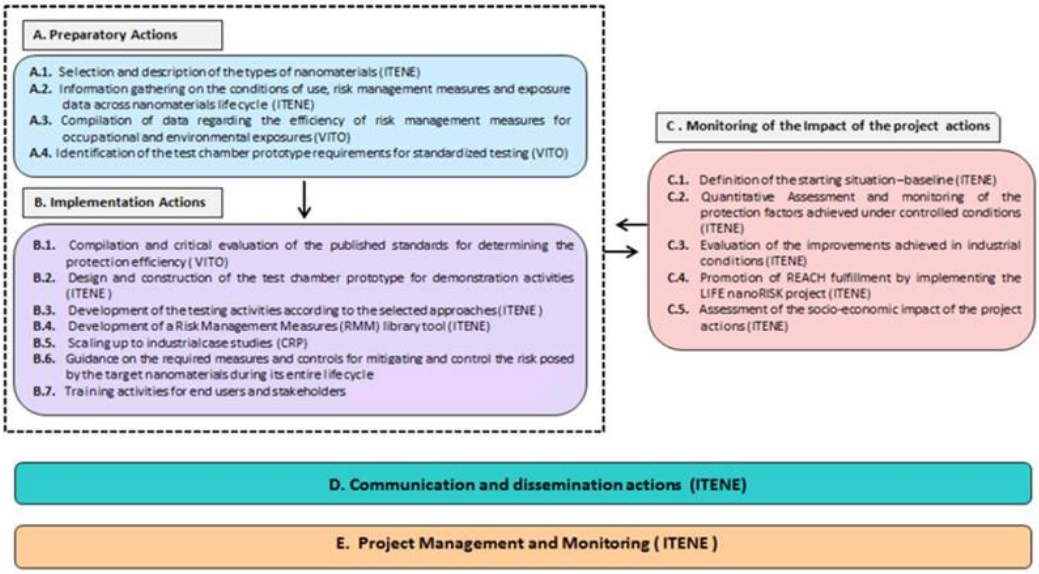


Figure 3. Scheduled actions

The overall objectives of each activity are explained below:

1. Preparatory Actions (A1 – A4): a set of four preparatory actions have been conducted aiming at clearly define a set of representative ENMs in the context of REACH, identify critical processes "exposure scenarios" at all stages of the life cycle, evaluate the feasibility and accuracy of the current approaches for RMMs testing, and define in detail the technical requirements of the test chamber prototype.

2. Implementation Actions (B1 – B7): a set of seven implementation actions were completed, being focused on: 1) the development of harmonized testing protocols (SOPs), 2) construction of the test chamber and validation, 3) experimental characterization in the chamber of the performance of common PPE and technical measures following SOPs developed, 4) design and development of the computerized RMMs library, 5) implementation of the RMMs tested in case studies, 6) drawing up and edition of the multimedia guidance on recommended RMMs, and 7) dedicated training activities to assist companies on the use and implementation of the tools developed within the project.

3. Monitoring Actions (C1 – C5): these actions were 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 these activities, in order to achieve an optimal management and use of the project across the EU, a set of management and dissemination actions were completed.

The actions and related task were conducted following the timetable depicted in the figure below (Fig.4).

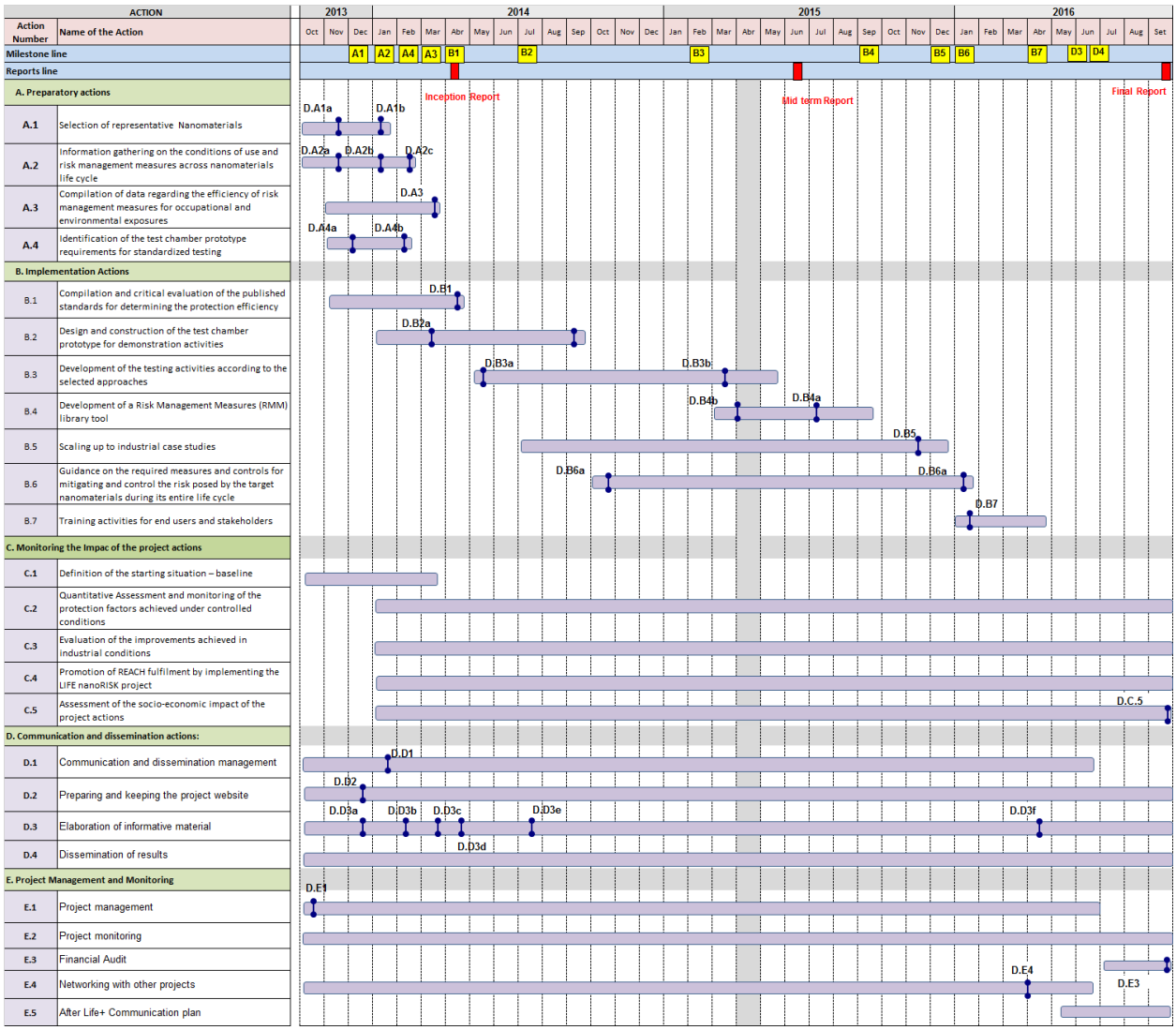


Figure 4. NanoRISK timetable

4.1.2. Project Organization and management

The project has been coordinated by the Packaging, Transport and Logistics research center, ITENE. Carlos Fito was appointed as **project manager**, assuming the overall responsibility of analysing and approving the results of each of the actions.

The overall objective of the consortium management tasks has been to guarantee the efficient and productive functioning of the project to ensure that the objectives of the different actions are reached, tasks and deliverables completed and milestones achieved in accordance with the time schedule. The main tasks conducted were:

- Clear definition of contractual requirements and relationship;
- Scheduling of tasks, deliverables and communication activities;
- Organization of project meetings: hosting, preparation and reporting;
- Financial and administrative management;

- Monitoring of the partners activities and overall work done within the project;
- Analysis of internal reports and deliverables issued by the action leaders;
- Managing the project intranet site, accessible exclusively for the project partners;

Concerning the responsibilities of each beneficiary, due to the complexity of the project activities, a specific organigram was defined including the main functions and tasks to be covered (Fig. 5).

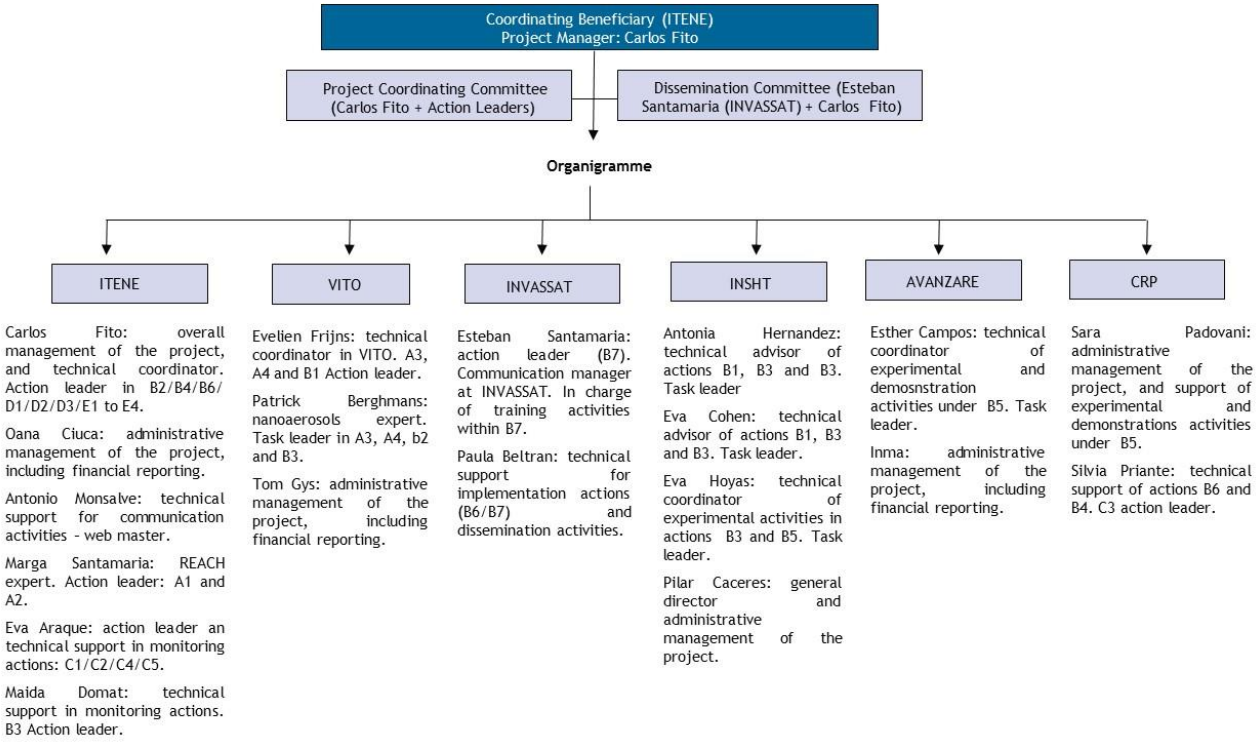


Figure 5. Organigramme of the NanoRISK project

The meetings organized during the meeting were of special relevance to achieve the milestones and results scheduled. Six general assembly meetings in addition to the project kick off and the final meeting were organized during the life of the project, where all beneficiaries were represented. The list of meetings and main topics discussed are described below. Moreover, additional technical meetings were conducted during the project. The minutes of the meetings are attached in the annex section.

Table 2. Meetings organized under the project

Meeting	Date	Purpose	Location
Kick off meeting	23/10/2013	Kick off and project launching.	Valencia (ES)
1st G.A. meeting	03/06/2014	Evaluation of the progress so far, as well as on the definition of the activities to be completed.	Valencia (ES)
2nd G.A. meeting	03/12/2014	Scheduling of the experimental activities and evaluation of the SOPs developed	Sevilla (ES)
3rd G.A. meeting	07/05/2015	presentation of the results of the RMMs testing activities and the scheduling of the scaling up studies.	La Rioja (ES)
4th G.A. meeting	14/12/2015	Critical analysis of the progress so far and the scheduling of the dissemination activities to be completed. The project officer and the external monitoring team were present in the meeting.	Valencia (ES)

Meeting	Date	Purpose	Location
5th G.A. meeting	12-13/04/2016	Discussion of the final structure of the RMM library and multimedia guidance. Approval of deliverables	Antwerpen (BE)
6th G.A. meeting	30/06/2016	Final meeting of the project before the end date, being focused on the evaluation of the impact of the project and agreement on the after-life plan	Madrid (ES)
Final meeting	17/11/2016	Visit of the external monitoring team. Presentation of the main outcomes of the project.	Valencia (ES)

Regarding the official reporting activities, the partnership agreement was developed by the project coordinator with the support of the administrative department of ITENE. The inception report was also prepared by the coordinating beneficiary, being submitted last May 29th, 2014.

The Mid-Term report was submitted either to the external monitoring team and the commission services in July 17th, 2015. The last progress report summited is the present documents, to be completed no later than 3 months after the end of the project.

It shall be noted that there were no amendments or changes to be noticed regarding the project's management structure and scheduled activities within the proposal

4.1.3. Changes due to amendments to the Grant Agreement

As reported within the mid-term report, an amendment to the Grant Agreement was requested in 2014 due to the withdrawal of one of the members of the consortium (ISTAS). To solve this constraint, the project coordinator, Carlos Fito, on behalf of the NanoRISK consortium started a dialogue with several institutions considered appropriate to cover the scheduled activities.

In view of the capacities declared by a number or organizations, the management committee decided to select two relevant institutions with wide experience in dissemination activities, REACH implementation, RMMs testing and chemical safety of chemical substances. These two organizations were INSHT and INVASSAT, both public bodies focused on the promotion of the safety and Health at work.No additional amendments have been done.

4.2. Evaluation of the management system

The management of the project was coordinated by the administrative department of ITENE and under the supervision of the project manager, Carlos Fito. Much of the activities have been related with technical coordination and the financial reporting, where ITENE gives support and advice to the members of the consortium. The doubts in terms of financial reporting have been periodically consulted with the external monitoring team represented by Maria Rodriguez. A close cooperation between ITENE and the external monitoring shall be noticed. Three project reviews have been conducted: February, 2014, June 2015 and December 2016.

In relation with the partnership, the members of the consortium worked in line with the responsibilities stated in the partnership agreement. As stated in the previous chapter, the main issue to be noticed in this point was the withdrawal of ISTAS at the beginning of the project due fundamentally to the internal restructuring process conducted by the Governing Council of the entity after the reception of the approval letter of the project, as well as the withdraw of the movement of researcher in charge of the project actions to another institution.

4.3. Answers to the official letters received from the European Commission

The consortium has considered the instructions communicated in the annex section of the official letters received so far. The main issues and actions carried out are detailed below:

Issues after evaluating the inception report (Ref.Ares (2014)2379640 – 17/02/2014)

a) Technical Issues

No deviations shall be noted on action B1. The results from the action are aligned with the indicators of progress defined, including the evaluation of more than 100 standards and the edition of one detailed protocol for each risk management measure studied.

b) Monitoring actions

A complete report summarizing the results from each monitoring actions was conducted, being included in the annex section

c) Dissemination and networking

The contents of the web site were improved in line with the Commision´s recommendations, including information on the achievements, public deliverables and main products (i.e. RMM library and Guidance on recommended measures to control the exposure to ENMs). In addition, the contents of the newsletter were reviewed, including relevant milestones and events, as well as considering a 4 pages' format.

Issues after the mid-term evaluation (Ref.Ares (2015)3796778 – 14/09/2015)

a) Technical issues

- Action C2. A final report with the main achievements of this action included in the annex section.
- Action D3. The newsletters produced under the LIFE of the project are included in the annex section.
- Web site: following instructions, the web site was updated with all information available to the public, including the Layman report.
- A complete analysis of the dissemination ad networking activities conducted has been included on the present report.
- An assessment of the long-term qualitative and quantitative economic, environmental and social benefits of the project has been included on the present document.

b) Financial issues

- Valid VAT certificates for the beneficiaries CRP, INSHT and INVASSAT included in annex section.
- A complete description of the methodology employed to calculate the annual number of working hours of INSHT and ITENE included under the financial part.
- An Excel table detailing the different concepts used in the calculation of the annual gross salary for all project staff for each partner and a short description of each element included in the financial part.

- Daily rates for the persons listed and supporting documents included included in the financial part.
- Explanation of the travel costs of Carla Sanchis and Otten Gert explained
- Cost of the corporate image allocated in the external assistance category
- Amounts declared in seq. nº 28 of ITENE revised in the financial part.

Issues after the third monitoring visit (Ref.Ares (2016)754538 – 12/02/2016)

c) Technical issues

Following the instructions outlined on the letter received, the present report includes information on the policy and legislation implications of the project, its innovation and demonstration value, as well as socioeconomic effects. Moreover, the final output indicators table, Layman´s report and After LIFE communication plan are included in the annex section.

All deliverables mentioned in the project documents and not yet submitted are included in the annex section.

d) Financial issues

The financial part of the present document includes fully completed financial forms and relevant comments regarding the financial execution of the project.

5. Technical Part

5.1. Technical Progress

This chapter describes the activities undertaken and outputs achieved so far in quantifiable terms conducted since the beginning of the project. A more detailed description of the results is provided in the deliverables developed according with the work plan.

5.1.1. Action A1. Selection of representative ENMs

Action status: Achieved
Timescale in Proposal: October 2013 - January 2014 / **Actual**: October 2013 - December 2013.
Objective: to define a set of representative ENMs in the context of REACH, taking into account the scope and exemption of REACH provisions.

Activities Conducted: action A1 was focused on the **selection of a list of relevant ENMs** on the basis of the tonnage level in which they are manufactured or imported, forms in which the ENMs are placed on the market, hazard profile and uses in the supply chain.

To this end, a set of specific activities were conducted, including the establishment of selection criteria within task A1.1, the compilation of relevant information on the use and forms of ENMs placed on the market within A1.2, and the selection of target ENMs according with their industrial relevance and potential risks (A1.3).

A comprehensive review of the additives used by the polymer based composites industry was conducted. These additives include materials and substances at the nanometer scale used, manufactured or imported in volumes of 1 tonne or more per year, for which a chemical safety assessment is mandatory on the basis of REACH provisions considering current tonnage level in which the ENMs are used, manufactured or imported, (eco)toxicological profile, fate and environmental behavior.

The sources of information used to support the selection of ENMs included questionnaires sent to the main stakeholders of the project, as well as technical and scientific data retrieved from peer reviewed publications, existing databases, and finished and ongoing projects.

The last activity conducted focused on the description of the ENMs selected, including detailed information on nano-specific physiochemical and (eco)toxicological properties organized following the OECD Harmonised Templates (OHTs). The action was completed with success last November 2013, including the definition and description of 12 relevant ENMs covering the four sectors indicated in the proposal. The following Gantt-chart shows the progress:

		2013			2014			
Action / Task		Oct	Nov	Dec	Jan	Feb	Mar	Apr
Action A1. Selection and description of the types of NMs	Proposed		A1a		A1b			
	Actual			**A1a**	**A1b**			

Results and deliverables: the analysis of the information gathered within the tasks results in a list of 12 ENMs, considering different forms and different chemical composition. These materials are depicted in table 3.

Table 3. Selected Engineered Nanomaterials (ENMs)

GROUP	NANOMATERIAL	Sector
INORGANIC NON-METALLIC	Silicon dioxide (SiO2)	Packaging & building
	Titanium dioxide (TiO2)	
	Zinc oxide (ZnO)	
	Cerium dioxide (CeO)	
	Iron oxide (Fe3O4)	Automotive & electronics
	Silver (Ag)	Packaging, building, Automotive & electronics
CARBON-BASED	CNTs	Automotive & electronics
	Graphene	
	Carbon black (CB)	
	Fullerenes (C60)	Electronics
Natural NMS	NanoClays	Packaging, building, Automotive & electronics
	Nanocellulose	

The table below (table 4) shows an overview of the main attributes considered to select the ENMs listed in the previous table (table 3). A complete description of the selected ENMs is provided within deliverable A1a.

Table 4. Main Properties of the selected ENMs

ENMs	Hazard profile	Exposure routes	Form	Annual production	Main uses	Commercial interest
TiO_2	High	Inhalation	Rods	High	Cosmetics, composites	High
ZnO	High	Inhalation	Cubic	High	Cosmetics, composites, ceramics, health care	High
SiO_2	High	Inhalation	Cubic	High	Rubber composites, food and health products	High
CeO_2	High	Inhalation	Cubic	High	Electronics, fuel catalysts, paints	High
Fe_3O_4	High	Inhalation	Cubic	High	Paints, cosmetics, electronics	High
Nano Ag	High	Inhalation	Cubic	High	Textiles, coatings, composites	High
CNTs	High	Inhalation	Tube	High	Composites, plastics, lubricants	High
Graphene flakes	High	Inhalation	Irregular flakes	low (est)	Sensors, composite materials for aircraft and automotive	low
Carbon Black	High	Inhalation	Spherical	High	Tyres and composites	High
Fullerenes	High	Inhalation	Spherical	Medium	Composites sports equipment	low
Nanoclays	High	Inhalation	Platelets	High	Composites packaging	High
Nanocellulose	Controversial	Inhalation	Whisker	low (est)	Composites packaging	Growing

Deliverable A1b shows a complete description of the current state of the art concerning the application of the provisions laid down on REACH regulation to substances at the nanometer scale. This deliverable presents an extensive review of the requirements established by REACH regulation in order to ensure that risks are adequately controlled, with special emphasis in those **critical information requirements** that should be presented in the REACH registration dossiers submitted to the European Chemicals Agency (ECHA) when registering nanomaterials.

The analysis conducted within deliverable A1b concluded that REACH sets the best possible framework for the risk management of ENMs when they occur as substances or mixtures but more specific requirements for ENMs within the framework have proven necessary. A **base set of recommendations for the safety assessment and risk management of ENMs** beyond current REACH information requirements was defined.

A list of **68 key endpoints** that shall be reported under the scope of the chemical safety report when registering ENMs or nanoforms was defined, including nano-specific parameters such as particle size distribution, surface area or dustiness.

It should be noted that additional data, potentially derived from NM specific testing, may thus be necessary to demonstrate the safety of NMs. The provisions that apply to the registration of NMs under REACH are the same that must to be fulfilled for any other substance. However, in line with scientific developments, there are specific considerations that the registrant should report for specific endpoints to facilitate the evaluation of whether the tests performed and the data obtained are adequate for the safety assessment of NMs. Table 5 to 7 illustrates key nanospecific considerations for relevant physicochemical, toxicological and ecotoxicological properties to be analyzed during the chemical safety assessment of ENMs on a regulatory basis.

Table 5. Recommendations concerning physicochemical properties

Endpoint	Nanospecific considerations
Water solubility	Nanosized materials may be more soluble than the same substance in bulk form. A review of OECD TG 105 (water solubility), with respect to NM testing, is ongoing (OECD 2016a). OECD (2014a) previously concluded that TG 105 is not appropriate for NMs and a new TG should be created to address the dissolution behavior of NMs
Partition coefficient n-octanol/water	The current Test Guidelines for n-octanol/water partition coefficient (OECD TG 107, 117, 123) might be applicable under some circumstances, although further work is required.
Flash-point	OECD concluded that the Test Guideline relevant to characterising the flashpoint (i.e. OECD TG 113) is considered applicable to NMs (OECD 2009).
Flammability	Flammability and explosive properties may differ between nano and bulk form of a same substance. The following properties have been defined as important for estimating the explosive risk of NMs: i) particle size, size distribution and shape; ii) surface area and surface charge; and iii) particle and surface composition.
Granulometry	In ECHA guidance (ECHA 2012a) specifies that in the case of NMs, shape and specific surface area are inseparable parts of granulometry. A number of methods are provided for determining the particle size fractions, which are then used to assess the possible health effects resulting from inhalation of airborne particles in the workplace.
Dissociation constant	This endpoint should be taken into consideration especially when dealing with surface treated nanoparticles. OECD (OECD 2012a) highlighted that surface acidity (related to dissociation constants of surface ionisable sites) is an aspect of surface chemistry that may be particularly relevant
Viscosity	OECD concluded that the Test Guideline on relevant viscosity characterization (i.e. OECD TG 114) is not applicable to ENM or, if applicable, provides no useful information.

Table 6. Recommendations concerning toxicological properties

Endpoint	Nanospecific considerations
Skin irritation or skin corrosion	Standard test methods applicable. Non-testing approaches applicable when a scientific justification is available
Eye irritation	Standard test methods applicable. Non-testing approaches applicable when a scientific justification is available
Skin sensitization	Standard test methods applicable. Non-testing approaches applicable when a scientific justification is available
Mutagenicity	The majority of the test methods are applicable. However, the bacterial reverse mutation test (Ames test) is not considered reliable for the assessment of NMs and should not be used as a single test for mutagenicity (ECHA 2012a, 2013a, OECD 2014b).
Acute toxicity	For NMs, inhalation may be the most likely route of exposure. ECHA may require testing by inhalation when the substance is a solid with inhalable particle size (ECHA 2015). Non-testing approaches applicable when a scientific justification is available
Repeated toxicity	Consideration of aspects on lung overload in the interpretation of the study needed.
Toxicokinetics	Group Assessing Already Registered Nanomaterials (GAARN) encouraged evaluating toxicokinetic data for grouping and read-across as well as for extrapolation of information from in vitro to in vivo

Table 7. Recommendations concerning eco toxicological properties

Endpoint	Nanospecific considerations
Aquatic toxicity	Standard test methods applicable. However, special attention needed concerning solubility and particle deposition.
Degradation	OECD (2014c) identified degradation (abiotic and biotic) of NMs among the important pieces of information to be known before further tests in water compartments are conducted. ECHA (2012b) clarified that a majority of OECD TGs on biodegradability are applicable for those NMs that are of organic nature.
Bioaccumulation in aquatic species, preferably fish	Measured bioconcentration factor (BCF) values are required and, in connection, it is important to consider changes in e.g. size of aggregates and agglomerates during testing (ECHA 2012c). For dissolving NMs, information on the form of the substance present in the animal tissue is important (ECHA 2012c). Non-testing approaches applicable when a scientific justification is available.
Effects on terrestrial organisms	Estimates based on partitioning may not be relevant, as substances may be distributed in the environment as particles (ECHA 2012c). It was stated that guidance on detection techniques for NMs in soil is needed, and understanding the state of the NM in soils was considered critical for interpreting results.
Effects on sediment organisms	

Indicators of progress according to planned outputs and time scheduled.

Table 8. Indicators of Progress in Action A1

Indicator	Measure of success	Results	Status
Nº of ENMs	A minimum of 10 NMs will be studied.	12 ENMs were selected	Achieved
ENMs profile	Carbon-based materials (CNTs) metal based NMs (NPs-Metal and Metal Oxides) and natural occurring NMs (Nanoclays & Nanocellulose).	The target ENMs include carbon based ENMs, metals, inorganic metal oxides and natural ENMs	Achieved
Applications	Four industrial applications, including the automotive industry, packaging, building and wire/cable industry.	Target ENMs cover 4 industrial sectors: packaging, construction, automotive and electronics	Achieved

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

Action status: Achieved
Timescale in Proposal: October 2013 - February 2014
Actual: October 2013 - March 2014

Objectives: the main goal of this action is to compile information on the operative conditions and risk management measures implemented during the manufacturing and downstream use of the ENMs, as well as data on the concentration of ENMs, their aggregates and agglomerates in indoor workplaces.

Activities Conducted: the activities conducted were in line with the scheduled tasks. Within task A2.1 we conducted a complete study of existing processes and operative conditions at all stages of the life-cycle, from production, use, accidental spills, and consumer use, to end-of-life treatments, identifying key activities and processes where a potential exposure to ENMs via inhalation and dermal contact can be expected.
Within task A2.2, the activities identified were described according with the use descriptors systems defined in the chapter R.12 of the Guidance on information requirements and chemical

safety assessment published by ECHA on 2010. The last activity conducted within the action was the compilation of data on the levels of exposure from peer reviewed publications and measured data analyzed by ITENE and VITO in measurement campaigns. The following Gantt-chart shows the progress of the action.

		2013			2014			
Action / Task		Oct	Nov	Dec	Jan	Feb	Mar	Apr
Action A2. Information gathering on the conditions of use, risk management measures and exposure data across nanomaterials life cycle	Proposed		A2a		A2b	A2c		
	Actual		A2a		A2b	A2c		

Results and deliverables: on the basis of the available information, 30 exposure scenarios (ES) were identified and grouped in four main generic exposure scenarios (GES), considering all life cycle stages of ENMs used for manufacturing polymer based nanocomposites.

An exposure scenario is the cornerstone of the chemical safety assessment and the related communication in the supply chains under REACH. These scenarios must be identified along the entire life cycle of the substance, including a complete description of the conditions under which the risks associated with the identified use(s) of a substance can be controlled. Within this action, operative conditions and risk management measures (RMMs) for workers were described for each handling activity. The following table depicts the list of generic exposure scenarios defined under the scope of the project.

Table 9. Generic exposure scenarios identified

Number	Life Cycle Stage	Exposure Scenario	Use
GES 1	Nanoparticles production	ES 1	NP's synthesis
		ES 2	NP's Functionalization
GES 2	Formulation	ES 3	Manufacture of intermediates (blending/mixing)
		ES 4	Formulation
GES 3	Industrial use. Uses of additives in Polymer Production	ES 5	As component for production of dispersions, pastes and other viscous matrices
		ES 6	As component for solid blends and matrices
GES 4	Service life	ES 7	Industrial use of nanocomposites
		ES 8	Professional use of nanocomposites

Each Generic exposure scenario is decomposed into different specific scenarios for each ENMs, all of them described using the use descriptor system recommended under the framework of REACH by the European Chemicals Agency. An example of these scenarios is provided in table 10. In addition, the actives conducted under each exposure scenario were also compiled to provide a better understanding of the current operative conditions applied at industrial level.

An example of the task conducted under the ZnO synthesis exposure scenario are included in tables 11a and 11b.

Table 10. List of exposure scenarios identified for metal oxide NPs

GES CODE	NUMBER	BRIEF DESCRIPTION OF EXPOSURE SCENARIO	LIFE CYCLE STAGE COVERED BY THE EXPOSURE SCENARIO					SECTORS OF USE (SU)	CHEMICAL PRODUCT CATEGORY (PC)	PROCESS CATEGORIES (PROC)	ENVIRONMENTAL RELEASE CATEGORIES (ERC)	ARTICLE CATEGORIES NO RELEASE INTENDED (AC)
			MANUFACTURE	FORMULATION	FINAL USE							
					INDUSTRIAL USE	PROFESSIONAL USE	CONSUMER USE					
GES 1	ES 1	Nanoparticles synthesis	X					SU9		PROC 1 PROC 2 PROC 4 PROC8b	ERC2	
	ES 2	NP's Functionalization	X					SU9		PROC 1 PROC 2 PROC 4 PROC8b	ERC2	
GES 2	ES 3	Manufacture of intermediates		X				SU 10	PC 19	PROC 1 PROC 2 PROC 4 PROC8b	ERC 3	
	ES 4	General Formulation		X				SU 10		PROC 3 PROC 5	ERC 3	
	ES 5	Laboratory reagent		X				SU 10 SU 24		PROC 15	ERC 3	

Table 11a. Activities contributing to the exposure during the synthesis of ZnO nanoparticles

ES1: Synthesis of nano ZnO						
Contributing exposure Scenario		Process Category (PROC)	Sector of Use (SU)	Product Category (PC)	Article Category (AC)	Environmental Release Category (ERC)
Task 1	Handling	**PROC 15:** Use of laboratory reagents in small scale laboratories **PROC 19:** Hand-mixing with intimate contact (only PPE available)	SU 3 SU 8 SU9	-	-	ERC 1 ERC 4
Task 2	Weighing	**PROC 26:** Handling of solid inorganic substances at ambient temperature.				
Task 3	Bagging	**PROC 8a:** Transfer of chemicals from/to vessels/ large containers at non dedicated facilities **PROC 8b:** Transfer of chemicals from/to vessels/ large containers at dedicated facilities **PROC 9:** Transfer of chemicals into small containers (dedicated filling line)				
Task 4	Cleaning and maintenance	**PROC 0:** Cleaning and maintenance				

Table 11b. Operative conditions during the synthesis of ZnO nanoparticles

	OPERATIVE CONDITIONS							
	Process	PROC	Physical form	Conc.	Applied amount	Duration and frequency	Tª	Process Type
Synthesis	Handling	PROC 15 PROC 19	Liquid, vapour pressure < 0.5 kPa	Aqueous solution of zinc acetate (5 to 25 wt%)	Medium Quantities (several kg)	2-4 h/day 2-3 days/week	25 °C	Manual
	Weighing	PROC 26					25 °C	Automatic
	Bagging	PROC 8a PROC 8b PROC 9	Solid, high dustiness	100 %			25 °C	Automatic
	Cleaning and maintenance	PROC 0		100 %		0.5-2h/day; 2-3 day/week	25 °C	Manual

Regarding the number of Risk Management Measures, we have developed an excel spreadsheet containing **25 RMMs selected** on the basis of the information retrieved from questionnaires and peer reviewed publications.

Table 12. List of Risk Management Measures defined within the project

	Control group	Specifications
1	Disposable filtering half mask	P1 (FFP1)
2	Disposable filtering half mask	P2 (FFP2)
3	Disposable filtering half mask	P3 (FFP3)
4	Unpowered Half mask	Filter type P1L
5	Unpowered Half mask	Filter type P2L
6	Unpowered Half mask	Filter type P3L
7	Unpowered Half mask	Gas-vapor-particulate filter (combined filter)
8	Unpowered Full face mask	Filter type P1L
9	Unpowered Full face mask	Filter type P2L
10	Unpowered Full face mask	Filter type P3L
11	Unpowered Full face mask	Gas-vapor-particulate filter (combined filter)
12	Chemical protective gloves	Nitrile
13	Chemical protective gloves	Neoprene
14	Chemical protective gloves	Polyvinyl chloride (PVC)
15	Chemical protective gloves	Butyl
16	Chemical protective gloves	Latex
17	Body protection	Laboratory Coats / Pants
18	Body protection	Disposable coveralls
19	Body protection	Full Body Suit (Tyvek / Saranex)
20	Body protection	Chemical Splash Suit
21	Eyes protection	Safety glasses
22	Receiving hoods (LEV Systems)	Canopy hoods
23	Capturing hoods (LEV Systems)	Movable capturing hoods
24	Enclosing hoods (LEV Systems)	Fume cupboard (without glove bags)
25	Enclosing hoods (LEV Systems)	Glove bag (ventilated or kept under negative pressure)

Finally, the data retrieved from relevant publications concerning the levels of exposure in occupational settings showed exposure levels higher than **45.000 particles/cm^3** in relevant stages of the life cycle, with a maximum peaks higher than **3x10^6 particles/cm3** during compounding operations.

Figure 6 shows average exposure levels at several stages of the life cycle, highlighting exposure levels higher than 150.000 NPs / cm^3 during grinding and compounding operations.

On the basis of the levels of ENMs reported in the different studies, it can be affirmed that during the compounding process, the high level of energy applied can led both to a thermo-mechanical degradation of the nanocomposite (especially the thermoplastic matrix) and off-gassing, thus enabling embedded nano-objects to go airborne.

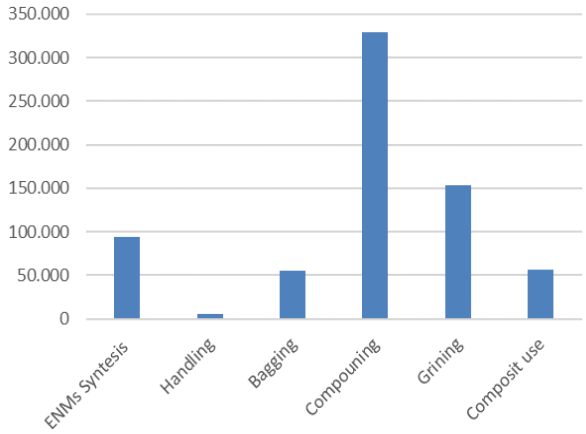


Figure 6. Exposure levels across NMs Life Cycle - Average concentration (NPS/cm3)

On the other hand, on the basis of the publications, the grinding process generates a large amount of airborne particles, mostly small pieces of polymer containing nano-fillers. Moreover, a phase which seems to be critical is the discharging of the materials, including both nanofillers as such or the masterbach granulates (1-4 mm). In the second option, the mixed material containing the nanofilliers is exposed to temperatures close to those of the precessing's conditions, meaning potential thermal degradation and emission of otherwise entrapped gases or particles.The activities conducted within the action are reported in deliverables A2a, A2b and A2c, all attached to the present document.

Indicators of progress according with planned outputs and time scheduled:
Table 13. Indicators of Progress in Action A2

Indicator	Measure of success	Results	Status
Nº of Endpoints covered	Study of 4 different processes for each one of the 4 industrial applications selected in task A1, automotive industry, packaging, building and construction and wire/cable industry.	We have identified the following processes in the life cycle: manufacturing, formulation, industrial use (compounding / injection) and professional uses.	Achieved
Risk management Measures	In this task, it will be analysed a minimum of 10 control measures for each of the NMs Considered.	More than 10 different types of RMMs have been studied, including respirators, protective clothing, protective gloves, eye protection, and fume cupboards.	Achieved
Exposure levels	Information on the exposure levels for at least 10 different processes.	Current levels of exposure available for 12 different processes.	Achieved

5.1.3. Action A3. Compilation of data regarding the efficiency of risk management measures for occupational and environmental exposures

Action status: Achieved
Timescale in Proposal: November 2013 - March 2014
Actual: November 2013 - March 2014

Objectives: The aim of this action is to collect information on the effectiveness of the risk management measures, including data on the efficacy of engineering controls, personal protective equipment and administrative controls.

Activities Conducted: the action was completed successfully, including the definition of the factors to be studied when evaluating the effectiveness of the RMMs selected (i.e. performance factors), the identification of reliable information on the effectiveness of personal protective equipment (PPE) and technical measures against ENMs from peer reviewed publications, and the critical evaluation of the experimental approaches retrieved from the literature.

A review of journals was undertaken for each type of RMMs. A computerized search using Google Scholar, PubMed and Web of Science was conducted to locate peer-reviewed publications that quantitatively reported results on the efficacy of RMMs. Moreover, relevant references mentioned in the RMM-library developed by CEFIC, and the Control Efficacy Library (ECEL) (www.ecellibrary.com), which contains data on the effectiveness of RMM to control inhalation (personal) exposures to airborne contaminants, were also studied.

The following Gantt-chart shows the progress of the action. The following Gantt-chart shows the progress of the action.

		2013			2014			
Action / Task		Oct	Nov	Dec	Jan	Feb	Mar	Apr
Task A3.1. Definition of performance factors	Proposed							
	Actual							
Task A3.2. Identification of reliable information on RMM effectiveness	Proposed							
	Actual							
Task A.3.3. Evaluation of available information of the definition of RMM efficiency	Proposed						A3	
	Actual						A3	

Results and deliverables: a compendium of **10 performance factors** were defined within task A3.1. In addition, a list of **29 priority references containing data on the RMMs efficiency** were classified as reliable within task A3.2. The list of performance factors evaluated to study the level of protection provided by PPE and ventilation is depicted in table 14:

Table 14. Performance factors studied within the NanoREG project

Measures	RMM Type	Performace
Respiratory protective equipment (RPE)	Filtering Facepiece (FFP)	Total Inward Leakage (TIL) Nominal protection factor (NPF)
	Half-Face mask (HM) Full-Face mask (FM)	Inward Leakage (IL) Total Inward Leakage (TIL) Nominal protection factor (NPF)
Dermal protective equipment	Chemical protective gloves (DPE-Gloves	Permeation Penetration Nominal protection factor (NPF)
	Protective clothing	Total Inward Leakage (TIL) Nominal protection factor (NPF)
Eye protection	Safety glasses Safety googles	Total Inward Leakage (TIL)
Ventilation	Local Exhaustive ventilation	Capture efficiency (Cf)

This level of protection “performance factor” is defined as a product (risk management measure) characteristic which tells us quantitatively how capable the product is in reducing the risk (directly or indirectly). Within the project, the performance factors to be studied were determined by studying litera-ture and current standardsAn overview of relevant and reliable literature collected for each risk management measure is given in the following table.

Table 15. Published studies on the effectiveness of respiratory and dermal protective equipment against nanomaterials.

PPEs	Type	ENM	Size (nm)	Efficiency (ENMs)	Certified efficiency	Reference
Filtering facepiece respirators (FFP)	N95 (free of oil)	NaCl	20–500	P95 > 85 % N95 > 91 – 99 %	≥ 95 %	Gao S, et al. 2015
	P95 (oil resistant)					
	N95	NaCl	10–400	98.79 - 99,10%	≥ 95 %	Vo E, et al. 2015.
	P100			99.77 - 99,98%	≥ 99.97 %	
	FFP1	NaCl	93-1600	93.60 – 95.00%	≥ 78 %	Lee SA, et al. 2016
	FFP2			91.90 – 93.50%	≥ 92 %	
	FFP3			86,50 – 93.90%	≥ 98%	

PPEs	Type	ENM	Size (nm)	Efficiency (ENMs)	Certified efficiency	Reference
Filtering facepiece respirators (FFP)	N95	NaCl	7 – 289	96,90%	≥ 95 %	Ramirez JA, et al. 2016
	N95			94,70%		
	N95	NaCl	50 - 200	81,10%	≥ 95 %	Huang et al; 2007.
	FFP1			94,20%	≥ 78 %	
	N95	NaCl	8 - 400	98,47%	≥ 95 %	Rengasamy et al; 2011b,
	P100			99,23%	≥ 99.97 %	
	FFP2			65,30%	≥ 92 %	
	FFP3			97,80%	≥ 98%	
	N95 A	NaCl	10 - 600	94 - 95,00%	≥ 95 %	Bałazy, A. et al. 2006
	N99	NaCl	< 0,1 µm	95,50 – 97.40	≥ 99 %	Eninger, R. M., et al.. 2008.
	N95 B			96,60%	≥ 95 %	
	N95 C	NaCl	45 - 52	97,30%		Mostofi et al; 2011;
Half-mask	N95	NaCl	10-400	>99,49%	≥ 95 %	Vo E, et al. 2015
	P100			99.98 - 99,99%	≥ 99.97 %	
Protective clothes	Cotton fabric	Graphite	35 - 40	F.F.E: 73,00%	≥70 %	Golanski L, et al. 2009
	HD Polyethylene textile			F.F.E: 99,40%	≥ 99.7 %	
	Cotton fabric	TiO2	9 - 90	F.F.E: 73%	≥70 %	Golanski L, et al. 2010,
	HD Polyethylene textile	Pt	9 - 19	F.F.E: 99,40%	≥ 99.7 %	
	Woven and fibrous fabrics	NaCl	100-500	F.F.E: 50 - 80%	≥ 97 %	Huang S.H, et al. 2007
	Nonwoven fabrics (A,B,C)	NaCl	14 – 400	F.F.E: A, B, C >99%	≥ 99.7 %	Ben Salah, et al 2016
	Woven fabrics (D, E)			F.F.E: 91.5%	≥ 97 %	
Protective gloves	Nitrile	TiO_2 NPs	5nm	Penetration observed	Only for liquids	Vinches et al. 2011
	Nitrile / Neoprene /Latex/ Vinyl	Graphite	40 nm	No penetration		Golanski et al. 2009a
	Latex / Nitrile	Silver	90 nm	Penetration observed		Park et al. 2011
	Nitrile and latex glove	Nanoclay Al2O3		No penetration		Ahn et al.

T.I.L: Total Inward Leakage / FFE: Fabric Filtration Efficiency

As can be derived from the table, in some cases, conflicting results have been found mainly due to differences on the experimental set up, including differences in the characterization measures, time of exposure and/or specifications of the samples tested.

The activities conducted within the action are reported in deliverable A3 “Efficiency of risk management measures (RMM) for occupational and environmental exposure to nanomaterials”, attached to the present document.

Indicators of progress according with planned outputs and time scheduled

Table 16. Indicators of Progress in Action A3

Indicator	Measure of success	Results	Status
Number of performance factors per control approach	At least 2 performance factors must be assessed for each control approach in order to support the comparative evaluations.	10 performance factors were finally identified and tested in further actions.	Achieved
Number of information sources per control approach	A minimum of 10 studies must be consulted in order to define a reliable value of effectiveness.	More than 30 publications were used to define a reliable value of effectiveness	Achieved
Types of RMM considered	The task will provide data for at least the effectiveness of: Administrative controls, chemical protective gloves, protective clothing, respirators, laboratory hoods, extracted booths, LEV captor hoods, safety Cabinets and safety glasses	The data retrieved from the literature includes data on the effectiveness of the types of RMMS initially defined	Achieved

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

Action status: Achieved
Timescale in Proposal: November 2013 – February 2014
Actual: November 2013 – February 2014

Objectives: the main goal of this action is to clearly define the technical requirements of the test chamber prototype for conducting standardized testing.

Activities Conducted: the action was finalized as scheduled. VITO and ITENE defined the list of experimental data that shall be controlled in the chamber during the execution of the experimental activities within task A4.1. The equipment needed to perform the experiment was defined within task A4.2, while the technical specifications of the chamber were defined during a face to face meeting held in Belgium last January, 2014, including: spatial dimensions, volume (m3), number of sampling points (aerosol inlets), number of aerosol outlets, proposed materials, range of environmental conditions and air flow.

The following Gantt-chart shows the progress of the action.

		2013			2014			
Action / Task		Oct	Nov	Dec	Jan	Feb	Mar	Apr
Task A4.1. Definition of Study Parameters	Proposed			A4a				
	Actual				A4a			
Task A4.2. Characterization of technical requirements	Proposed							
	Actual							
Task A4.3. Description of the test chamber requirements	Proposed					A4b		
	Actual					A4b		

Results and deliverables: The first task within action A4 was focused on the definition of the data that shall be retrieved using the aerosol testing chamber in view of the performance factors to be evaluated. The most relevant parameters defined are the following: Number Concentration, size distribution, mass, surface area, temperature, pressure, relative humidity, chemical nature of the particles, flow and aggregation /agglomeration patterns.

Regarding the equipment to be used, ITENE and VITO defined a list of measurement devices selected to measure the parameters defined within task A4.1. The list of devices and main specifications is depicted in the table below.

Table 17. Measurement devices selected

Nº	Measurement devices proposed
1	SMPS, TSI model 3936 (2.5 - 1000 nm), 1 to 10^8 p/cm^3
2	SMPS, TSI model 3034 (10 – 487 nm), 1 to 2.4×10^6 p/cm^3
3	NanoID (Naneum) model NPS500 (5 – 500 nm), p/cm^3
4	FMPS, TSI model 3091 (5.6 – 560 nm), p/cm^3
5	EEPS, TSI model 3090 (5.6 - 560 nm), p/cm^3
6	Aerotrak (handheld OPC), (TSI model 9303/9306 (≈300 – 25 000 nm), 2 * 10^6 p/cm^3
7	Aerotrak (OPC),(TSI different models (100 – 25 000 nm), 40 000 p/cm^3 (depends on model)
8	APS (OPC), TSI model 3321 (500 – 20 000 nm), 0.001–10^4 p/cm^3
9	MiniDiSC (10 – 300 nm), 10^3 – 10^6 p/cm^3
10	ELPI, DEKATI model (7 – 10 000 nm), p/cm^3
11	CPC (handheld), TSI model 3007 (10 - >1 000 nm), 10^5 p/cm^3
12	CPC (portable), (TSI models 3772, 3775, 3776, 3781, 3785, 3786, 3790 (≈2.5 – 3 000 nm), 10^7 p/cm^3 (depends on model)
13	P-trak (CPC), TSI model 8525 (20 – 1000 nm), 0 - 5x10^5 p/cm^3
14	NanoTracer, Aerasense Philips (10 – 300 nm), 1500 – 10^6 p/cm^3
15	Aerotrak, TSI model 9000 (10 – 1000 nm), 1 – 2 500 and 1 – 10 000 µm^2/cc
16	LQ1 1-DC (4 – 10000 nm), 0 – 2 000 µm^2/cm^3
17	EcoChem DC2000CE (~ 2 - 10 000 nm), ~ 10 to 1000 µm^2/cm^3
18	NSAM, TSI model 3550 (10 – 1000 nm), 0 – 2 500 and 0 – 10 000 µm^2/cm^3
19	Epiphaniometer (10 – 1000 nm), µm^2/cm^3
20	DustTrak, TSI models 8530, 8531, 8532 (100 – 10000 nm), 0.001 – 400 mg/m^3 (depends on model)
21	DustTrak, TSI models 8533, 8534 (100 – 15000 nm), 0.001 – 400 mg/m^3 (depends on model)
22	TEOM, model APM 1400ab (no PS), 0 - 50 00 000 µg/m^3
23	Aethalometer, model AE42-7 (0 – 950 nm), µg/m^3

Note: all relevant gravimetric methods will also be included if mass is presented (e.g. NIOSH method 7302)

The specifications of the test chamber requirements were defined. These specifications were defined on the basis of the special characteristics of the nanomaterials and the experimental set up requirements defined within different harmonized standards for PPE and EC testing.

The main characteristics of the chamber are described in the following paragraphs.

- Spatial dimensions. external dimensions excluding ventilation systems are approximately (L) 4200 x (W) 4350 x (H) 2500mm. The chamber will be divided into three main areas, including a **laminar flow chamber**, a **turbulent flow chamber**, as well as SAS or safe area.

- Ventilation: The ventilation system (blowing unit) is a key element of the testing activities, being located on the roof of the chamber, especially designed to allow the maintenance of the chamber, as well as the installation of new elements.
- Structure: The structure of the test chamber is made of **white partition walls** of 50 and 60 mm, commonly named sandwich panels. These panels meet the UNE-EN 14509:2006/AC: 2009 standard, and are covered with an antistatic resin to reduce the electrostatic interaction with airborne nanoparticles. The wall junctions will smoothed using cove-shaped profiles in order to make cleaning easier, reducing at the same time the likelihood of generating a turbulent flow.

  Beside the above, to reduce the release of nanomaterials, the design of the chamber includes a Safety Access System (SAS), commonly used in ISO class clean rooms. This SAS room is designed to maintain a positive pressure, and therefore, will ensure that the tested nanomaterials remain inside the testing rooms. The overall dimension of the SAS are (L) 2500 mm x (W) 1750 mm x (H) 2150 mm.

The quality of the air inside the chamber is controlled by means of a HEPA filtering unit fitted in the chambers. This HEPA filtering unit is designed to remove any nanomaterial or particulate matter from the air, avoiding the release of nanomaterials outside the room. To this end, a ventilation system **based on H14 class HEPA filters** able to collect NMs was considered. The figure on the right shows the CAD drawings of the testing chamber.

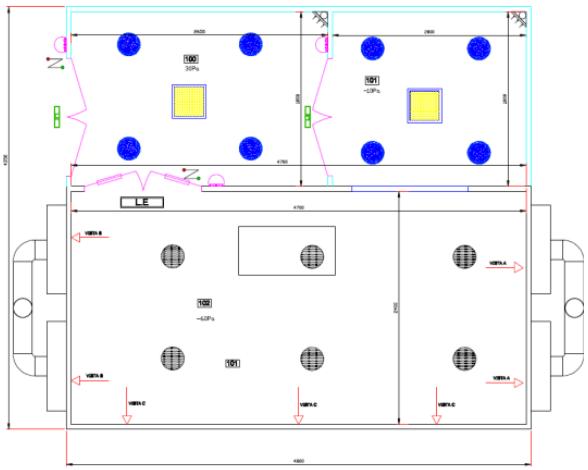


Figure 7. Nanoaerosol testing chamber prototype CAD drawing

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

Indicators of progress according with planned outputs and time scheduled:

Table 18. Indicators of Progress in Action A4

Indicator	Measure of success	Results	Status
Number of study parameters	The test chamber must be able to evaluate at least the 75 % of the study parameters defined.	The chamber and associated equipment was designed to allow the evaluation of the parameters defined, including number and mass concentration, size distribution and surface area, aggregation/agglomeration patters, humidity, pressure and temperature.	Achieved
Types of set up approaches	The test chamber must be able to reproduce at least the 50 different operational conditions.	The design in two separated rooms allow the simulation of more than 50 industrial operations.	Achieved

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

Action status: Achieved
Timescale in Proposal: November 2013 – April 2014
Actual: November 2013 – June 2014

Objectives: main goal of this action is to identify and compile the current standards and guidelines on RMMs effectiveness testing applicable under the scope of the project, evaluate the applicability of the experimental set up defined by the selected standards for ENMs testing, and 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.

Activities Conducted and progress so far: the action was completed last June 2014, two months later than initially expected. The task is divided into 3 main actions, considering the compilation of available standards in task B1.1, the definition of adequate protocols for RMMs testing within task B.1.2, and the critical evaluation of the protocols for ENMs testing.

VITO and ITENE have reviewed 58 standards related with the evaluation of the protection against chemicals agents in solid or powder forms in the context of task B1.1. Moreover, 10 standard protocols have been defined after the analysis of the standards retrieved from the literature in B1.2. Finally, the adequacy of the selected standards has been analyzed and described within task B1.3, being reported within deliverable B1.

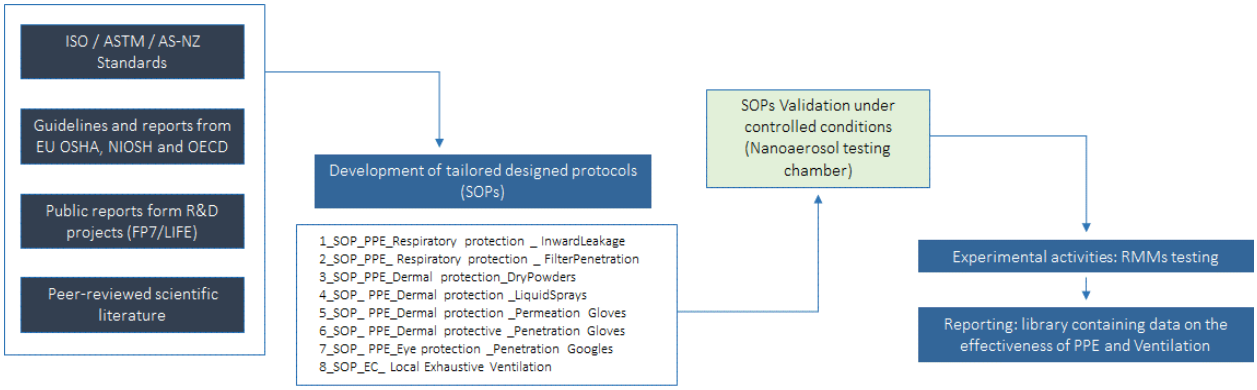


Figure 8. Flow-chart of the activities conducted within action B1.

The annex section of this report includes the protocols (SOPs) developed within action B1, which are intended to evaluate the effectiveness of common RMMs against ENMs. The adequacy of the current approaches defined in ISO and ASTM standards is also analyzed under deliverable B1.

The following Gantt-chart shows the progress of the action:

Action / Task		2013 Oct	Nov	Dec	2014 Jan	Feb	Mar	Apr	May	Jun
Task B1.1. Identification and compilation of available standards for RMM testing	Proposed									
	Actual									
Task B1.2. Definition and description of protocols for RMMs testing	Proposed									
	Actual									
Task B1.3. Adequacy of standards for testing the effectiveness of RMMs against ENMs	Proposed							B1		
	Actual									B1

Results and deliverables: 58 key standards dealing with the evaluation of the performance of relevant RMMs were identified and scrutinized. In detail, 31 standards are related with the effectiveness of respiratory equipment, 5 with dermal protection, 17 with protective clothing, 2 with safety glasses, and 3 more with safety shoes. Moreover, 10 standards refer the effectiveness and performance of ventilation systems. Table 19 summarizes the most relevant standards identified.

Table 19. Main standards applied to evaluate the effectiveness of RMMs

Standards	RMMs / Description
Respiratory Equipment	
EN 149:2001+A1:2009	Filtering half masks to protect against particles
EN 405:2002+A1:2009	Valved filtering half masks to protect against gases or gases and particles
EN 1827:1999+A1:2009	Half masks without inhalation valves and with separable filters to protect against gases or gases and particles or particles only
EN 136:1998/C2:2007	Full face masks – Requirements, testing, marking
EN 140:1998/C1:2000	Half masks and quarter masks – Requirements, testing, marking
EN 143:2000/A1:2006	Particle filters – Requirements, testing, marking
EN 13274-7:2008	Respiratory protective devices. Part 7: Determination of particle filter penetration
EN 13274-1:2001	Respiratory protective devices. Part 1. Determination of inward leakage and total inward leakage
EN 13274-2:2001	Practical performance tests
Dermal Protection	
EN 374-2:2003	Determination of resistance to penetration
EN 374-3:2003	Determination of resistance to permeation by chemicals
EN 16523-1:2015	Determination of material resistance to permeation by chemicals – Part 1: Permeation by liquid chemical under conditions of continuous contact
Protective Clothing	
ISO 13982-2:2004	Protective clothing for use against solid particulates. Part 2: Test method of determination of inward leakage of aerosols of fine particles into suits
EN 14325:2004	Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages
EN 14605/A1	Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections.
EN 13034:2005 +A1:2009	Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and PB [6])

Standards	RMMs / Description
ISO 17491-4:2008	Test methods for clothing providing protection against chemicals. Part 4: Determination of resistance to penetration by a spray of liquid (spray test)
Footwear protecting against chemicals	
EN 13832-2:2006	Requirements for footwear resistant to chemicals under lab. Conditions
Eyes Protection	
EN 168:2001	Personal eye protection – Non-optical test methods
ANSI Z87.1-2015	Personal eye protection. Eye and face protector for occupational applications
Ventilation	
EN 14175-4	Fume cupboards – Part 4: On-site test methods
ANSI/ASHRAE 110-1995	Method of Testing Performance of Laboratory Fume Hoods
DIN 12927	Ductless filtering fume enclosures – Requirements, test
ASRAE 52 2007	Method of testing general ventilation air-cleaning devices for removal efficiency by particle size
EN 1822:2009	Filter medium test, filter leakage test and filter overall efficiency test.

A compendium of 11 standards were finally selected as reference harmonized standards considering potential constrains related the specific properties of ENMs, including low solubility, stability in dispersion, or aggregation/agglomeration ratio, among others, as well as their applicability to the types of PPE and engineering controls selected under the scope the project. Table 20 includes the list of selected standards and related performance factors.

Table 20. List of selected standards to evaluate the effectiveness of RMMs under NanoRISK

Standards	RMMs	Performance factor
EN 13274-1:2001	Respiratory protective equipment (RPE)	Penetration, *P* (%): Inward leakage (IL) and Total inward leakage (TIL) Efficiency (%): *P* (%) – 100 Nominal protection factor (NPF)
EN 13274-7:2008	Respiratory protective devices: Particle filters	Penetration, P (%)
EN 374-2:2003	Chemical protective gloves	Resistance to penetration
EN 374-3:2003		Resistance to permeation
EN 16523-1:2015		Resistance to permeation under conditions of continuous contact
ISO/CD 19918 "		Cumulative permeation of chemicals with low vapour pressure through materials"
ISO 13982-2:2004	Protective clothing for use against solid particulates	Nominal Protection factor (NPF) and Total average inward leakage (TILA).
EN 168:2001	Personal eye protection – Non-optical test methods	Protection against gases and fine dust particles
AS/NZS 1337:1:2010	Personal eye protection.	
UNE-EN 14175-4:2005 ANSI/ASHRAE 52 2007	Local Exhaustive ventilation	Capture Efficiency (Cf)
UNE-EN 1822 ASHRAE 52 2007	Local Exhaustive ventilation	Capture Efficiency (Cf)

Regarding the testing protocols, **new testing protocols** based on ISO, BS, and ASTM standards have been developed within task B1.2. The protocols have been preparing following the structure of the ISO standards, including related standards and references, purpose and performance factors, detailed description of the methods and instrumentation.

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

The structure defined for each of the above-mentioned is depicted below:

1. Scope and objectives of the SOP

Chapter 1 defines the types of risk management measures covered by the SOP, reference standards, and main goal of the operating procedure.

2. Definitions

Chapter 2 contains definitions of technical terms used within the operating procedure.

3. Performance factor and principle of the method

Chapter 3 clearly defines the performance factor to be characterized under the scope of the procedure, as well as the working principle of the operating procedure.

4. Requirements

Chapter 4 defines basic considerations of the procedure, including minimum number of samples and replicates, testing concentration, sample conditioning, and issues concerning health and safety.

5. Measurement Equipment

Chapter 5 provides information on the specifications of the equipment to be used to characterize the performance of the RMM under the scope of the procedure.

6. Pre-requisites

Chapter 6 includes a list of elements to be considered before starting the test, including sampling storage, visual examinations or pre-testing, among others.

7. Operating procedure

Chapter 7 details the steps to be conducted to evaluate the performance of the risk management measures to be studied under the scope of the operating procedure. The experimental set-up and testing protocol are detailed in figures to support the reproduction of the procedure.

8. Calculation procedure

Chapter 8 provides instructions to analyse the data and calculate the values of the performance factors defined under the scope of the procedure.

9. Validation criteria

Chapter 9 provides information on the quality criteria to be considered to validate the results of the test completed.

10. Data treatment and reporting

Chapter 10 provides instructions to report the results of the test, including recommended forms, units and contextual information to be provided.

11. References

Chapter 11 provides a list of related harmonised standards and peer reviewed publications.

Indicators of progress according with planned outputs and time scheduled

Table 21. Indicators of Progress in Action B1

Indicator	Measure of success	Results	Status
Nº Protocols	At least 50 full described testing methods will be obtained from the information sources	58 protocols related with the effectiveness of RMMs were retrieved. List available in excel spreadsheets	Achieved
Nª testing methods	At least 100 published reports and standards from key organisations shall be studied	More than 100 standards reviewed	Achieved
Adequacy of testing approaches	The protocols developed shall be classified as adequate, with a score higher than 20 points.	Each protocols developed evaluated according with the scoring system defined	Achieved

5.1.6. Action B2. Design and construction of the test chamber prototype

Action status: Achieved
Timescale in Proposal: January 2014 – September 2014
Actual: January 2014 – September 2014

Objectives: the main goal of the action is to design and develop 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 construction, conditioning and validation.

Activities Conducted: the action was completed as scheduled last September 2014. The action was divided into 3 main tasks, including the design and development of the chamber within task B2.1, a preliminary validation of the specifications of the chamber within task B2.2, and a final validation based on the set up of several trials to evaluate the effectiveness of respirators, dermal protective equipment and local exhaustive ventilation (LEV) systems.

The chamber has been designed by ITENE and VITO on the basis of the requirements of the testing protocols detailed into relevant standards. The technical drawings were developed in January, 2014, being incorporated into a specification document used to contact potential contractors to develop the chamber. The specifications and CAD drawings of the prototype were described within deliverable DA4b, including a complete definition of the structure and spatial dimensions, equipment, and functionalities.

After the liaison with several providers, the Spanish company FE.LM Instalaciones was selected, starting the development in March, 2014. The construction of the chambers was finalized in April 2014, being preliminary validated by ITENE in May 2014.

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. In a second stage, several operating test were conducted to define the operating range of the chamber in term of airflows, illumination, pressure, temperature and humidity.Some improvements were done due to the need of achieving a laminar flow inside the chamber, being necessary the substitution of the blowing unit. Moreover, several improvements were conducted inside the nanoaerosol test chamber prototype to increase the negative pressure inside the chamber, making safer the testing environment. The following Gantt-chart shows the progress of the action:

		2014								
Action / Task		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
Task B.2.1. Computer assisted design	Proposed									
	Actual									
Task B.2.2. Preliminary validation	Proposed				B2a					
	Actual					B2a				
Task B2.3. Final validation of the test chamber for testing and demonstration	Proposed									B2b
	Actual									B2b

Results and deliverables: the specifications of the testing chamber are provided in deliverables A4 and B2, both attached to the present document. The main specifications defined were:

- Laminar flow
- Pressure inside the chamber lower than the atmospheric pressure
- Installation of several layers of filtration media
- Estimated airflow of 1500 m3/h
- Illumination IP667 or higher
- Controllable flow and pressure
- HEPA filtering
- Stainless steel sampling tubes
- Temperature and humidity monitoring and logging.

The abovementioned elements were implemented in the Nanoaerosol testing chamber, being directly specified in the operating conditions manual developed to support the construction of the chamber. As stated previously, the structure of the test chamber was made of white partition walls of 50 and 60 mm, commonly named sandwich panels. These panels meet the UNE-EN 14509:2006/AC: 2009 standard, and are covered with an antistatic resin to reduce the electrostatic interaction with airborne nanoparticles.

The figures in the next pages shown several stages of development of the chamber.

The front panel includes a number of polycarbonate windows specially designed to allow the monitoring of the airborne behaviour of the target nanomaterials, as well the activities inside the chamber. These panels have a dimension of 500x500x8mm, and can be easily removed and mechanized to support the connection of sampling tubes. It can be noted also the presence of big plenums to conduct the air from the right side to the left, and protected with a black cover.

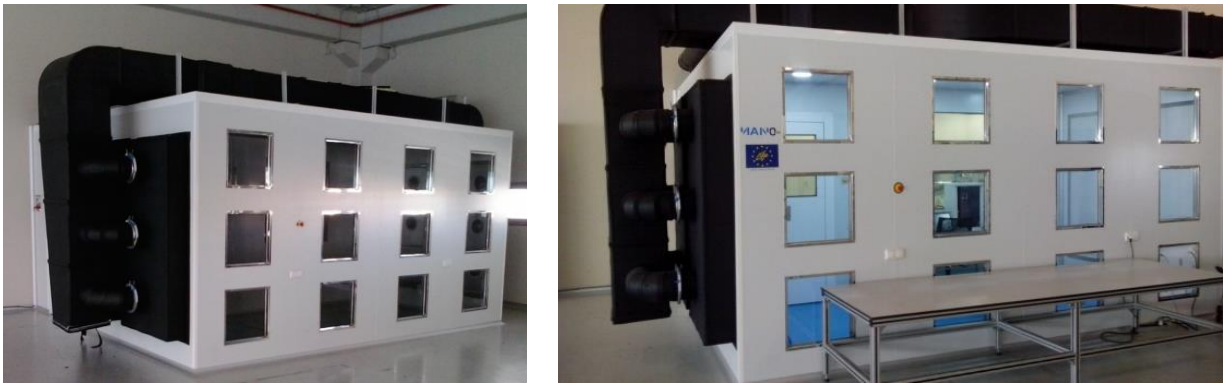


Figure 9. Basic structure (left). Picture of the testing chamber (right) in operation

The chamber was equipped with a digital control panel to regulate the flow and adjust the pressure inside the chamber. Under normal operating conditions, the chamber is designed to achieve a 60Pa negative pressure inside the laminar test room. The wet test room can be maintained in - 10Pa, while the SAS is normally operating at +30Pa. These conditions are optimized to avoid uncontrolled diffuse emissions.

Figure 10 shows pictures of the structural and operational elements of the nanoaerosol testing chamber.

Figure 10a. Control (left). Vacuum gauge (center). Emergency stop button (right)

Figure 10b. Ventilation diaphragms (left). Air exhaust (center). Flow diffusor (right)

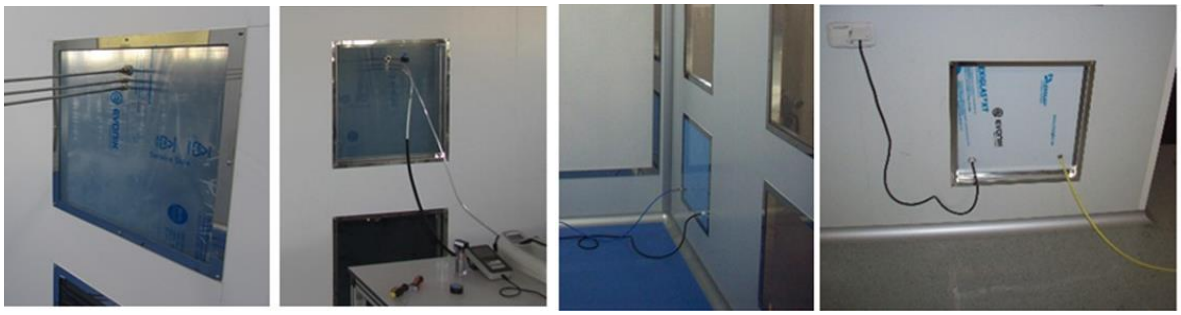


Figure 10c. Samplers inlets across the windows. Inside and outside view (right). / Pneumatic and electric connections through the windows. Inside and outside view (right).

Indicators of progress according with planned outputs and time scheduled

Table 22. Indicators of Progress in Action B2

Indicator	Measure of success	Results	Status
Variability for the selected performance indicators	The coefficient of variation for each performance indicators must be below 10 %.	Validation completed in May 2014 – New Improvements available	Achieved
Correlation between the outcomes from three pre-selected test	The coefficient of correlation must be greater than 90 %	Validation completed in September 2014 – New Improvements available	Achieved

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

Action status: completed
Timescale in Proposal: May 2014 – July 2015
Actual: May 2014 – November 2015

Objectives: The main aim of the action is to design the experimental set up to conduct the testing activities and the execution of the experiments according to the specifications of the standardized testing approaches evaluated within action B1.

Activities Conducted and progress so far: the action was completed with success last November 2015, four months later than initially expected.

This action focuses on the design of the experimental set up to conduct the testing activities from the standardized approaches developed within action B1, as well as the evaluation of the performance factors and RMMs selected under NanoRISK. The design of the experimental set up was conducted within task B3.1 considering the equipment and methodology defined within the protocols developed. ITENE, VITO and INSHT defined the type and number of samples to be tested, equipment needed to measure the performance factors, and reporting formats. and n terms of equipment, reagents and duration. The testing activities were conducted within action B3.2. A complete statistical analysis of the performance factors determined in each protocol was conducted, including the comparison of mean, minimum and maximum values retrieved from each test and performance factors, and the analysis of the standard deviation of the performance factor studied in each test. The analysis of the variability was also used to introduce improvements, and hence, refine the experimental set initially designed to perform the test.

The testing activities conducted within the project and performance factor analysed are depicted in the table below:

Table 23. Overall view of RMMs tested under the framework of the project.

RMM	Type	Sample ID		Models	Particles	Size
Respiratory protective equipment	Particulate filter	NR1	PF_P2	Model A	NaCl	42 ± 2
		NR2	PF_P3	Model A	NaCl	42 ± 2
		NR3	PF_P2	Model B	NaCl	42 ± 2
		NR4	PF_P3	Model B	NaCl	42 ± 2
	Filtering face piece	NR5	FFP_1	Model A	NaCl	42 ± 2
		NR6	FFP_2	Model A	NaCl	42 ± 2
		NR7	FFP_3	Model A	NaCl	42 ± 2
		NR8	FFP_1	Model B	NaCl	42 ± 2
		NR9	FFP_2	Model B	NaCl	42 ± 2
		NR10	FFP_3	Model B	NaCl	42 ± 2
	Half Mask	NR11	HM_P2	Model A	NaCl	42 ± 2
		NR12	HM_P3	Model A	NaCl	42 ± 2
		NR13	HM_C	Model A	NaCl	42 ± 2
	Half Mask	NR14	HM_P2	Model B	NaCl	42 ± 2
		NR15	HM_P3	Model B	NaCl	42 ± 2
		NR16	HM_C	Model B	NaCl	42 ± 2
	Full Mask	NR17	FM_P2	Model A	NaCl	42 ± 2
		NR18	FM_P3	Model A	NaCl	42 ± 2
		NR19	FM_C	Model A	NaCl	42 ± 2
	Full Mask	NR20	FM_P3	Model B	NaCl	42 ± 2
		NR21	FM_P2	Model B	NaCl	42 ± 2
		NR22	FM_C	Model B	NaCl	42 ± 2
	LEV filter	NR23	HF_H14	Model A	NaCl	42 ± 2
Chemical protective gloves	Nitrile Thin	NR24	PG_N1	Model A	NaCl	42 ± 2
	Nitrile Thick	NR25	PG_N2	Model A	NaCl	42 ± 2
	Vinyl	NR26	PG_V1	Model A	NaCl	42 ± 2
	Non powder Vinyl	NR27	PG_V2	Model A	NaCl	42 ± 2
	Non powder Latex	NR28	PG_L1	Model A	NaCl	42 ± 2
	Neoprene / Natural Latex	NR29	PG_NE	Model A	NaCl	42 ± 2
	PVC	NR30	PG_PV	Model A	NaCl	42 ± 2
	Butyl II	NR31	PG_B1	Model A	NaCl	42 ± 2
Protective clothing	Protective coverall (PE). Types: 4,5,6	NR32	PC_P4	Model A	NaCl	42 ± 2
	Protective coverall (PE). Types: 3,4,5,6	NR33	PC_P3	Model A	NaCl	42 ± 2
	Protective coverall (Neoprene)	NR34	PC_NE	Model A	NaCl	42 ± 2
	Spunbonded polypropylene	NR35	PC_SP	Model A	NaCl	42 ± 2
Eye protection	Tight-fitting	NR37	EP_C1	Model A	NaCl	42 ± 2
	Tight-fitting	NR38	EP_T1	Model B	NaCl	42 ± 2
LEV	Lab. Fume hood	NR39	FH_S1	Model A	NaCl	50 ± 2
	Capturing hood	NR40	CH_S1	Model A	NaCl	50± 2

As can be derived from the table, a total amount of 39 samples were analysed within the project, including 23 respiratory protective devices, 8 chemical protective gloves, 5 protective clothing, 2 eye protection devices, and 2 local exhaustive ventilation (LEV) systems.

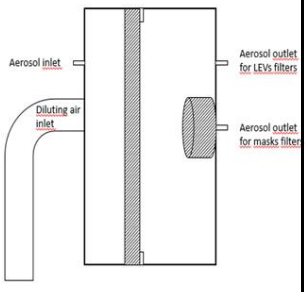
The last action focused on the evaluation of the effectiveness of common RMMs while performing common operations involving ENMs and/or nanocomposites. To this end, handling operations such as packing, stirring, weighting of ENMs in dry form or dispersed in liquid, pouring, harvesting, brushing and spraying were reproduced in the nanoaerosol testing chamber.

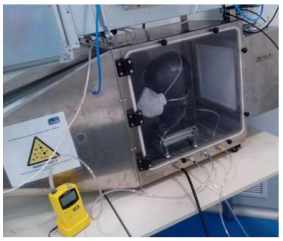
The testing experiments took place in the exposure chamber prototype installed in ITENE, aas well as in the facilities of VITO in Mol (Belgium) and INSHT in Sevilla (Spain). The results of the action are described in detail in deliverable B3a and B3b. B3a provides an in depth description of the experimental set up defined. For its part, B3b provides a complete analysis of the outcomes of the experimental activities completed. The following Gantt-chart shows the progress of the action

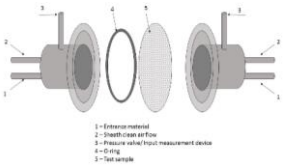
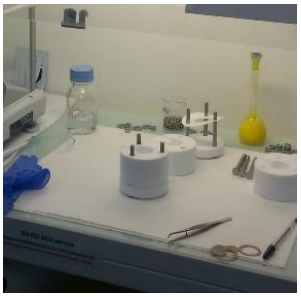
		2014								2015											
Action / Task		May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Agu	Sep	Oct	Nov
TB3.1. Experimental set up design	Proposed																			
	Actual								B3a											
Task B3.2. Testing activities	Proposed																			
	Actual																			
Task B3.3. Simulation studies	Proposed																			
	Actual																			B3b

Results and deliverables: an overall view of the experimental set up, including scope, performance factor and set up, is provided in table 24.

Table 24. Experimental set up for RMM testing

	PF	Description	Set up pictures
Respiratory protective equipment	Filter penetration	**Scope**: characterization of the penetration of ENMs through particulate filters during exposure to an aerosol flow. **Objective**: ensure that particulate filters are capable of providing a minimum level of protection against ENMs. **Reference substance**: NaCl particles (50 – 80 nm) **Set up:** the evaluation of the filter penetration is conducted using a metal box in which an aerosol containing NaCl nanoparticles is inserted and diluted with clean and dry air. The metal box is equipped with a filter holder especially structured to contain either the LEV filter or a masks respiratory filter. The levels of ENMs are measured upstream and downstream of the filter being tested by means of direct reading devices (CPC, OPS, P-Track, SMPS). **Performance factor**: particle penetration (P) $P(\%) = \frac{C_2}{C_1} * 100$ Efficiency $E(\%) = 100 - P(\%)$ Where, C_1 NaCl concentration before the filter; C_2 average concentration measured after the filter.	 

	PF	Description	Set up pictures
Respiratory Protective Equipment (RPE)	Inward Leakage (IL) / Total inward leakage (TIL)	**Scope**: characterization of the efficiency of respiratory protective equipment (RPE), including the experimental evaluation of Total inward leakage (TIL) and inward leakage (IL). TIL, is defined as the penetration of particles into the respiratory protection device (RPD), including face seal, valves and gaskets, and penetration through the filter. IL refers the penetration of particles into RPD excluding filters. **Objective**: ensure that RPD are capable of providing a minimum level of protection against airborne nanoparticles. **Reference substance**: NaCl particles (50 – 80 nm) **Set up (1)** – Test with a Sheffield head NaCl particles are conducted to the testing furnace, where a Sheffield head carrying a respirator is placed. The Sheffield head is a manikin head with internal pipes, which let to collect the air from the inside of the mask **Set up (2**) – Test with human subjects Subjects are placed on a treadmill and while walking, they are asked to do a list exercises defined in current ISO standards. In both set ups, the concentration of NaCl particles is measured inside and outside the RPD tested by means of direct reading devices (CPC, OPS, P-Track, SMPS). **Performance factor**: RPD efficiency and particle penetration (P) expressed as percentage. $Penetration\ \ P(\%) = 1{,}25 * \frac{C_2}{C_1} * 100$ Efficiency $E(\%) = 100 - P(\%)$ Where, C1: test concentration C2: average concentration measured inside the facepiece 1,25 is a correction factor due to the retention of sodium chloride in the lungs	 
Protective clothes	Particle penetration	**Scope**: characterization of the penetration of ENMs through chemical protective clothing (CPC) during exposure to an aerosol flow. **Objective**: ensure that CPC are capable of providing a minimum level of protection against airborne nanoparticles. **Reference substance**: NaCl particles (50 – 80 nm) **Set up:** tests can be performed using a mannequin (static) or volunteers (dynamic). Three points of the suit are selected to measure the concentration inside, which is then compared with the concentration outside the suit A sheath flow of clean dry air is supplied inside the suit at the same flowrate as the measuring devices are suctioning in order to no create depression or a false result. The sleeve ends of the suit, as well as seams, closures, zips, etc. are sealed to avoid penetration through opened parts and only test the suit material. **Test conditions (human subjects):** - 3 min standing - 3 min walking - 3 min squatting. - 3 measurement probes: chest, waist and knee - Six suits tested **Performance factor:** Nominal Protection factor (NPF) and Total average inward leakage (TIL_A). Total average inward leakage is reported as a ratio of the test particle concentration inside the suit and the test chamber (For all six suits, all the exercises and all 3 probes). $TIL_A = \frac{Concentration\ of\ test\ particles\ (inside\ suit)}{Concentration\ of\ test\ particles\ in\ the\ chamber}$ Nominal protection factor = 100/(TILA)	 

	PF	Description	Set up pictures
Chemical protective gloves	Particle Penetration	**Scope**: characterization of the penetration of airborne nanoparticles through glove material **Objective**: ensure that chemical protective gloves are capable of providing a minimum level of protection against airborne nanoparticles. **Reference substance**: NaCl particles (50 – 80 nm) **Set up**: a specimen is cut from the glove and clamped into a test cell as a barrier membrane. The "exterior" side of the specimen is exposed to airborne NaCl nanoparticles, and concentrations are measured at both sides of the glove and compared. **Performance factor:** particle penetration (P_n (%)) The percentage of penetration is calculated from the measurements at each side of the glove, considering C_{out} the concentration right before the glove and C_{in} after the glove sample. $P_n(\%) = \frac{C_{in}}{C_{out}} * 100$	
Protective gloves	Permeation	**Scope**: characterization of the penetration of nanoparticles diluted in a water based solution through the glove material by permeation mechanisms. **Objective**: ensure that chemical protective gloves are capable of providing a minimum level of protection against nanoparticles dispersed in water or solvents. **Reference substance**: NaCl particles (50 – 80 nm) **Set up**: to test permeation to liquid dispersions of nanoparticles, a Teflon cell is required. In this case, a circular sample of the glove is placed in rest between the liquid dispersion and a filter sampler that will be analyzed after 8 hours of being in contact. **Performance factor:** particle permeation	
(LEV) systems – Ventilated Laboratory Hood	Containment	**Scope**: characterization of the containment effectiveness of ENMs of a Ventilated Laboratory Hood. **Objective**: ensure that Ventilated Laboratory Hoods are capable of providing a minimum level of protection (containment) when handling ENMs. **Reference substance**: NaCl particles (50 – 80 nm) **Set up**: The test method is based on the generation and dispersion of nanosized NaCl inside the work space of a fume cupboard. The containment factor is defined as the ratio of calculated concentration of tracer gas in the work space of the fume cupboard to the measured concentration in the inner or outer measurement plane. The method proposed is based on the dispersion of NaCl particles by means of a diffusion system positioned inside the work space of the fume cupboard, and the sampling of the concentration of NaCl particles at three different distances from the source. **Performance factor**: Capture efficiency (Cf) estimated comparing the concentration at 100% aerosol capture (C_{100}) and the measured mean concentration (Cm) at different sampling points: Cf = (C100 – Cm)/ C100*100	

	PF	Description	Set up pictures
(LEV) systems - movable capturing hood	Capture efficiency	**Scope**: characterization of the capture efficiency of ENMS using a movable capturing hood. **Objective**: ensure that movable capturing hoods are capable of providing a minimum level of protection when handling ENMs. **Reference substance**: NaCl particles (50 – 80 nm) **Set up**: Nanoparticle capture efficiency of a capture hood is tested by atomizing an aqueous solution of NaCl (50 nm). The aerosol is released through several diffuser pipes at the work area. First 100% aerosol capture is obtained by placing the diffuser pipes as close as possible to the exhaust duct inside the exhaust hood. With a CPC aerosol concentration shall be measured inside the duct. The concentration at different diffuser distances are compared with the concentration levels during the 100% aerosol capture experiment. **Performance factor**: Capture efficiency (Cf) is the ratio of measured concentration of tracer gas in the duct of the capture hood with 100% aerosol capture (at 0 cm height) to the measured concentration of tracer gas in the duct of the capture hood with the hood positioned at a specific height above the work surface.	

**An extended version of each SOPs is included within the annex section.*

A summary of the outcomes from the experimental studies is provided below.

- **Respiratory protection**

A wide range of test were conducted by the research team, including assays using a test head (static) and assays on human subjects (dynamic). The following table summarizes the results retrieved form the experimental activities conducted concerning respiratory protection equipment.

Table 25. Efficiencies of different kinds of masks and particulate filters tested for NaCl NPs.

RPD	*Specifications*	*Measures*	*Standard Efficiency*	*Protection (NMs)*	*Reference particle*
Filters	P2 Filter	Efficiency	94 %	99.83 %	NaCl
	P3 Filter	Efficiency	99.95 %	99.97 %	NaCl
Half Mask	New Mask P3 Filter	Efficiency	99.95%	99.47 ± 0.83 %	NaCl
	Aged Mask P3 Filter	Efficiency	99.95%	99.77 ± 0.29 %	NaCl
Full Mask	New Mask P3 Filter	Efficiency	99.95%	99.73 ± 0.25 %	NaCl
	Aged Mask P3 Filter	Efficiency	99.95%	99.78 ± 0.16 %	NaCl
Disposable	FFP1	Efficiency	80%	75.63 %	NaCl
	FFP3 (Model a)	Efficiency	99%	99.77 ± 0.29	NaCl
	FFP3 (Model b)	Efficiency	99%	95.63 ± 4.39	NaCl

The results showed that Full and Half Mask Respirators provided adequate performance levels of filtration efficiency against NMs. Total inward leakage (TIL) ratios determined in relevant studies suggest that face seal leakage, and not filter penetration, is a key parameter to be considered when working with nanoparticles.

- **Dermal protection**

Several tests were conducted to evaluate the effectiveness of common dermal protective equipment against ENMs, including chemical resistant gloves and protective clothing. In the

case of protective clothing, as for respiratory protection, tests for the resistance against penetration of ENMs can be performed with human subjects when the aerosolized material is NaCl, to exam the suits in movement, or with a mannequin with any other material.

The results of the evaluation of the effectiveness of the protection suits are summarized in table 26. To d-termine the performance classification, the average inward leakage value per activity (standing, walking and squatting) calculated (TIL) is depicted in the table.

Table 26. Efficiencies of recommended protective coveralls against chemicals (Category III) using NaCl NPs. Measurements concerning particle penetration (Total Inward leakage).

RPD	*Specifications*	*Measures*	*Standard Efficiency*	*Protection (TIL for NMs)*	*Reference particle*
Protective coverall (PE) High performance for liquids	Knee	T.I.L (%)	≤15%	< 3 %	NaCl
	Waist	T.I.L (%)		< 6 %	NaCl
	Chest	T.I.L (%)		< 10 %	NaCl
	Global	T.I.L (%)		**< 7 %**	NaCl
Protective coverall (PE) Types: 3,4,5,6	Knee	T.I.L (%)	≤15%	< 4 %	NaCl
	Waist	T.I.L (%)		< 3 %	NaCl
	Chest	T.I.L (%)		< 12 %	NaCl
	Global	T.I.L (%)		**< 6 %**	NaCl

The "highest" performance class (performance class of 3,) can be assigned when the highest value for the inward leakage measured for each of the three activities (TIL_E) is less than 15%.

According to this classification, the suits provided a proper level of protection for ENMs, however, in some studies penetration levels up to 40 % were observed. Greater inward leakage was observed, generally, when subjects were asked to do squats, probably because this movement caused a compression or deformation in the suit, allowing the apparition of gaps between the suit and the skin by which the NPs could enter inside.Different protective gloves against chemical and biological risks, with distinct materials and thickness, were also tested. The types of protective gloves selected were: latex (without powder), vinyl (with and without pow-der), nitrile (two thickness), and reusable, such as neoprene, polyvinyl chloride or butyl. Table 27 shows the measured efficiency of the samples evaluated within NanoRISK.

Table 27. Efficiencies of chemical protective gloves against ENMs

SPE	*Material*	*Measures*	*Thickness (mm)*	*Protection (NMs)*	*Reference particle*
Disposable protective gloves	Nitrile Thin	I.L (%)	0.07-0.09	0.040	NaCl
	Nitrile Thick	I.L (%)	0.11-0.15	0.006	NaCl
	Vinyl	I.L (%)	0.08	0.103	NaCl
	Non powder Vinyl	I.L (%)	0.08	0.013	NaCl
Reusable	Neoprene / Natural Latex	I.L (%)	0.7	1.63	NaCl
	PVC	I.L (%)	1.30	3.17	NaCl
	Butyl II	I.L (%)	0.36	-	NaCl

In view of the table, the efficiency of the gloves increases with the thickness. Performance depends strongly on the material of the glove, and although generally there are no pores in their surface, some small defects or gaps can be enough to offer a way in to the glove.

- **Ventilated Laboratory Hood**

Three independent tests were performed to test the containment effectiveness of Ventilated Laboratory Hoods. To support the understanding of the experimental results, the test is based on the use of test gas injector which consists of a punctured hollow stainless steel (SS) cylinder.

A single jet atomizer is connected to the injector to generate 50 nm NaCl particles. A sampling grid made of SS sampling tubes are connected to 9 particle counters (CPC) using conductive tubing to measure particle number concentration simultaneously. The measurements with the nine CPCs are performed at the intersection of two horizontal and three vertical equally spaced lines (outermost 130 mm, lines in between <600 mm, figure 11a) and compared with the generated particle number concentrations.

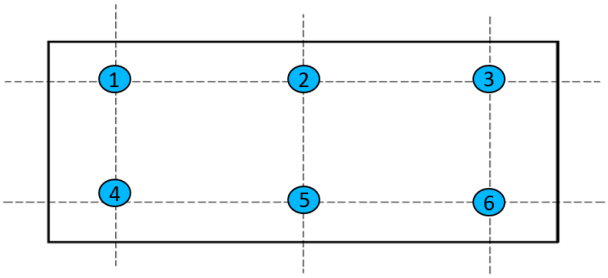


Figure 11a. Measurement positions used to determine the capitation efficiency of ventilated laboratory hoods.

At the exhaust of the injector about 35,000 particles per cm3 were measured. Highest particle number concentrations were measured at sampling position 5 as can be seen in figure 11b.

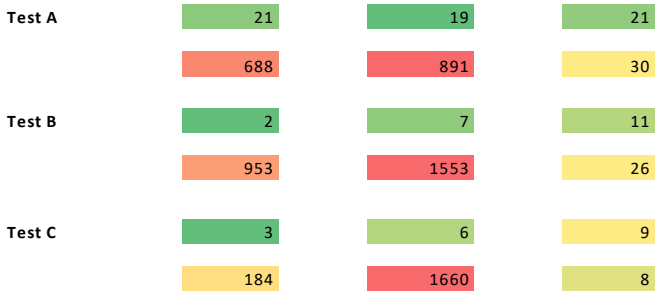


Figure 11b. Six measurement positions (top) with particle number concentrations in pt/cm3 (below) during three test (A,B,C)

Average particle number concentration of all three tests and positions was about 300 particles per cm^3 resulting in an efficiency of **99.04 ± 0.36** %.

- **Movable capturing Hood**

A **mobile capture hood** was evaluated. Particle number concentration at 100% aerosol capture is compared with the particle number concentration at different capture hood-diffuser distances to calculate the efficiency. Table 28 shows differences on the capture efficiency depending on the position of the hood.

Table 28. Results capture efficiency experiments

RMMs	Specifications	Performance factors	Static
Capture Hood	Nederman Filtercart Carbon Tilted	Capture Efficiency related to distance	0 cm 100% ± 14% / 15 cm 79% ± 4% 40 cm 72% ± 2% / 65 cm 63% ± 5%
	Nederman Filtercart Carbon Top	Capture Efficiency related to distance	0 cm 100% ± 5% / 5 cm 79% ± 6% 20 cm 53% ± 43% / 45 cm 82% ± 2% 70 cm 66% ± 20%
Partial Enclosure / Fume Cupboard	Derpa S.A. (l x w x h) Cupboard 120x78x165 cm Inner plane 120 x78x85 cm	Containment efficiency	99.04 ± 0.63%

The results of the tilted capture hood show a decrease in efficiency when the distance increases from 0 to 65 cm. With a vertically positioned hood efficiency decreases gradually at 5 cm and drops significantly at 20 cm. At 45 cm a more or less similar efficiency is measured compared with 5 cm efficiency. The drop at 20 cm is probably the result of considerable turbulence when the capture hood is positioned at this distance.

A complete report on the experimental results is provided within DB3b. The reliability of the data was also analyzed to ensure a correlation up to 95 between replicas. The reproducibility was evaluate by means of the analysis of the deviation among three replicates. A complete statistical analysis of the performance factors determined in each protocol was conducted, including the comparison of mean, minimum and maximum values retrieved from each test and performance factors, and the analysis of the standard deviation of the performance factor studied in each test. The last stage of the action focused on the evaluation of the performance of respiratory and body protection equipment under common operative conditions. The table below shows the specific types of activities reproduced in the exposure chamber.

Table 29. Simulation studies conducted in the nanoaerosol testing chamber

Stage / Process	Activities	RMMs tested
Handling of dry ENMs	Weighing operations of ZnO and Graphene (< 100 mg)	Half mask respirator (P3)
Handling of ENMs dispersions	Weighing operations of ZnO and TiO2 based dispersions (< 200 mL)	Half mask respirator (P2)
Transfer into small containers	Transferring of graphene platelets (>1 Kg)	Full mask respirator (P3) Protective coverall
IBC filling	Transfer of larger quantities (>25 Kg) of SiO2	Full mask respirator (P3) Protective coverall
Harvesting	Collection of TiO2 from a pilot scale mixer (>100 Kg)	Full mask respirator (P3) Protective coverall
Spraying	Spraying of paints and coatings in plastic surfaces and walls	HEPA filtered ventilation Filtering face piece FFP3
Roller application or brushing	Application of paints and coating in walls	HEPA filtered ventilation Filtering face piece FFP2
Manual maintenance	Cleaning operations after filling operations	Full mask respirator (P3) Protective coverall
Machining (sawing)	Machining of surface coated bricks	Movable LEV systems Filtering face piece FFP3
Machining (demolition)	Demolition of concrete functionalized with nano-reinformced mortar	Movable LEV systems Filtering face piece FFP3

As can be derived from the table, a lower performance of the equipment during the simulations operations was observed. Such behavior was attributed to a low fitting of the respiratory protective equipment during the simulation studies, as well as to deficiencies in the selection and donning of the protective coveralls studied. In the case of LEVs, a low level of performance was also observed due to an inadequate selection of the configuration of the hood and flow.

Indicators of progress according with planned outputs and time scheduled

Table 30. Indicators of Progress in Action B3

Indicator	Measure of success	Results	Status
Variability between replicas	Correlation between the data obtained in each replica must be greater than 0.9. Maximum concentration of NPs achievable inside the chamber	The measured correlation was higher than 95 % for PPE. For LEV systems, correlations between 91 and 93 % are reported.	Achieved

Indicator	Measure of success	Results	Status
Comparability and correlation between the reproduced and real conditions	• Variability in Temperature, Pressure and Relative Humidity below 5 % • Correlation between the amount of NMs used at pilot scale and industrial settings > 0.9 • Correlation between the background levels measured in terms of NPs/cm3, surface area and average size > 0.9 • Correlation between exposure levels > 0.9	The results so far show correlations > 0.9 in cases 1 and 3. The correlations between the background levels measured in terms of NPs/cm3, surface area and average size are being analyzed.	Achieved
Experimental studies	• A complete description of the experimental set up for the protocols developed • A complete report on the effectiveness of the RMMs selected, including: respirators, gloves and protective clothing, eye protection, filtration performance of particulate filters, capitation efficiency of fume hoods, cabinets and other extraction methods.	• Report on the experimental set up completed • Report on the effectiveness of RPE, protective gloves, protective clothes, eye protection and LEVs completed. • Performance factors: T.I.L / I.L / PF / Permeation / Captation efficiency.	Achieved

5.1.8. Action B4. Development of a Risk Management Measures (RMM) library tool

Action status: completed
Timescale in Proposal: March 2015 – September 2015
Actual: March 2015 – May 2016

Objective: The objective of this action is to develop a Microsoft excel® based risk management measures library aimed at assisting companies on the selection of proper personal protective equipment (PPE) and technical measures against target ENMs on the basis of the chemical, toxicological and ecotoxicological properties of the ENMs used as well on the operative conditions implemented during the process involving ENMs.

Activities Conducted: the action was conducted following the tasks initialed scheduled, including the definition of the main contents to be included in the library within task B4.1, the design of the structure of the tool, functionalities, lay out and programming language within task B4.2, and the development of the RMM library with the support of the members of the consortium within task B4.3. A stated in the mid-term report, the first task within the action focused on the definition of contents of the library on the basis of the current needs of the nanotechnology related industries. To this end, a phone call was organized by ITENE to discuss with partners the specific data to be considered, including types of measures, protection factors, reference levels and additional information.

Beside the above, the information contained in the questionnaires developed under action C3 and C4 were also scrutinized to identify risk management measures of special interest and critical processes. This information together with the outcomes from internal discussions was considered to define the contents of the library developed.

The second task focused on the design of the library using Microsoft excel®. The structure of the library was defined considered the contents outlined in task B4.1, the programming requirements of Microsoft excel®, as well as the structure of the RMM library developed by the European Chemical Industry Council (CEFIC) to assist companies when dealing with bulk

substances. The RMM library was finally structured in 9 spreadsheets grouped into 6 sections.

1. Preface
2. Control_home (Main Menu)
3. Guidance start
   - 3.1. Input Exposure Situations
   - 3.2. Input Risk Management Measures
   - 3.3. Run Assessment
4. List of Individual measures
5. Sector packages
6. References

These spreadsheets were designed following easy-to-use principles, including free text and drop down list to support the user on the selection of proper measures. Relevant commands such as “save”, “print”, “return” or “home” were defined to improve the operability of the spreadsheets developed.

The last action conducted focused on the development of the library in Microsoft excel®. In this regard, the library was developed using VBA (Visual Basic for Application) and the Macro Recorder. For each of the spreadsheets designed a list of text boxes and selection menus were edited with the visual basic editor.

The last stage to complete the action focused on the population of the library with the information generated within the project or retrieved from peer reviewed publications. Once completed, the RMM library was uploaded into the web site using Excel Web App, being accessible in the project web side under the section “Interactive Tools”. The following Gantt-chart shows the progress of the action.

		2015										2016								
Action / Task		Mar	Apr	May	Jun	Jul	Agu	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
TB4.1. Identification of the library contents	Proposed																			
	Actual																			
TB4.2. Design of the dataset	Proposed																			
	Actual																			
Task B4.3. Library development	Proposed																			
	Actual															B4				

Results and deliverables: the contents and main structure of the library was defined in May 2015 and revised in July 2015 in view of the information retrieved from the questionnaires conducted in actions A4, C3 and C4.

The library follows a structured divided into 6 main sections. A welcome page with general information of the project was included. The current version of the RMM library is available in English and Spanish. New languages, including Italian and French will be released in March 2017 according with the after-LIFE plan. The sections defined are described below:

- Section 1 - **Guidance**: on line manual to assist companies on the use of the library.
- Section 2 – **New study**: main section of the library including several forms to compile information on the properties of the ENMs used, operative conditions and implemented risk management measures.

- Section 3 – **Open / Refine study**: section included to open a previously completed study.
- Section 4 – **Library of Individual Measures**: section compiling data on the effectiveness of individual PPE and technical measures.
- Section 5 – **Sector / Process related RMMs**: section compiling data on the effectiveness of PPE and technical measures under critical operations in relevant industrial sectors.
- Section 6 – **References**: section compiling the sources of information used to assign performance factors "effectiveness" of the compendium of measures included in the library.

Each section includes one or more spreadsheets where the user interacts with the tool. Figure 12 shows a screenshot of the preface and welcome spreadsheets developed.

Figure 12. Left: Preface with project information. Right: Welcome / home page

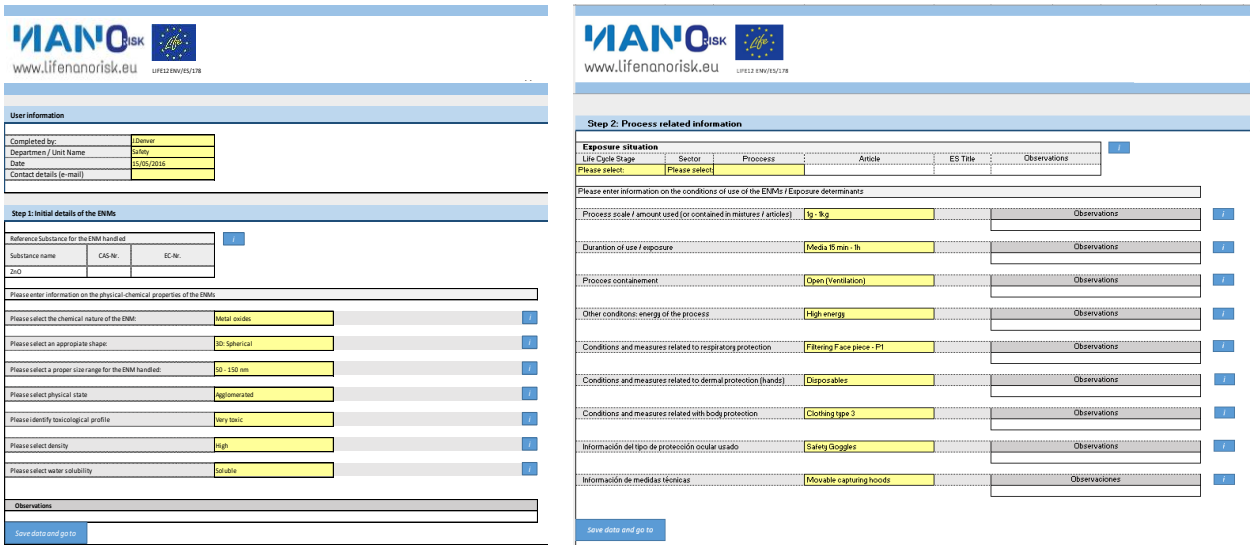


Fig. 13. New study section. Left: spreadsheet to describe the properties of the ENM is use. Right: spreadsheet to provide information on the conditions of use.

Figure 14 depicts the spreadsheet developed to describe the specific types of risk management measures implemented by the company in the use or process under evaluation. It shall be noted that the library include on line support buttons “i” to support the user in the description of the ENMs, operative conditions and controls.

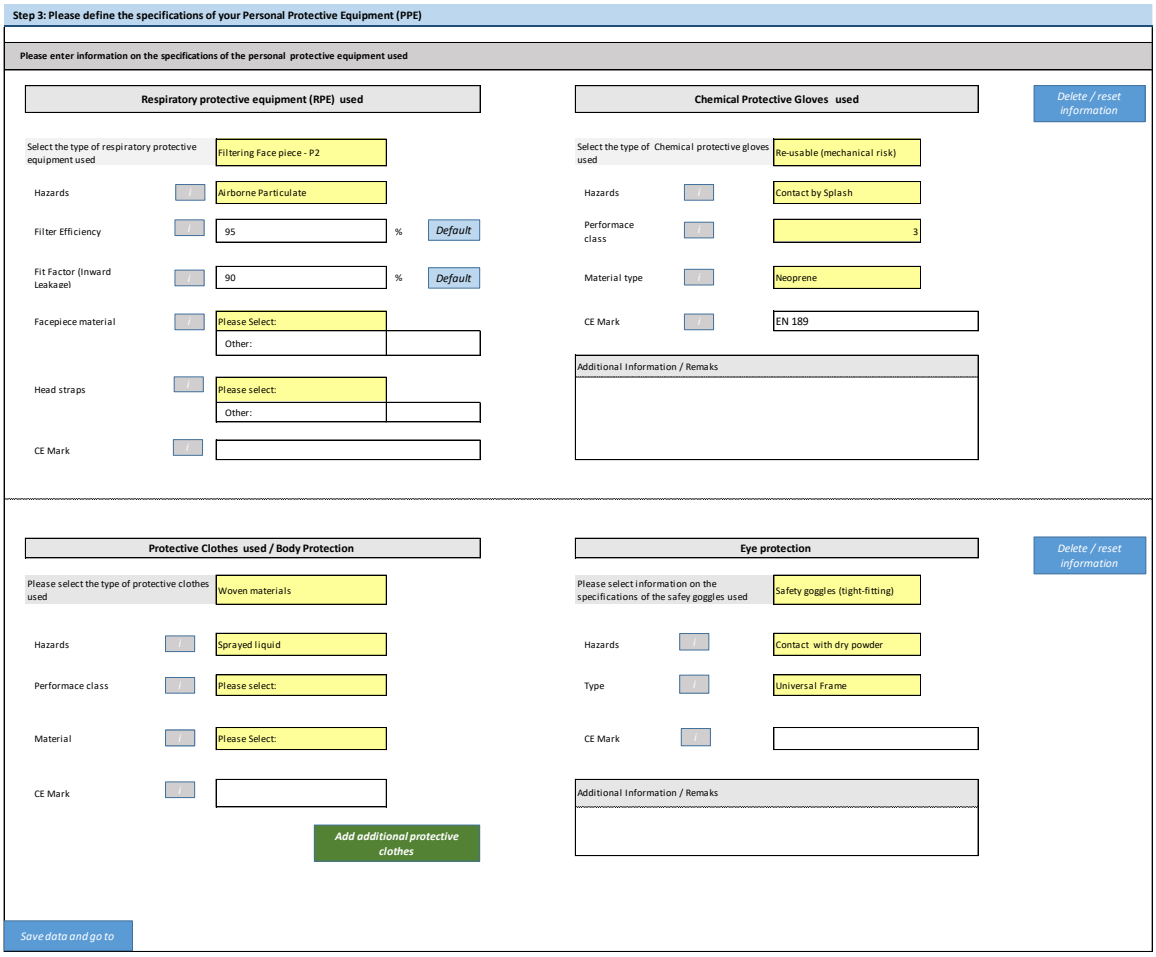


Figure 14. RMM details spreadsheet. Note that additional protective clothes can be added.

Once the users compile the information and save data, the run assessment spreadsheets provides information on the efficiency of the currently implemented measures and calculates the efficiency of common measures, recommending only those with performance above 98 %.

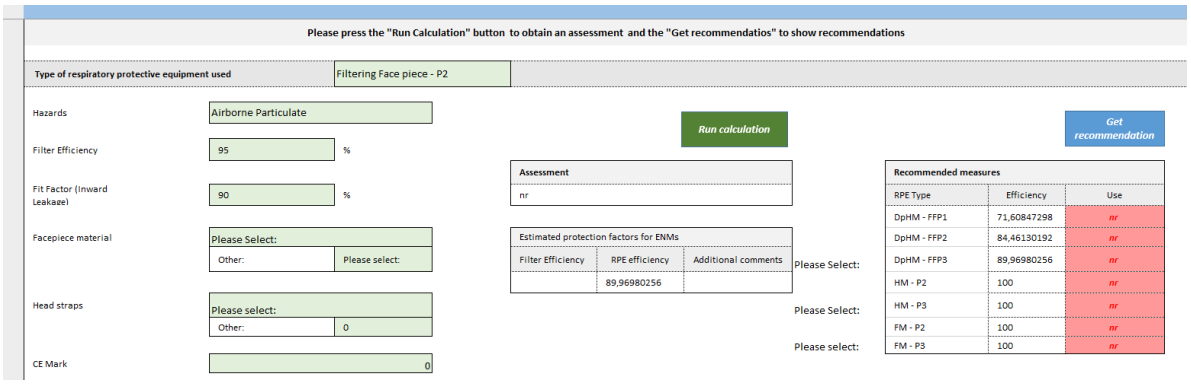


Figure 15. Run Assessment spreadsheet

Indicators of progress according with planned outputs and time scheduled

Table 31. Indicators of Progress in Action B4

Indicator	Measure of success	Results	Status
Type of Personal Protective Equipment	- A Body protection & Hand protection - Respiratory protection - Face / Eye protection	The RMM library developed contains the whole range of PPE defined	Achieved
Type of Ventilation control	- Local Exhaust Ventilation - (partial) enclosure - Laminar Flow Booths & Laminar Flow Benches - Local Exhaust Ventilation - captor hoods - Local Exhaust Ventilation - receptor hoods - LEV - specialized applications - Dilution Ventilation	To date, all exhaust ventilation systems have been included.	Achieved
Organizational measures	- Operating Practice - Competence and training - Supervision - Monitoring - Health Surveillance - Good Hygiene Practices & Housekeeping	All the management / administrative controls have been included	Achieved
Number of RMM considered per material	The library of Risk Management Measures will contain a minimum of 10 control measures for each of the NMs considered.	A total of 16 RMMs have been defined per ENMs	Achieved

A complete manual on the use of the RMM library is available on the project web site and reported within deliverable B4, enclosed under the annex section.

5.1.9. Action B5. Scaling up to industrial case studies

Action status: completed
Timescale in Proposal: July 2014 – December 2015
Actual: July 2014 – April 2016

Objective: The objective of this action is to implement the RMMs evaluated within B3 in a compendium of case studies representing the life cycle stages and critical exposure scenarios identified in occupational settings.

Activities Conducted: the action was completed by March 2016, five months later than initially scheduled due to the need of visit the companies and measure the improvements achieved during the production of ENMs and nanoproducts, both activities conducted upon request by clients.

The scaling up stage was divided into four main stages, including 1) the **implementation** of selected personal protective equipment, technical measures and administrative controls in 5 case studies, 2) the **evaluation of effectiveness** of relevant measures during critical operations with the aim of evaluate in situ the average reduction of the levels on exposure in the workplace, 3) the **validation** of the applicability of selected measures in terms of average reduction and costs, and 4) the **definition of a list of 10 priority measures** to achieve a reduction of the exposure and release by at least 20 %.

The results of the validation studies are reported within deliverable D.B5, included in the annex section of the present report. The case studies were conducted in 5 companies, including Avanzare and CRP, as members of the consortium, and Tec Star, LATI, and the Andalusian Innovation Centre for Sustainable Construction (CIAC) as invited companies.

Tec Star (Italy) represent a pilot scale manufacturer of nanomaterials (Metal oxides) respectively. LATI (Italy) is a downstream user of nanomaterials focused on the production of carbon nanotube based nanocomposites. For its part, the Andalusian Innovation Centre for Sustainable Construction (CIAC) is a downstream user of ENMs to develop photocatalytic concrete and coatings for building applications.

The implementation stage was completed in April 2015 in parallel with the evaluation of the effectiveness of selected RMMs under simulated condition within action B3. This phase was mainly focused on the identification of critical exposure scenarios in the case studies defined, the analysis of the RMMs implemented, and the definition of an implementation plan for selected personal protective equipment (PPE) and engineering controls (EC). These activities were supported with training actions and scoping visits to characterize the levels of exposure using existing controls in order to define a starting situation or baseline to support further studies.

The second task (TB5.2) focused on the evaluation of the effectiveness of a set of risk management measures selected in view of the properties of the ENMs handled and operative conditions. This task was divided into two main sub-tasks, including 1) the implementation by the companies of recommended measures, and 2) the evaluation of the exposure and release levels of NMs, theirs aggregates and agglomerates by means of real time measuring device and sampling pumps equipped with filtration media able to collect and retain particles in the nanometer range.

The third task focused on the validation of the RMM recommended, including the analysis of the data gathered in scoping visits, and the definition of the reduction of the exposure achieved in each case study completed. To support the validation, a set of performance criteria specifically developed to test the operability and accuracy of the RMMs were analyzed. These criteria are listed below:

1. Levels of exposure measured in the head airways, body (chest) and far field areas.
2. Effectiveness of RMMs measures used before implementation in terms of protection factors.
3. Levels of exposure measured in the head airways, body (chest) and far field areas after the implementation phase
4. Level of reduction achieved

The action was completed in April 2016 after the selection of a list of 10 RMMs able to reduce the exposure and/or release considering a not relevant increase of the costs for the companies. The following Gantt-chart shows the progress of the action

		2014			2015											2016				
Action / Task		J/A	S/O	N/D	J/F	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	Jun
Task B5.1. Implementation of the RMMs	Proposed																			
	Actual																			
Task B5.2. Quantitative measure of the effectiveness of RMMs	Proposed																			
	Actual																			
Task B5.3. Validation of the RMM effectiveness	Proposed																			
	Actual																		B5	

Results and deliverables: a list of 25 critical exposure scenarios where a potential exposure to ENMs, their aggregates and agglomerates is feasible were identified. The recommended measures for each exposure scenarios where defined by VITO and ITENE, being communicated to the person(s) with responsibility in the implementation phase. The list of measures recommended and evaluated are listed below:

- **Process design**

- Use of partial enclosures equipped with HEPA filtered local exhaust ventilation (LEV)
- systems.
- Maintain a Slightly negative pressure in the facilities where the use of NPs takes place
- Technical conditions and measures to control dispersion from source towards the
- worker
- Maintain a good standard of general or controlled ventilation with a minimum of 10
- air changes per hour
- Minimum performance: 95 % / Dust and Solvents capture
- Use of Capturing Hoods or glove box (enclosure) at laboratory scale activities
- Provide the operation with a properly sited receiving hood for large scale processes.

- **Organisational measures to prevent /limit releases, dispersion and exposure**

- Cleaning after each operation.
- Good housekeeping: containment of spills and keeping the workplace surface clean.
- Use of a HEPA-filtered vacuum cleaners, absorbent materials and liquid traps;
- Information, instruction and training.

- **Personal protective equipment:** Use of safety googles, polyethylene textiles, half mask respirator with a combined filter (Dust + solvents), and chemically resistant nitrile gloves.

- **Technical on-site conditions and measures to reduce or limit discharges, air emissions and releases to soil.**
- Use ventilation to extract vapours during the functionalization stage.
- Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings.
- Waste water neutralisation system (effectiveness >95%) must be installed before discharging to sewage treatment plants.
- Hazardous wastes from onsite risk management measures and solid or liquid wastes from production, use and cleaning processes should be disposed of separately to hazardous waste incineration plants or hazardous waste landfills as hazardous waste.

The implementation of the measures recommended together with good hygiene practices and proper training were evaluated to validate if an adequate level of protection to the human health and the environment is guaranteed.

The following table details the list of the measures implemented in each critical exposure scenario.

Table 32. List of recommended measures

ENMs / Nanoenabled products	SHORT ES TITTLE	GES CODE	RMM Implemented on site		Recommended measures	
			Technical measures	PPE	Technical measures	PPE
Graphene	Weighing operations of graphene platelets	GES1	General ventilation	Full Mask P3 PE coverall Nitrile Gloves	Movable LEV system (tilted)	Half Mask P3 with improved fitting PE coverall Nitrile Gloves
Graphene	Weighing Graphene GR8	GES2	General ventilation	Full Mask P3 PE coverall Nitrile Gloves		
Nano-TiO2	TiO_2 synthesis in liquid state	GES3	General ventilation	Half Mask P3 PE coverall Nitrile Gloves		
Nano-SiO2	SiO_2 synthesis in liquid state	GES4	General ventilation	Half Mask P2 PE coverall Nitrile Gloves		
	SiO_2 synthesis in solid state + vacuum cleaning + applying LEV + sieving	GES5	General ventilation	Half Mask P2 PE coverall Nitrile Gloves		
Graphene / SiO2 / TiO2	Cleaning with sweeping brush, and vacuum cleaning	GES6	General ventilation	Half Mask P2 PE coverall Nitrile Gloves		
Nano-SiO2	SiO_2 synthesis in liquid state (blank)	GES7	General ventilation	Half Mask P2 PE coverall Nitrile Gloves		
Graphene	Weighing Graphene Platelets + LEV vacuum cleaner	GES8	General ventilation	Half Mask P2 PE coverall Nitrile Gloves		
Graphene	Weighing Graphene Spheres + with and without LEV	GES9	General ventilation	Half Mask P2 PE coverall Nitrile Gloves		
Nano-TiO2	PMMA + TiO2 extrusion w/o exhaust	GES10	Movable ventilation system	Disposable mask Laboratory coat Nitrile Gloves	Canopy hoods	Half Mask P3 with improved fitting PE coverall Nitrile Gloves
	PMMA + TiO2 w/ exhaust	GES11	Movable ventilation system	Disposable mask Laboratory coat Nitrile Gloves	Canopy hoods	
Blank	PE extrusion	GES12	Movable ventilation system	Disposable mask Laboratory coat Nitrile Gloves	Canopy hoods	
Nano-TiO2	NP feeder cleaning	GES13	Movable ventilation system	Disposable mask Laboratory coat Nitrile Gloves	Same	Half Mask P3 PE coverall Nitrile Gloves
Graphene	Filling feeder with Graphene (clean room)	GES14	Movable ventilation system	Disposable mask Laboratory coat Nitrile Gloves	Same	
	Extrusion polymer + graphene	GES15	Movable ventilation system	Disposable mask Laboratory coat Nitrile Gloves	Canopy hoods	Half Mask P3 PE coverall Nitrile Gloves
	Extrusion polymer + graphene LEV open	GES16	Movable ventilation system	Disposable mask Laboratory coat Nitrile Gloves	Canopy hoods	
Blank	Extrusion PP to clean extruder	GES17	Movable ventilation system	Disposable mask Laboratory coat Nitrile Gloves	Same	Disposable FFP3 PE coverall Nitrile Gloves
Blank	PP extrusion/ cleaning LEV open	GES18	Movable ventilation system	Disposable mask Laboratory coat Nitrile Gloves	Same	
Nano-TiO2	Synthesis of TiO2	GES19	Laboratory fume hood	Disposable mask Laboratory coat Nitrile Gloves	Same	Half mask P2 PE coverall Nitrile Gloves
Nano-ZnO	Synthesis of ZnO	GES20	Laboratory fume hood	Disposable mask Laboratory coat Nitrile Gloves	Same	

ENMs / Nanoenabled products	SHORT ES TITTLE	GES CODE	RMM Implemented on site		Recommended measures	
			Technical measures	PPE	Technical measures	PPE
Carbon Nanotubes	Filling feeder with CNT based composites (clean room)	GES21	Full enclosure	Laboratory coat Nitrile Gloves	Same	Disposable FFP3 Laboratory coat Nitrile Gloves
Carbon Nanotubes	Extrusion polymer + CNT LEV open	GES22	Full enclosure	Laboratory coat Nitrile Gloves	Same	
Nano-TiO2	Mixing of TiO2 additive	GES23	General ventilation	Disposable mask FFP3 lothes + spin bounded coverall Nitrile Gloves	Movable LEV system (top)	Half Mask P3 PE coverall Nitrile Gloves
	Application of TiO2 based concrete (2 %)	GES24	General ventilation	Disposable mask FFP3 Woven clothes + spin bounded coverall Nitrile Gloves	Movable LEV system (top)	Half Mask P3 PE coverall Butyl Gloves
	Demotion operations involving TiO2 based concrete	GES25	General ventilation	Disposable mask FFP3 Woven clothes + spin bounded coverall Nitrile Gloves	Movable LEV system (top)	Half Mask P3 PE coverall Butyl Gloves

The overall reduction achieved in each case study after the implementation phase is depicted in table 33. An **average reduction of 20.7 %** was achieved after implemented the measures recommended on the basis of the effectiveness measured in the nanoaerosol exposure chamber.

Table 33. Average reduction of the exposure / release after the implementation of the project

Case Study	ENMs / Nanoenabled products	SHORT ES TITTLE	GES CODE	Recommended measures		Improvement of the overall reduction from the starting situation
				Technical measures	PPE	
ENMs manufacturing at pilot scale (Avanzare)	Graphene	Weighing operations of graphene platelets	GES1	Movable LEV system (tilted)	Half Mask P3 with improved fitting PE coverall Nitrile Gloves	19
	Graphene	Weighing Graphene GR8	GES2			17
	Nano-TiO2	TiO_2 synthesis in liquid state	GES3			19
	Nano-SiO2	SiO_2 synthesis in liquid state	GES4			14
		SiO_2 synthesis in solid state + vacuum cleaning + applying improvised LEV + sieving	GES5			16
	Graphene / SiO2 / TiO2	Cleaning with sweeping brush, and vacuum cleaning	GES6			17
	Nano-SiO2	SiO_2 synthesis in liquid state (blank)	GES7			18
	Graphene	Weighing Graphene Platelets + LEV	GES8			23
	Graphene	Weighing Graphene Spheres + with and without LEV	GES9			14

Case Study	ENMs / Nanoenabled products	SHORT ES TITTLE	GES CODE	Recommended measures		Improvement of the overall reduction from the starting situation
				Technical measures	PPE	
Melt compounding of PNC-ENMs (CRP)	Nano-TiO2	PMMA + TiO2 extrusion w/o exhaust	GES10	Canopy hoods	Half Mask P3 with improved fitting PE coverall Nitrile Gloves	24
		PMMA + TiO2 w/ exhaust	GES11	Canopy hoods		21
	Blank	PE extrusion	GES12	Canopy hoods		26
	Nano-TiO2	NP feeder cleaning	GES13	Same	Half Mask P3 PE coverall Nitrile Gloves	19
	Graphene	Filling feeder with Graphene (clean room)	GES14	Same		21
		Extrusion polymer + graphene	GES15	Canopy hoods	Half Mask P3 PE coverall Nitrile Gloves	31
		Extrusion polymer + graphene LEV open	GES16	Canopy hoods		22
	Blank	Extrusion PP to clean extruder	GES17	Movable ventilation system	Disposable FFP3 PE coverall Nitrile Gloves	18
	Blank	PP extrusion/ cleaning LEV	GES18			21
ENMs manufacturing at industrial scale (TecStar)	Nano-TiO2	Synthesis of TiO2	GES19	Laboratory fume hood	Half mask P2 PE coverall Nitrile Gloves	16
	Nano-ZnO	Synthesis of ZnO	GES20	Laboratory fume hood		18
ENMs based polymers manufacturing (LATI)	Carbon Nanotubes	Filling feeder with CNT based composites (clean room)	GES21	Full Enclosure	Disposable FFP3 Laboratory coat Nitrile Gloves	23
		Extrusion polymer + CNT LEV	GES22	Full Enclosure		36
Manufacturing of photocatalytic concrete (CIAC)	Nano-TiO2	Mixing of TiO2 additive	GES23	Movable LEV system (top)	Half Mask P3 PE coverall Nitrile Gloves	26
		Application of TiO2 based concrete (2 %)	GES24	Movable LEV system (top)	Half Mask P3 PE coverall Butyl Gloves	26
		Demotion operations involving TiO2 based concrete	GES25	Movable LEV system (top)	Half Mask P3 PE coverall Butyl Gloves	29

Figure 16 shows a graphical representation of the results achieved in each scenario.

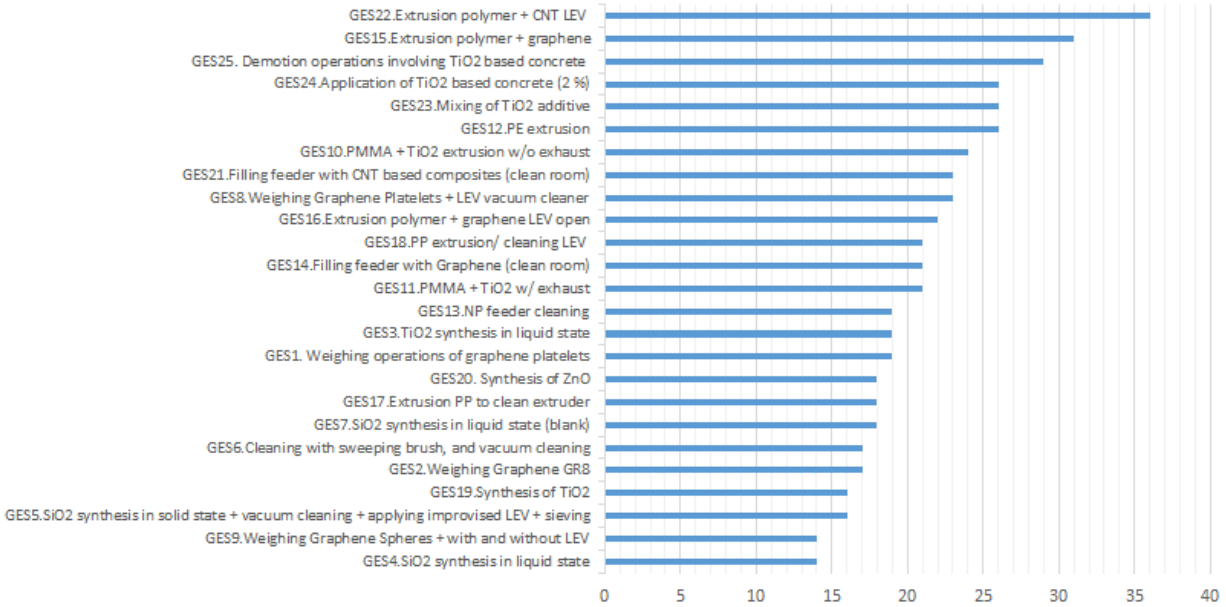


Figure 16. Overall reduction achieved in exposure scenario

A can be derived from the figure; a major reduction is achieved in process involving the use of ENMs in a matrix. A minor reduction was achieved when dealing with ENMs in dry/ powder forms as expected due to a higher dustiness index.

Concerning the validation of the operability tools developed, a total amount of 980 questionnaires were distributed to the target audience to gather data on their opinion at the time of writing 217 answers were compiled and analyzed. These questionnaires included 90 companies manufacturing ENMs and/or nanoproducts, 32 companies manufacturing personal protective equipment, and 39 companies non-directly related with the manufacture and use of ENMs, and 56 occupational hygienists working in risk management.

The data show a more than 70 % of the companies are satisfied with the outcomes of the project, especially when asking about the performance of the guidance on recommended measures. It shall be noted that the data revealed the need of provide additional information on the use of the RMM library, which is mainly due to the need for interpretation of the input values used to support the calculation of efficiency values.

Indicators of progress according with planned outputs and time scheduled

Table 34. Indicators of Progress in Action B5

Indicator	Measure of success	Results	Status
Reduction in exposure and release	Reduction in the levels of exposure and release by at least 50 % to be considered implemented	Reductions of the concentration levels up to 80 %., meaning an improvement up to 20.7 % of the situation using non recommended RMMs at the beginning of the project.	Achieved
Number of case studies	The implementation of the proven RMMs will be conducted in at least 5 voluntary industrial cases studies.	5 companies have been selected, including Avanzare, CRP, CIAC, LATI and Tec Star	Achieved

5.1.10. Action B6. Guidance on the required measures and controls

Action status: Completed
Timescale in Proposal: October 2014 – January 2016
Actual: December 2014 – June 2016

Objective: The main goal of this task is to develop a guidance to support the implementation of effective RMMs for mitigating and control the risk posed by the target nanomaterials during its entire life cycle, considering the compendium of contributing scenarios presented at all stages of nanocomposites production, use and disposal.

Activities Conducted: the action was completed last June 2016, five months later than initially scheduled due to the delay in action B5, where relevant results concerning the effectiveness of recommended measures when dealing with ENMs in real situations. Moreover, an in depth review of the data and information included in the guideline was conducted by technicians from Spanish Institute of Occupational health (INSHT), being necessary the incorporation of several improvements on the text, figure and tables.

The activities were conducted following the scheme of activities initially scheduled. The definition of the structure and main contents to be included in the guideline was conducted within tasks T6.1. To this end, two main activities were conducted, including several phone meetings to define the contents and structure, as well as face-to-face meeting with two manufacturers of personal protective equipment, including the international company 3M, and a SMEs from Basque Country, Medop. The outcomes of the meeting were summarized in a list of priority contents that were reflected on the structure proposed and detailed in the text.

Within action T6.2, an analysis of the annual cost of the list of risk management measures studied within the project was conducted. To this end, CRP and AVANZARE asked for quotations of a wide range of dermal and respiratory protective devices, fume hoods and movable ventilation systems in order to quantify whether the recommended measures involve a relevant increase of the annual investment. Only RMMs with an increase below 18 % were considered assumable by SMEs.

Finally, the last action completed focused on the development of the guidance on recommended RMMs to control the exposure to ENMs. The drawing up of the guidance was conducted by the all the members of the consortium. To this end, the responsibilities of each member where decided in a phone meeting organized in July 2015. Two versions of the guidance were conducted. One .pdf version, available since March 2016, and multimedia version, available on line since June 2016. Both versions incorporate the comments of partners and the results of the testing activities conducted.
As initially scheduled, the multimedia version was developed using Adobe InDesign CS6, including multimedia elements such as videos and visualizations options. The following Gantt-chart shows the progress of the action:

		2014			2015											2016				
Action / Task		Oct	N	D	J/F	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	Jun
TB6.1. Guidance structure and contents	Proposed																			
	Actual				B6a															
TB6.2. Cost Effective Analysis and definition of best available RMMs	Proposed																			
	Actual																			
TB6.3. Development of the Guidance	Proposed																			
	Actual																			B6b

Results and deliverables

The guidance structure, contents and functionalities was reported within deliverable B6a last February 2016. The guidance developed and upload into the web site comprise deliverable B6b, being both documents enclosed under the annex section. The structure of the guideline is depicted below:

1. Abbreviations and acronyms
2. Summary
3. Introduction: Environmental, health and safety (EH&S) issues in Nanotechnology

3.1. Nanotechnology: main concepts and overview of current applications on the market
3.2. Environmental, Health and Safety Considerations for Nanotechnology

4. Regulations and standards
4.1. Regulatory aspects
4.2. Standards for personal protective equipment

5. Basics on Risk Management Measures
5.1. Hierarchy of Safety and Health Controls
5.2. Technical Measures
5.3. Organizational measures
5.4. Personal protective equipment

6. Effectiveness of common RMMs against occupational exposure to ENMs
6.1. Current knowledge on the effectiveness of PPE and LEVs
6.2. Testing approaches followed under NanoRISK

7. List of measures for the safe handling and control of exposure
7.1. List of measures for controlling occupational exposures to ENMs
7.2. Personal protective equipment selection charts
7.3. Emission Control Technologies and procedures

8. Health Surveillance

9. Instruction sheets

10. Annexes

The contents of the guidance are briefly detailed under this document. Both pdf and multimedia version of the guidance are available in the project web site under section “interactive tools”.

A screenshot of the on-line access allocated to download the guidance is shown on figure 17. Current versions available at:

http://www.lifenanorisk.eu/index.php/interactive/multimedia-guideline

Fig. 17. On line access to the guidance.

The Front page and back page are shown in figure 18. The project name and number, as well as reference to LIFE funding scheme is included.

Figure 18. Front page and back page of the NanoRISK guidance.

Figure 19 shows two relevant pages from several sections. Section 6 summarize the results of the experimental activities conducted within the project. Due to the final user of the guide, the data on the performance factors were summarized in tables, including comprehensive test to ensure a proper understanding of the guide.

Figure 19a. Screenshots of the sections 2, 3 and 4.

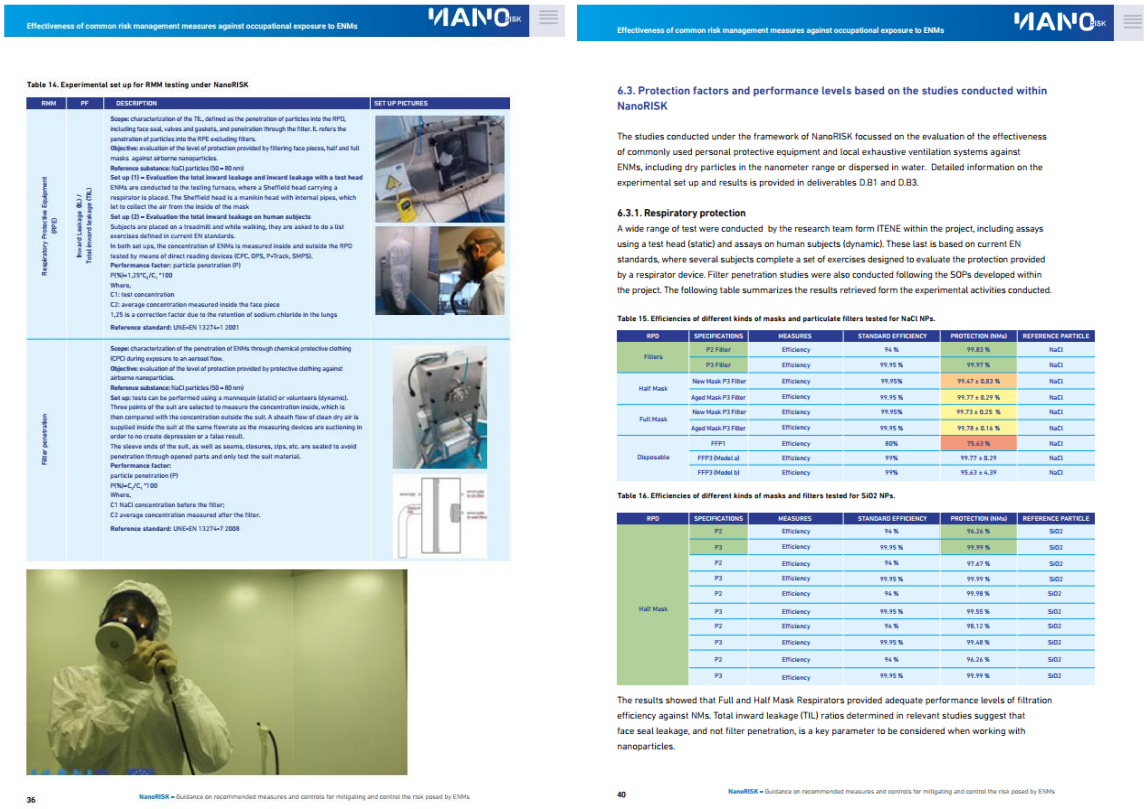


Figure 19b. Screenshots of the section 6.

Figure 20 shows screenshots of the relevant pages from section 7, where the list of recommended measures to control the exposure was included. This section is the key element of the guideline, where several tables, pictures and flow-charts are included to guide the user on the selection of a proper measure to control the exposure under relevant situations

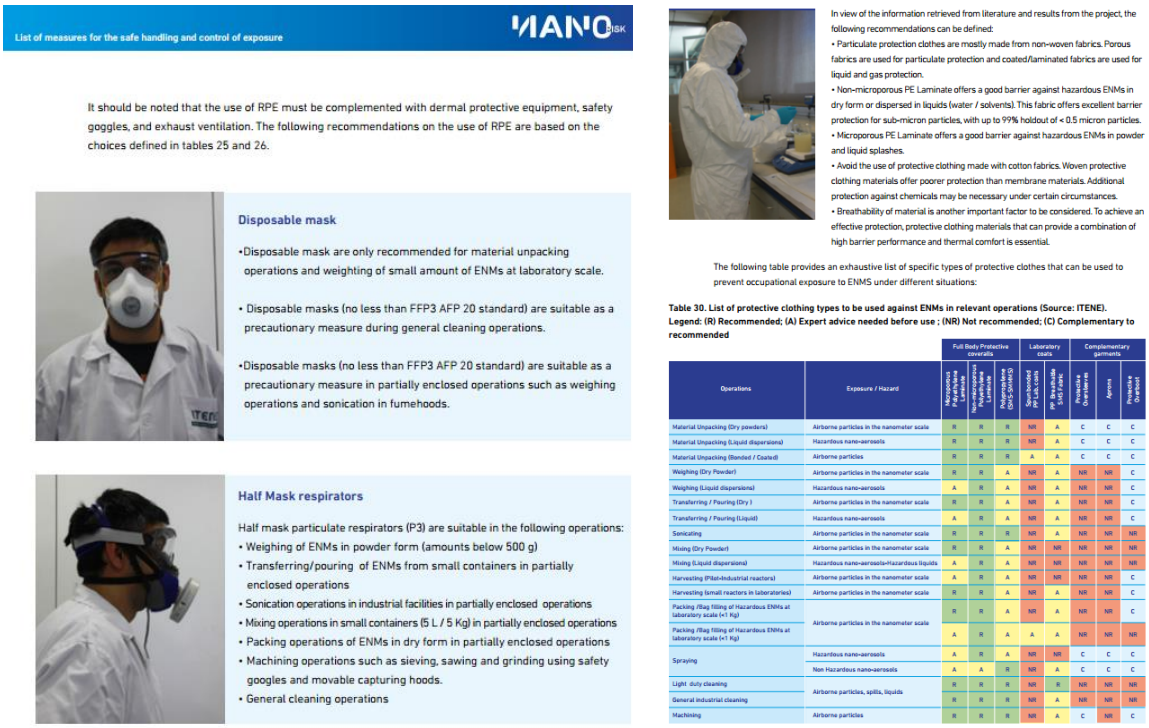


Figure 20. Screenshots of the section 7.

The figure below shows an example of the contents of section 9. This sections includes instruction sheets and videos to support the reader on the selection, use and maintenance of recommended measures.

Figure 20 Screenshots of the section 9.

Due to the importance of a proper fitting of the PPE, detailed videos for removing and putting on respirators and protective garments were included. The following figure shows examples of the transition effects used to give a page turn and the multimedia videos embedded into the guidance.

Figure 21. Screenshots of the multimedia version

Indicators of progress according with planned outputs and time scheduled

Table 35. Indicators of Progress in Action B6

Indicator	Measure of success	Results	Status
Cost Effectiveness	The cost of the risk management measures must be below 3.000 €, including installation for the engineering techniques.	Only measures with cost below 2700 € where considered feasible.	Achieved
Publication	The Guidance must be completely developed by january 2016	Guidance available on the project web site. A delay on the publication of 2 months for the pdf copy shall be noted.	Achieved

5.1.11. Action B7. Training activities for end users and stakeholders

Action status: Completed
Timescale in Proposal: January 2016 – April 2016
Actual: March 2016 – September 2016

Objective: The objective of this action is to transfer the outcomes of the project to relevant stakeholders, including workers and professional users who use ENMs as such, in mixtures or incorporated into articles in research or production processes, health and safety advisors, occupational hygienists, experts from industry associations, and experts from standardization (i.e. ISO committees) and/or regulatory bodies.

Activities Conducted: the action was completed last September 2016, five months later than initially scheduled due to the need for completing the final versions of both RMM library and the multimedia guideline developed.

The activities within action B7 focused on the organization of training activities to ensure the proper use of the tool by the target audience of the project. To this end, three main activities were conducted, including the design and development of a compendium of training materials based on the outcomes of the project and the needs of the industry under B7.1, and the organization of training sessions within B7.2.

The training materials developed included power point presentations, on-line webinars and videos designed to support the control and mitigation of the exposure to ENMs in the workplace. These materials are all available in the project web site, being expected further improvements during the afterlife period.

The e-learning activities where organized by ITENE and included the organization of two webinars using the adobe connect application. The first webinar focused on the use of presentation of the risk management measures library, describing in detail how to use the library to identify proper measures to control the exposure and evaluate the effectiveness of those personal protective equipment and technical measures implemented by the user.

The second webinar focused on the on-line presentation of the structure and contents of the guidance on recommended measures, including practical exercises to guide SMEs and stakeholders in using the guide to guarantee a safe working environment.

The last action conducted focused on the organization of 3 training sessions oriented to companies and professionals working with ENMs, and one workshop oriented to profesionals working in public organizations with competences on safety and health at work. INVASSAT was in charge of this action, including the preparation of the agenda and organization of the panel of sessions conducted.

More than 96 persons attended the training session organized in Valencia, Castellon and Alicante, workshops, including health and safety advisors from companies and research organizations dealing with ENMs, professional users and researchers from private and public universities. Similarly, more than 35 attendees from public institutions were present during the workshop organized in Valencia to train public bodies on the challenges of the nanotechnology on the occupational safety at work. The following Gantt-chart shows the progress of the action.

		2016								
Action / Task		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	sep
Task B.7.1.Development of training material	Proposed									
	Actual									
Task B7.2. Training sessions	Proposed									
	Actual									

Results and deliverables: the training materials were developed by ITENE and INVASSAT, being available in the project website. As stated before, the materials developed included a complete training manual to guide the industry and target stakeholders in the use of the RMM library and the multimedia guideline to select proper measures to control and mitigate the exposure to ENMs in the workplace. The structure and contents of the training manual are the following:

1. Scope and objectives of the training manual
2. Lesson 1. Safety Issues and Regulatory Challenges of Nanomaterials
3. Lesson 2. Effectiveness of personal protective equipment (PPE) and technical measures for controlling the exposure to ENMs in the workplace
4. Lesson 3. Safe handling and use of ENMs: recommended measures to reduce the exposure to ENMs during the manufacturing and downstream use of ENMs as such, in mixture or embedded into a matrix.
5. Lesson 4. Available tools for risk assessment and risk management
6. Practical exercises

The contents were developed using power point presentations, being complemented by practical exercises to support a proper understanding of the theoretical information compiled in the training manual.

Concerning the training sessions, a total of 96 persons attended the sessions, including representative persons from academia, industry and public bodies. The list of attendees to the sessions have been included in the annex section. The e-learning platform has been included in the web site of the project, containing the training materials and webinars carried out within the task. The program of the workshops and pictures published in social media are shown in figure 22 and 23.

Fig. 22 (up). Pictures during training sessions in Castellon (left) and Alicante (right).

TALLER

Aplicación práctica de medidas de protección frente a nanomateriales. Proyecto life NanoRISK

Fecha:	15 septiembre
Horario:	10 a 14 horas
Organiza:	Centro Territorial INVASSAT de Alicante
Domicilio:	C/ Hondón De Los Frailes, 1
Contacto:	965934948 sec-ali.invassat@gva.es
Director curso:	D. Esteban Santamaría Coria. Jefe de Servicio de Promoción y Desarrollo de la Prevención del INVASSAT en Valencia.

10:00 – 10:15	PRESENTACIÓN. OBJETIVOS DEL PROYECTO Y RESULTADOS ALCANZADOS. *D. Esteban Santamaría Coria.*
10:15 – 10:45	EVALUACIÓN DE LA EFECTIVIDAD DE MEDIOS DE PROTECCIÓN FRENTE A NANOMATERIALES. TIPOS DE ENSAYO, PARAMETROS DE EFICACIA Y RESULTADOS *Dª Maidá Domat. ITENE*
10:45 – 11:15	PRESENTACIÓN DE LA GUÍA RELATIVA A MEDIDAS Y CONTROLES RECOMENDADOS, PARA LA REDUCCIÓN DEL RIESGO DE EXPOSICIÓN A NANOMATERIALES *D. Carlos Fito. ITENE*
11:15 – 11:45	PRESENTACIÓN DE LA BIBLIOTECA INTERACTIVA PARA LA SELECCIÓN DE MEDIDAS A ADOPTAR FRENTE A LA EXPOSICIÓN DE NANOMATERIALES, USO DE LA MISMA PARA LA ELECCIÓN DE LOS EQUIPOS DE PROTECCIÓN MÁS ADECUADOS, MEDIANTE CASOS PRÁCTICOS CONCRETOS *Dª Maidá Domat. ITENE*
11:45 – 12:00	*PAUSA*
12:00 – 12:45	DEMOSTRACIÓN INTERACTIVA Y EJERCICIOS PRÁCTICOS DEL CORRECTO USO Y COMPROBACIÓN DE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL *Dª Paula Beltrán. INVASSAT*
12:45 – 13:15	EJERCICIO PRÁCTICO PARA LA SELECCIÓN DE MEDIOS DE PROTECCIÓN EN ESCENARIOS DE USO COMUNES EN LABORATORIOS DE INVESTIGACIÓN Y ACTIVIDADES INDUSTRIALES
13:15 – 13:30	ATENCIÓN A DUDAS Y CONSULTAS.

Fig. 23 (right). Training in Alicante (Spain) held on September, 15th 2016.

Indicators of progress according with planned outputs and time scheduled:

Table 36. Indicators of Progress in Action B7

Indicator	Measure of success	Results	Status
End users trained	A minimum of 75 attendees representing 50 companies must be trained	A total of 96 persons attended	Achieved
Number of training sessions	A least 4 training session to be conducted	Training sessions completed in Valencia, Castellon, Alicante and Sevilla.	Achieved

5.1.12. Action C1. Definition of the starting situation regarding REACH regulation fulfillment and environmental problems

Action status: Achieved
Timescale in Proposal: October 2013 – March 2014
Actual: October 2013 – March 2014

Objectives: the main goal of the task is to estimate the current degree of protection of workers and the environment on the basis of the study of the effectiveness of the RMMs commonly used at industrial level, data on the current levels of exposure and estimated amount of ENMs that can reach the environment on the basis current production levels and RMMs efficiency defined**.**

Activities Conducted and progress so far: the scheduled activities have been completed according with the proposal, including the identification of the default protection factors of the RMMs applied in the nanocomposite industry within tasks C1.1 and C1.2, the estimation of the levels of release by means of predictive modeling approaches developed by ITENE with C1.3, and the calculation of the current levels of exposure to ENMs across the nanocomposites life cycle by means of data retrieved from questionnaires and peer reviewed publications. The following Gantt-chart shows the progress of the action.

	2013	2014

Action / Task		Oct	Nov	Dec	Jan	Feb	Mar	Apr
Task C.1.1. Default values of RMMs effectiveness	Proposed							
	Actual							
Task C.1.2. Survey on the use of RMMs	Proposed							
	Actual							
Task C.1.3. Environmental release of ENMs	Proposed							
	Actual							
Task C.1.4. Worker´s exposure	Proposed							
	Actual							

Results and deliverables: the results from action C1 were described under the Interim report C1, attached to the inception report. In summary, the main results achieved were:

- Up to 101 references containing data on the effectiveness of common RMMs.
- The analysis of the surveys conducted among stakeholders showed that most of the companies are currently using half mask respirators with effectiveness up to 95 %, dermal protection with high permeation resistance and protective clothing with effectives up to 70 % for powders.
- Concerning the expected concentration of ENMs in relevant environmental compartments, data retrieved from peer reviewed publications showed concentrations of ENMs in **soil** ranging from 8 µg/kg to 810 µg/kg. In the **water** compartment ranged from 0.9 µg/L to a maximum of 88 µg/L.
- The **estimated levels of exposure** in the workplace according with peer reviewed publications and data from measurement campaigns conducted by the members of the consortium ranged from 4,000 particles/cm3 in the synthesis process to 200,000 particles/cm3 during the compounding phase.

As a result of the task conducted within action C1, it can be stated that there is an urgent need to design and develop PPE and technical measures able to reduce the exposure up to 98 %, as well as emission treatment technologies able to capture particles up to 90 %, guaranteeing that the production and downstream use of ENMs will not pose a risk to workers and the environment.

Indicators of progress according with planned outputs and time scheduled

Table 37. Indicators of Progress in Action C1

Indicator	Measure of success	Results	Status
Contents of the data matrix	- 100 references containing information on the effectiveness of the RMM studied in the project - 25 references including information of the environmental releases of nanomaterials for each environmental compartment - 25 references containing information on the levels of exposure for each process considered	The data matrix developed contains the scheduled references, including reports and peer reviewed publications	Achieved
Involvement of the project audience	The questionnaires received shall include: - 5 Public Authorities - 5 Industrial Associations - 10 Large Enterprises - 150 SMEs.	The list of contacts include more than 200 contacts. We have obtained 5 answers from public authorities, 3 from I. Associations, 10 LE and 85 SMEs	Achieved
Nº of questionnaires	Number of questionnaires received > 200	204 questionnaires received	Achieved

5.1.12. Action C2. Quantitative Assessment and monitoring of the protection factors achieved under controlled conditions

Action status: completed
Timescale in Proposal: January 2014 – July 2016
Actual: February 2015 – July 2016

Objectives: the main goal of the action is to define the improvement in the protection levels at industrial level derived from the use of proven RMMs defined during the project.

Activities Conducted and progress so far: this action was completed last July 2016. As stated in the mid-term report, the activities started in February 2015 and in 2014 due to the need for considering the outcomes from action B3. The scheduled activities focused on the definition of the overall protection factors achieved using a combination of PPE and technical measures, the analysis of the variations of such protection factors due to the incorporations of improvements in the design, and the quantification of the reduction in the release of ENMs to the environment.

The quantification of the reduction of the amount of ENMs released to the environment was achieved using a probabilistic material flow model (MFM) developed by ITENE to support the calculation of the predicted environmental concentration (PEC) values for ENMs. This model allows the user to predict the concentration of specific nanomaterial in the environment depending on an emission coefficient calculated experimentally in the nanoaerosol testing chamber prototype. These emission coefficients (TCs) where calculated for several conditions of use, being graphically represented to identify under which conditions a low level of release is expected.
The following Gantt-chart shows the progress of the action:

		2014				2015				2016		
Action / Task		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
T.C2.1. Establishment of the control protection factor	Proposed											
	Actual											
T.C2.2. Monitoring of further improvements in RMMs protection factors	Proposed											
	Actual											
T.C2.3. Assessment and monitoring of the release ratio	Proposed											
	Actual											

Results and deliverables: interim report C3 compiles the outcomes of the action. A list of 31 protection factors were defined in view of the data retrieved from the experimental activities and considering a combined use of PPE, technical measures and emission treatment technologies.

A summary such protection factors is depicted in table 38.

Table 38. Effectiveness levels under static and simulated conditions

Recomended RMM occupational	Penetration (%)	Efficiency (%)	PF

Recomended RMM occupational		Penetration (%)	Efficiency (%)	PF
Respiratory protection	DpHM - FFP1	29,633	70,367	3
	DpHM - FFP2	17,003	82,997	6
	DpHM - FFP3	11,59	88,41	9
	HM - P2	0,24	99,76	417
	HM - P3	0,1	99,9	1000
	FM - P2	0,45	99,55	222
	FM - P3	0,31	99,69	323
Chemical Protective Gloves	Disposables	0,96	99,04	104
	Re-usable	2,4	97,6	42
	Specific chemical resistance	0	100	-
Chemical Protective Clothes	Woven materials	40	60	3
	Non-woven materials (disposable)	6,183	93,817	16
	Elastomeric material re-usable	0	100	-
Eye protection	Universal Frame	40	60	3
	Goggles	20	80	5
Administrative Controls	Management Systems	0	*100*	-
	Operating Practice	0	*100*	-
	Competence and training	0	*100*	-
	Supervision	0	*100*	-
	Monitoring	0	*100*	-
	Health Surveillance	0	*100*	-
	Good Hygiene Practices & Housekeeping	0	*100*	-
Local Exhaust Ventilation	Wetting at release source	10	90	10
	Containment - no extraction	1	99	100
	Canopy receiving hoods	50	50	2
	Fixed capturing hoods	10	90	10
	Movable capturing hoods	50	50	2
	On-tool extraction	10	90	10
	Laboratory Hood (Partial enclosure)	1	99	100
	Horizontal/downward laminar flow booth	10	90	10
	Glove bag (ventilated or under pressure)	0,1	99,9	1000
	Laboratory glove box	0,03	99,97	3333
	Partial personal enclosure with ventilation	30	70	3
	Complete personal enclosure (ventilated or kept under negative pressure)	0,4	99,6	250
	Down-flow spray room	20	80	5

A summary of the protection factors (PFs) measured after the implementation of improvements such as variations on the conformation of the filtering devices used or surface treatments of chemical protective suits are summarized in table 39.

Table 36. Effectiveness levels for improved versions of respiratory protective equipment

RMM	Improvement	Max. % of improvement	New PF
FFP2	Chin tab for ease of donning and adjustment	1	6,2
	Aluminum adjustable nose piece welded with high resistance and internal Polyethylene (PE) Foam nose pad	5	7,8
	Adhesive material to the face in edges	2,2	6,6
FFP3	Chin tab for ease of donning and adjustment	1	9,3
	Aluminum adjustable nose piece welded with high resistance and internal	5	13,9

RMM	Improvement	Max. % of improvement	New PF
	Polyethylene (PE) Foam nose pad		
	Adhesive material to the face in edges	2,2	10,4
Half Mask P2	Rolled-edge for enhanced face-seal efficiency	0,05	526,0
	Sealing material in filter and facepiece threads	0,08	624,3
	Adhesive material to the face in edges	0,23	9476,9
Half Mask P3	Rolled-edge for enhanced face-seal efficiency	0,05	1998,0
	Harness with 4 adjustable fixing points	0,01	1111,0
	Sealing material in filter and facepiece threads	0,02	1249,7
	Head strap retaining points integrated in the mask body	0,08	4980,1
	Adhesive material to the face in edges	0,09	9910,8
Full Mask P2	Head harness with 5 fixing points	0,08	270,0
	Coverage of remaining head and neck with hood attached to the facepiece	0,17	356,2
	Adhesive material to the face in edges	0,25	497,2
Full Mask P3	Head harness with 5 fixing points	0,1	475,5
	Live joints	0,2	904,0
	Sealing material in filter and facepiece threads	0,15	623,2
	Coverage of remaining head and neck with hood attached to the facepiece	0,29	4784,9
	Adhesive material to the face in edges	0,3	9149,1

Concerning protective clothes, the improvements studied focussed on a better fitting of the coveralls to the body of the operator, as well as the application of surface treatments on the fabrics. The improvements achieved applying these measures are summarized in figure 24.

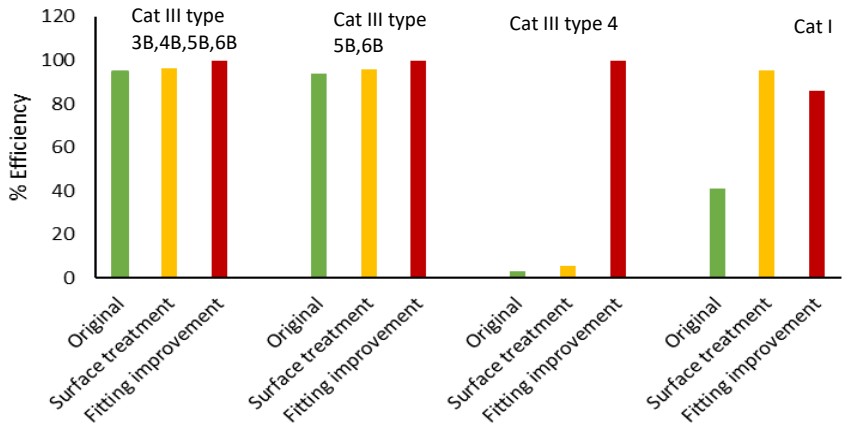


Figure 24. Evolution of the %efficiency against NMs from the original suit (green) and applying surface treatments (yellow) and fitting improvements (red).

Finally, the improvement on the protection factor achieved in the case of local exhaustive ventilation (LEV) systems is depicted on table 40.

Table 40. Summary of the improvements proposed for the different type of LEVs

Type of LEV	Improvement	Max % of improvement	New % of efficiency
Laboratory hood	Increase of the flow rate	3.1	99.4
Canopy hood	Partially enclosure of the emission source	1598	88.3
	Increase the flow rate	38.5	7.2
	Total enclosure of the emission source with moveable window	1721	99.9
On-tool hood	Addition of flaps	8.1	97.3

Type of LEV	Improvement	Max % of improvement	New % of efficiency
Moveable hood	Addition of flaps	0.01	99.9
	Addition of flaps + Increase the flow rate	0.01	99.9

The last stage, focused on the characterization of the concentration of ENMs in the environment derived from the release of ENMs from production sites. The evaluation of the environmental concentration of ENMs related with direct emission from release scenarios of interest has been performed starting from a probabilistic Material Flow Model taking as input the amount of ENMs used during the manufacturing of products.

Material Flow Models aim to predict the concentration levels of ENMs in a well-defined system, quantifying their flows between the different compartments. The transfer coefficients applied in the model take into account all the stages of the ENM life cycle, being fixed according to the ECHA Guidance on information requirements and Chemical Safety Assessment. The results for expected environmental concentrations of target ENMs before and after the use of recommended measures are shown in Table 41.

Table 41. Estimated values of ENMs released to air, water and soil for the critical scenarios and corresponding values of PECs. No RMM is applied

Scenario	Air Release (t/y)	PEC Air (µg/m3)	Water Release (t/y)	PEC Water (µg/L)	Soil Release (t/y)	PEC Soil (µg/Kg)	PEC Air RMM (µg/m3)	PEC Water RMM (µg/L)	PEC Soil RMM (µg/Kg)
GES1	0,21	0,16	0,14	19,43	0,05	78,83	**0,08**	**19,40**	**78,65**
GES2	0,37	0,29	0,25	34,30	0,08	138,02	**0,15**	**16,78**	**137,78**
GES3	0,25	0,19	0,17	23,21	0,06	94,18	**0,10**	**11,29**	**93,60**
GES4	0,30	0,24	0,20	27,62	0,07	111,95	**0,12**	**13,52**	**111,90**
GES5	0,43	0,34	0,29	40,04	0,10	163,32	**0,18**	**19,83**	**162,70**
GES6	0,30	0,24	0,21	28,29	0,07	114,23	**0,12**	**13,87**	**113,92**
GES7	0,70	0,54	0,48	65,88	0,16	259,53	**0,28**	**31,57**	**259,12**
GES8	0,10	0,08	0,07	9,25	0,02	36,93	**0,04**	**4,56**	**36,65**
GES9	0,28	0,22	0,19	25,53	0,06	104,27	**0,11**	**12,81**	**103,72**
GES10	0,52	0,41	0,35	47,70	0,12	196,75	**0,21**	**23,64**	**196,43**
GES11	0,30	0,23	0,20	27,66	0,07	111,83	**0,12**	**13,44**	**111,65**
GES12	0,00	0,00	0,00	0,00	0,00	0,00	**0,00**	**0,00**	**0,00**
GES13	0,39	0,31	0,27	37,35	0,09	147,17	**0,16**	**18,05**	**146,90**
GES14	0,28	0,22	0,19	25,90	0,06	104,12	**0,11**	**12,76**	**103,83**
GES15	0,49	0,39	0,33	45,39	0,11	185,10	**0,20**	**22,41**	**184,93**
GES16	0,36	0,29	0,25	33,92	0,08	136,52	**0,15**	**16,70**	**135,95**
GES17	0,00	0,00	0,00	0,00	0,00	0,00	**0,00**	**0,00**	**0,00**
GES18	0,00	0,00	0,00	0,00	0,00	0,00	**0,00**	**0,00**	**0,00**
GES19	0,25	0,20	0,17	23,48	0,06	93,93	**0,10**	**11,38**	**93,65**
GES20	0,70	0,55	0,47	64,05	0,16	261,73	**0,28**	**31,76**	**261,58**
GES21	0,17	0,14	0,12	16,25	0,04	64,85	**0,07**	**8,06**	**64,77**
GES22	0,30	0,24	0,21	28,43	0,07	115,50	**0,12**	**13,64**	**115,20**
GES23	0,40	0,31	0,27	36,83	0,09	150,85	**0,16**	**18,20**	**150,58**
GES24	0,44	0,34	0,29	40,17	0,10	163,23	**0,18**	**19,76**	**161,77**
GES25	0,53	0,41	0,35	48,44	0,12	195,98	**0,21**	**23,75**	**195,47**

The information on the levels of release measured and concentration values expected depending of the type of risk management measures implemented were compiled in a dedicated database and plotted using different graphs and charts.

Indicators of progress according with planned outputs and time scheduled

Table 42. Indicators of Progress in Action C2

Indicator	Measure of success	Results	Status
Number of Protection factors	At least 25 protection factors will be established to define the baseline (point of reference) regarding the reduction in exposure and release achieved by the RMM evaluated at the beginning of the project.	31 protection factors have been defined to date.	Achieved
Time series recorded	The recorded data must contain data collated for at least 12 months.	Data gathered between March 2015 and May 2016 available.	Achieved
Number of entries for the graphical representations	The graphical representation of the evolution of the release ratios must contain at least 20 measured data for each equipment evaluated.	26 release ratio measured under controlled conditions available.	Achieved

5.1.13. Action C3. Evaluation of the improvement achieved in industrial conditions

Action status: Achieved
Timescale in Proposal: January 2014 – July 2016
Actual: October 2014 – July 2016

Objectives: this action focused on the evaluation and monitoring of the reduction of the levels of exposure due to the use and implementation of risk management measures at process level by the target audience of the project, considering data from case studies and data retrieved using tailored designed surveys.

Activities Conducted and progress so far: this action was completed last July 2016, following the scheduled plan and the progress indicators stated on the proposal. The first activity conducted was the drawing up and development of a monitoring plan to evaluate and monitor the overall reduction of release of ENMs into the environment and occupational exposure after the implementation of recommended risk management measures. This plan was divided into three sections, considering:

- Section 1, containing a list of risk management measures with information on the effectiveness when working with ENMs, cost per unit and applicable exposure scenarios.
- Section 2, including a stepwise procedure to implement adequate risk management measures.
- Section 3, containing a set of indicators to measure the reduction on the emission rates and occupational exposure levels.

The second focused on the monitoring of the improvements achieved in the cases studies conducted within action B5 following the set of indicators defined in the abovementioned implementation plan. ITENE, VITO and CRP analyzed 8 indicators in each case study, considering the specifications of the ENMs used, existing operative conditions and the type of

PPE and technical measures implemented. The last action, task C3.3, focused on the evaluation and monitoring of the potential impact of the project in the nanocomposite sector. To this end, an interactive questionnaire was developed to support SMEs and large companies in the estimation of the reduction of the exposure and emission rates after the implementation of recommended risk management measures. A list of more than 500 companies were invited to fill this interactive questionnaire in March 2015, being completed by 183 companies at the end of the project. The following Gantt-chart shows the progress of the action:

		2014				2015				2016		
Action / Task		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
TC.3.1. Development of a monitoring plan to evaluate emissions / exposure reduction	Proposed											
	Actual											
TC.3.2. Monitoring and interpretation of the improvements achieved in industrial case studies	Proposed											
	Actual											
TC.3.3. Monitoring the impact of the actions in the nanocomposite sector	Proposed											
	Actual											

Results and deliverables: the main result from the action is a complete implementation plan aimed at supporting a quantitative evaluation of the reduction of the levels of exposure and emission rates using proper RMMs, as well as data on the average reduction of the levels of ENMs achieved in indoor workplaces implementing proper RMMs. The contents of the implementation plan are summarized below.

Section 1. List of Risk Management Measures: section 1 contains a list of 19 recommended RMMs, including data on protection factor, cost and exposure situations where the implementation is recommended. Table 43 an extract from the list of RMMs included.

Table 43. Overview of the descriptive list of RMMs.

			Exposure situations*											
Measures	**Cost**	**PF**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Full Mask P3	27 € / unit	323												
Half Mask P2	16 € / unit	417												
Protective suits (laminated)	8 € / unit	16												
Movable capturing hoods	750 € / unit	2												
HEPA filtered hoods	3400 € / unit	10												
Canopy hoods	> 5000 € / unit	2												
Flat-panel filters	1860 € / unit	10												
Cluster Filter System	> 5000 € / unit	10												

*Note: 1. Material Unpacking (Dry Powder) / 2. Material Unpacking (Liquid dispersions) / 3. Weighing (Dry Powder) / 4. Transferring / 5. Sonicating / 6. Mixing (Dry r) / 7. Mixing (Liquid) / 8. Production (physical and chemical synthesis) / 9. Packing /bag filling / 10. Spraying / 11. Machining (sawing , grinding, etc) / 12. Compounding / injection molding.

Section 2. Implementation steps: a stepwise procedure considering the steps depicted in figure 25 was developed. The cornerstone part of the plan is the set of 10 monitoring indicators defined, including:

1. Particle number concentration measured in the particle breathing zone
2. Particle number concentration measured in the far field (1 to 5 m from the source)
3. Size distribution of particles retained in polycarbonate filters

4. Size distribution of particles retained in surface swab samples (industrial area surfaces)
5. Removal efficiency of respiratory equipment: on site measurement of inward leakage
6. Removal efficiency of protective clothing: on site measurement of inward leakage
7. Captation efficiency of movable fume hoods: particle size distribution of particles using cascade impactors pre-installed.
8. Differential pressure across HEPA filtered units
9. Concentration of metal oxides in wastewater
10. Concentration of particles below 1 µm in exhaust systems

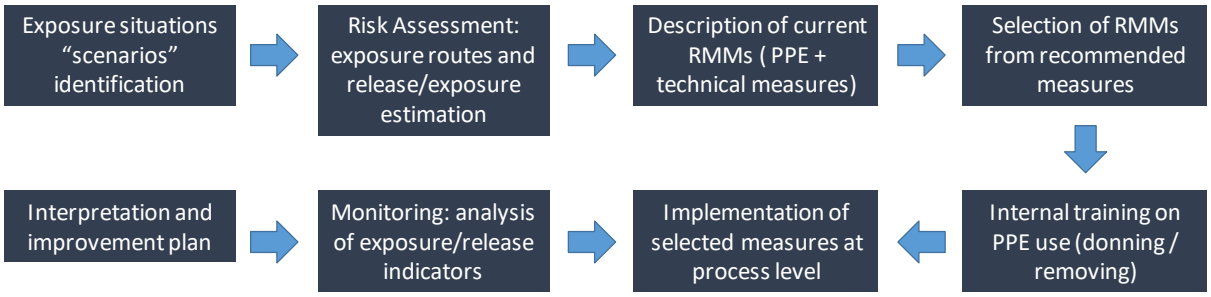


Figure 25. Implementation steps

Concerning the reduction on the levels of exposure in industrial case studies, an average reduction of 20.7 % was achieved in a 12 months' period. An example of the reduction of the exposure levels achieved in ES1 to 10 is depicted in figure 26.

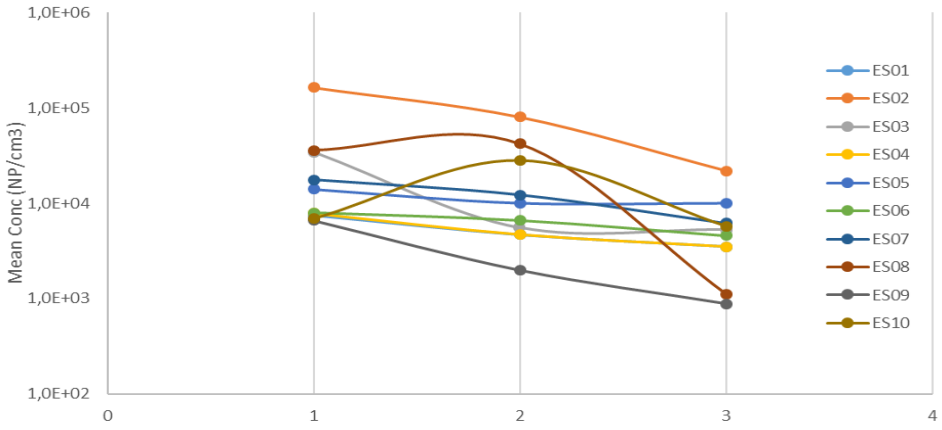


Figure 16. Exposure reduction in the successive campaigns for each Exposure Scenario

Finally, a complete study of the use of the controls used in the nanocomposite sector was conducted. As stated on deliverable C3, 183 answers were achieved, and an evident increase on the safe use of ENMs was detected in view of the increase of RMMs implemented.

Indicators of progress according with planned outputs and time scheduled

Table 44. Indicators of Progress in Action C3

Indicator	Measure of success	Results	Status
Monitoring plan	The monitoring plan must be developed by month 15.	The monitoring plan was completed in January 2015 (M 15)	Achieved

Indicator	Measure of success	Results	Status
Number of records provided	At minimum of 30 records must be filled by the pilot companies where the monitoring plan will be implemented	A list of 40 records were compiled from case studies	Achieved

5.1.14. Action C4. Promotion of REACH fulfillment

Action status: Completed
Timescale in Proposal: January 2014 – July 2016
Actual: May 2014 – September 2016

Objectives: the main goal of the action is to evaluate the suitability of the actions conducted within the project to support the implementation of REACH.

Activities Conducted and progress so far: this action was completed last September 2016. The purpose of this action is to evaluate the success of the project to support the implementation of REACH. To this end, three main activities were performed, including the design and distribution of questionnaires to gather information on the implementation of REACH and use of risk management measures among the main target audience of the project, definition of REACH implementation indicators, evaluation and monitoring of risk characterization ratios (RCR) on the basis of the nature of the operative conditions and risk management measures applies in the nanocomposite industry.

The questionnaires were developed by ITENE and VITO, being designed to elucidate the degree of implementation. Due to the low involvement of the target audience in a first attempt, new and easy-to-complete questionnaires were developed and distributed by email and/or by direct contact in conferences, workshops and relevant meetings. Moreover, direct interviews by phone with 117 companies were conducted to achieve the minimum number of questionnaires defined.

Within task C4.2, VITO and ITENE evaluated a sample of 20 cases studies to monitor the applicability of the project to reduce the risk posed by the use of ENMs. A set of 26 exposure scenarios from 12 companies were selected, including a complete characterization of the risk before and after the implementation of REACH. The methodology applied was based on the risk assessment approach defined under REACH, where the risk index is called “Risk Characterization Ratio (RCR)”. These RCR were calculated and evaluated following a scoring system and performance indicators tailored designed to evaluate the improvement on the risk management due to the use of recommended RMMs. The changes in the risk characterization ratio to measure qualitatively the improvements were scored as follows:

- Variation > 1: High improvement
- 1 > Variation > 0.5: Medium Improvement
- 0.5 > Variation > 0.25: Low Improvement
- 0.25 > Variation > 0.1: No improvement detected

The last activity, task 4.3, focused on the development of an action plan to promote the implementation of REACH by means of the use of adequate PPE, technical measures and emission control technologies. The following Gantt-chart shows the progress of the action.

		2014				2015				2016		
Action / Task		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
TC.4.1. Development of Questionnaires and performance indicators.	Proposed											
	Actual											
TC.4.2. Evaluation of the Risk Characterization Ratios (RCR)	Proposed											
	Actual											
TC.4.3. Development of an action plan to promote the REACH implementation	Proposed											
	Actual											

Results and deliverables: in relation with the implementation of REACH, 218 questionnaires have been finally compiled. Figure 27 summarizes information retrieved form surveys conducted in 2014, 2015 and 2016, with the purpose of observe clearly the evolution suffered in the implementation of REACH during this period.

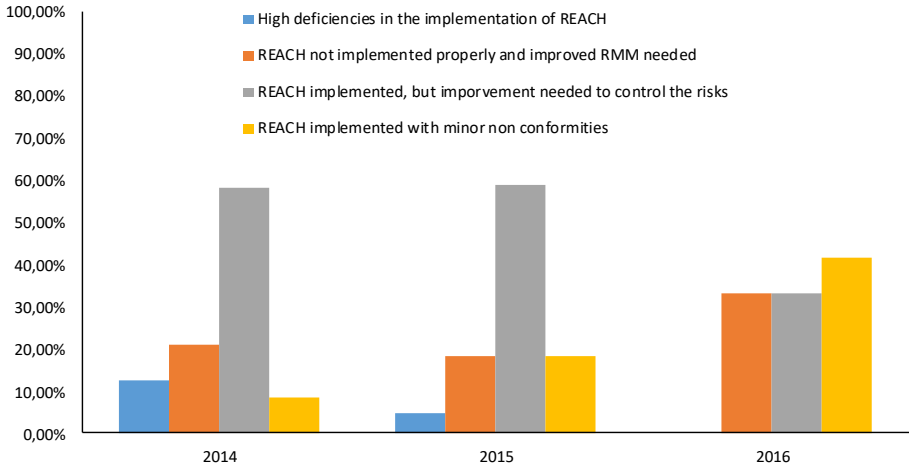


Figure 27. Evolution in the implementation of REACH during the period comprised between 2014 and 2016.

As can be seen in figure 27, there is an improvement in the implementation of REACH. It is important to remark the decrease in the number of companies with “High deficiencies in the implementation of REACH”, which has reached the value of 0%.

Concerning the reduction on risk potential, the analysis of the data provided by the companies showed a high improvement in the occupational risk control when using the operative conditions and risk management measures recommended in the RMM library, with more than one units of variation for 36% of studies cases (13 cases), and a medium improvement of more than 0.5 units of variation in the 46% of studied cases (9 cases).

A complete excel worksheet containing information on the RCRs from 12 end users has being developed. This file contains data for 17 ENMs and 25 activities. The data show that the exposure levels decrease considerably for most scenarios after the implementation of the risk management measures taken into account, which implies a reduction of the RCRs. The variation on the RCRs demonstrated that a safe use of ENMs is feasible using proper RMMs. As depicted in table 42 most of the RCRs achieved are below or around 1, implying that the worker is adequately protected by potential risks.

Table 45. Values of human RCRs for the different scenarios studied.

ENM	Scenario	RCR	RCR	
			On-site RMM	Recommended RMM
Graphene	GES1	3,50	3,15	1,75
	GES2	0,11	0,10	0,05
Nano-TiO2	GES3	2,24	2,01	1,12
Nano-SiO2	GES4	0,01	0,01	0,00
	GES5	0,02	0,01	0,01
Graphene	GES6	1,00	0,90	0,50
Nano-SiO2	GES7	0,01	0,01	0,00
Graphene	GES8	1,75	1,58	0,88
	GES9	0,05	0,05	0,03
Nano-TiO2	GES10	1,47	0,74	0,17
	GES11	0,76	0,38	0,09
Blank	GES12	x	x	x
Nano-TiO2	GES13	5,65	2,82	2,82
Graphene	GES14	0,92	0,46	0,46
	GES15	2,08	1,04	0,24
	GES16	1,08	0,54	0,00
Blank	GES17	x	x	x
	GES18	x	x	x
Nano-TiO2	GES19	5,71	0,03	0,03
Nano-ZnO	GES20	138,57	0,83	0,83
Carbon Nanotubes	GES21	29,00	0,03	0,03
	GES22	1100,00	1,10	1,10
Nano-TiO2	GES23	0,52	0,47	0,26
	GES24	5,18	4,66	0,03
	GES25	13,53	12,18	0,01

Finally, and as can be observed in figure 28, a high improvement in the environmental risk control, with more than one units of variation, can be achieved for 9% of studied cases (4 cases) when using the operative conditions and risk management measures as recommended in the NanoRISK guidance.

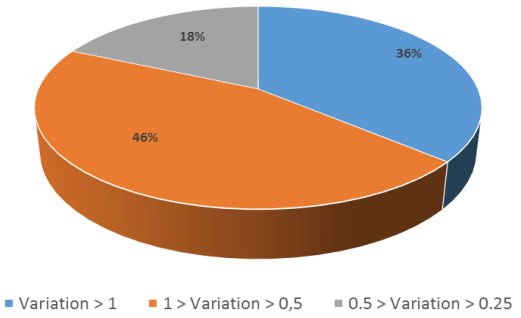


Figure 28. Percentage of reduction of Human risk characterization ratios

Indicators of progress according with planned outputs and time scheduled:

Table 46. Indicators of Progress in Action C4

Indicator	Measure of success	Results	Status
Involvement of the project audience	The questionnaires received must cover the main target audience, including end-users, trade associations and policy makers.	The questionnaires developed include questions designed to gather information from the target audience defined	Achieved
Number of RCR recorded	At least must be received 200 questionnaires	To date, 218 questionnaires have been received	Achieved
Number of indicators assessed	Full Assessment of at least six of the eight indicators identified in the action	Information available from 6 of the 8 indicators identified	Achieved

5.1.15. Action C5. Assessment of the socio-economic impact of the project actions

Action status: Completed
Timescale in Proposal: May 2015 – September 2016
Actual: May 2015 – September 2016

Objectives: the main goal of the action is to evaluate the impact of the project on economy and population, considering benefits for human health and the environments, as business

promotion. The evaluation of the socioeconomic impact has been conducted by the project coordinator, being supported by representative persons from INVASSAT and INSHT. For a better quantification of the impacts, a set of specific indicators were defined, including:

1. Direct cost for REACH implementation
2. Increase of the business opportunities and competitiveness
3. Changes in the amount of environmentally hazardous NMs releases (reduction)
4. Changes in the level of employment at ENMs producers and downstream users.
5. Enhancement of the performance of risk management measures
6. Insurance cost related with health damage of workers
7. Reduction of Occupational diseases
8. Public spending for public heath damage

Results and deliverables: the specific set of indicators defined within the project, as well as the base line and expected results are depicted in the table below.

Table 47. Socio-economic impact based on state of the are based assumptions

Impact Indicators	Baseline	Short term	Medium term (2 y)	Medium Term (5 y)	Long Term	Impact
Direct cost for REACH implementation	€ 7.000 per company I_1: 7000 x 2707= €18.949.000	15.348.690 (-€ 3.600.310)	14.590.730 (€ -4.358.270)	13.264.300 (€ -5.684.700)	12.316.850 (€ -6.632.150)	- 35 %
Increase of the business opportunities and competitiveness	I_2: € 190.000 millions	€ 193.800 million	€ 205.200 million	€ 209.000 million	€ 228.000 million	+ 20%
Changes in the amount of environmentally hazardous NMs releases (reduction)	I_3: 74.300 tons released	72.071 Tons	67.613 Tons	59.440 Tons	52.010 Tons	- 30%
Level of employment at ENMs producers / downstream users	I_4: 90.000 jobs in Europe	90.900	94.500	99.000	108.000	+ 20%
Insurance cost related with health damage of workers	I_6: € 180 millions	€ 171 millions	€ 162 millions	€ 148 millions	€ 135 millions	- 25%
Reduction of Occupational diseases	I_7: 4500 cases	4.680 cases	4.420 cases	3.640 cases	3.120 cases	- 30%
Public spending for public heath damage	I_8: € 720 millions	€ 706 millions	€ 684 millions	€ 648 millions	€ 612 millions	- 15%
Exposure reduction	I_9: 25 µg /m³ (50.000 pt/cm³)	22,75 (45.000)	21,25 (42.500)	18,75 (37.500)	16,25 (32.500)	- 35%

The estimations depicted in the table are based on consultation with affected industries combined with expert opinions from the members of the consortium. There are uncertainties, mainly about the insurance cost, which is mainly related with the volume of the company. We have considered a total amount of NMs placed on the market of 2.5 million tons, a total number of 2.707 companies dealing with ENMs, including manufacturers and downstream users, as well as current market of € 190.000 million at EU scale. A summary of the estimated impact of the project considering initial assumptions for each category are depicted in the table below. A detailed analysis is provided within deliverable C5.

The most prominent link between NanoRISK and benefits for workers' health was identified as the generation of robust information on the effectiveness of RMM, enhancing the

implementation of existing workers' protection legislation. The effectiveness of NanoRISK in reducing occupational damage was estimated in a 30 % in the long term, being quantified in at less 1.380 less workers affected by a disease caused by a direct exposure to ENMs, meaning a reduction on the medical care between 2 and 7 million € in 5 years. It was also estimated a reduction in at least 15 % of the public spending to compensate damage caused by ENMs, which means a maximum reduction of € 58 million in 5 years.

The benefits of the project related to the environment include: 1) less actual damage to the environment, 2) lower spending to remediate or compensate for environmental damage and, 3) lower risks of damage to the environment.

The impact of the project has been assumed at '15% average reduction' of exposures (in line with similar assumptions in previous appraisals) and is stated to mainly stem from reduced releases of environmentally ENMs (and to a lesser extent to market withdrawal) due to proper selection of risk management measures and a reduction of the use of hazardous NMs.

5.2. Dissemination actions

5.2.1. Objectives

The objective of the dissemination actions is to maximise the influence of the project and to promote the foreground generated by it. In more detail, the objectives of dissemination are:

- To raise public awareness about the project, its expected results and progress within defined target groups using effective communication means and tools
- To exchange experience with projects and groups working in the domain of creating safer environments for those working in industries applying nanotechnologies, and in particular in the reduction of the potential environmental risk posed by the use of ENMs,
- To disseminate the fundamental knowledge, the methodologies and technologies developed during the project, with special emphasis on the RMM library and the NanoRISK guidance on recommended measures.

The dissemination strategy and activities conducted follow the principles and best practices recommended by LIFE + Guidelines:

- All public results are accessible from the project website and usable from all parties who may benefit from them, and specially the target audience of the project. Internal project reports are not publicly available as a default, but can be available upon request via the web site,
- The communication materials developed within the project clearly reference the LIFE financial support, including the LIFE logo. For audio-visual material, the credits at the beginning or at the end include an explicit and readable mention of the LIFE support.
- All public results/reports will be duly reviewed and a copy will be sent to relevant partners involved in the project before these are published or disseminated. When appropriate, the reports will refer to other research projects and build on the existing results and literature,
- All partners contributing to the project activities will be informed of the presentation of the project outcomes during the after LIFE period.

5.2.2. Dissemination: Overview per activity

The dissemination activities are conducted under the scope of actions D, and specifically D1, D2, D3 and D4. An overview of the goals, planned activities and outcomes is provided below.

Action D1. Communication and dissemination management

Status: Achieved

Planned activities and objectives reached: the action focused on the management of the dissemination actions of the project, including the definition of communication objectives and target audience, communication tools and evaluation methods. The action was coordinated by Antonio Monsalve from ITENE, and supported by INSHT and INVASSAT. The action was completed as scheduled, including the development of a dissemination plan, design of the dissemination strategy and coordination of the activities. In addition, a set of indicators was defined to measure the quality and success of the activities completed.

Results: the dissemination management was completed with success, achieving a proper dissemination of the actions and results of the project, including the generation of dissemination materials, web site updates, participation in media, and internal reporting. Two versions of the dissemination plan were approved, and the indicators defined achieved.

Deliverables: D1. Dissemination plan completed

Table 48. Indicators of Progress in Action D1

Indicator	Measure of success	Results	Status
Alignment with the dissemination plan	The dissemination manager will generate quarterly reports to ensure the compliance with the communication and dissemination strategy defined	Carlos Fito has developed quarterly reports describing the dissemination activities conducted. A specific template was prepared as scheduled. The quarterly reports conducted are included under the annex section.	Achieved
Feedback form stakeholders	A compendium of a minimum of 50 comments about the project must be recorded	The feed backs wer recorded by the dissemination manager during the events where the project is described.	Achieved
Publishable reports	A minimum of 3 public reports will be published in the project web site including the dissemination actions carried out.	These publishable report were completed, being available via the project web site.	Achieved
Web site publications and updates	A minimum of 50 publications will be uploaded in the web site during the project development. A minimum of 3 revisions will be performed every year regarding the validity of the web site contents.	To date, 56 publications are accessible via the project web site.	Achieved
Internal periodic reports	Quarterly reports will be generated to report the results of the dissemination and communication actions. A minimum of 16 quarterly reports must be generated.	The progress was recorded by the dissemination manager by means of a short summary prepared every 3 months.	Achieved

Action D2. Preparing and keeping the project website

Status: Achieved

Planned activities and objectives reached: the action focused on the creation and exploitation of the project web site to support the dissemination of the progress and results of the project.

The tasks conducted included the design of the web site, contents management and publication of key events, news, outcomes and results. Eva Araque was in charge of the web site.

Results: the website was launched in month 2 under the domain *www.lifenanorisk.eu* to reinforce the EU focus and interest of the project, being structured and developed following the recommendations published in the LIFE web site. Figure 29 shows screenshots of the website. For its part, table 44 details the results achieved.

Figure 29. Screenshot of the project web site

Deliverables: D.2 project web site

Table 49. Indicators of Progress in Action D2

Indicator	Measure of success	Results	Status
Delivery of the project web site	The project web site must be completely operative in month 2	The project web site was published on line last December 2013, month 3	Achieved
Feedback form stakeholders	The contents of the project web site must be approved by the consortium ¡	The contents are always sent to the members of the consortium in advance	Achieved
Web visitors	A minimum of 1500 visitors must be achived	The number of visitors according google analytics were 4.209 in September 2016	Achieved

Action D3. Elaboration of informative material

Action status: Achieved
***Timescale in Proposal**: October 2014 – September 2016*
***Actual**: October 2014 – September 2016*

Planned activities and objectives reached: this task is focused on the elaboration of materials to disseminate the results of the project. To date, ITENE, INSHT and INVASSAT, in charge of dissemination activities, have developed two project brochures, two roll ups, one factsheet, three newsletters, and two project videos. Spanish and English versions are available.

Results / Deliverables: as stated previously, the main outcomes of the tasks are the project brochure (D3a), the project factsheet (D3b), the Notice Board "Roll Up" to be used in relevant events (D3c), project newsletters, the Informative video (D3e) and the Layman report (D3d). These materials are included in the annex section and are available in the web site. The indicators of progress are depicted in table 50.

Table 50. Indicators of Progress in Action D3

Indicator	Measure of success	Results	Status
Edition of material	- Brochure: 1500 copies (SP/EN) - Newsletters. 3 publications - Videos: 2 promotional videos (ES/EN) - Roll up: 2 Roll Ups (SP/EN)	Materials: 2 promotional videos available, 2 roll up printed, 3000 brochures distributed and 4 newsletters published	Achieved
Layman Report	At least 1.500 institutions must download or confirm interest	Layman report sent to 3.723 contacts	Achieved

Action D4. Dissemination of results

Action status: Achieved
***Timescale in Proposal**: October 2014 – September 2016*
***Actual**: October 2014 – September 2016*

Planned activities and objectives reached: this task focused on the dissemination of the results of the project at regional and European scale. The scheduled activities included: distribution of dissemination materials, presence in conferences, publication in relevant journals and edition of the six guidelines scheduled. The activities were completed, including:

- Regional workshops organized in Valencia in June 2013 and November 2014.
- Edition of printed copies of dissemination material in English and Spanish.
- A compendium of three press releases published by partners.
- Presentation of project posters in relevant conferences and workshops.
- Social networks (twitter, Facebook and LinkedIn)
- Networking oriented activities to support dissemination
- Organization of a EU dissemination event in Sevilla (Spain) at the end of the project.

The list of events where the project actions and outcomes was communicated is depicted below.

a) General Public events
- NanoRISK. Lessons learned from cases studies in 2015. Organized by INSHT

b) *Specialised audience (e.g. decision-makers)*
- Presentation of the project outcomes in the Nanoscience week, organized by the autonomous Catalan government
- Laboralia 2016. Valencia (Spain)

c) *Very specialised audience (e.g. experts, academics)*
- ISES “Interdisciplinary approaches for heath and the environment” – Netherlands, Utrech
- NanoSpain conference. Logroño, 2016
- NanoSD Security and defense. Madrid, 2015.
- NanoSafe conference 2016. Grenoble (France)
- New Tools and Approaches for Nanomaterial Safety Assessment Conference
- Poster presented by ITENE during the Aerosol technology conference 2014. June 2014. Karlsruhe, Germany
- Poster presented by VITO during the International Conference Nanosafe. October 2014. Grenoble (France)

- Poster presented by ITENE during the Aerosol technology conference 2016. June 2016. Barcelona, Spain.
- Poster presented by VITO during the Aerosol technology conference 2016. June 2016. Barcelona, Spain.

d) *Dissemination events (co)organized by NanoRISK*

- Nanostruc workshop, co-organized with LIFE SIRENA
- Join Workshop on Risk Assessment and Risk Management, co-organized with LIFE Ecotexnano and REACHnano
- Join Workshop on Tools for Risk Assessment Purposes, co-organized with LIFE NanoMONITOR

The materials developed, conference programs and guidelines developed are available under the annex section. The indicators of progress of this action are depicted in table 51.

Table 51. Indicators of Progress in Action D4

Indicator	Measure of success	Results	Status
Number of scientific journals, publications and press releases	The project must be mentioned in more than 20 paper based on digital media over the project lifetime	Project activities mentioned in more than 27 digital publications over the project lifetime.	Achieved
Scientific papers	A minimum of 6 scientific papers must be published.	Six papers prepared including information based on the project outcomes.	Achieved
Number of events	One interregional conference shall be organized	One inter-regional conference organized in Sevilla	Achieved
Publication of materials	The totality of the copies edited must be published over the project period	All the dissemination materials available in pdf and paper	Achieved

The abovementioned dissemination activities were complemented with networking actions managed by Carlos Fito from ITENE. In this regard, the project has been discussed in the framework of the risk management working group of the EU Nanosafety cluster, the risk assessment working group of the US-EU Communities of Research, the OECD Working group of Manufactured NMs. Table 52 details the most relevant networking activities completed so far under the framework of the project.

Table 52. Relevant networking activities completed

Date	Event	Actions	Location	Purpose
23/10/2014	ECHA workshop on nanomaterials	Presentation of the project activities by Carlos Fito	Helsinki (FL)	Networking with the members of the European chemical agency and leading researchers
11/12/2014	Nanosafety cluster review meeting	Compilation of opinions from cluster members	Brussels (BE)	Networking with key researchers Feedback and opinions
30/03/2015	SUN-SNO-GUIDENANO Conference	Compilation of opinions from end users	Venice (IT)	Networking with producers and downstreams users of NMs

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Besides the above, several phone meetings were organized with coordinators from other LIFE projects such as SIRENA, Ecotexnano, and i-NanoTool. The main outcome from the networking activity is related with the cooperation of the project with other relevant initiatives, including EU projects and platforms were the scope and outcomes of the project are of particular

interest. A list of priority contacts were defined, including project coordinators from EU projects, as well as key persons from relevant organizations such as ECHA and OECD. Ten phone calls were organized to date to discuss the outcomes from the project, including meetings with Maria Blazquez (LIFE SIRENA), Raquel Villalba (LIFE Ecotexnano), Emilio Benfenati (LIFE ANTARES) and Paula Subirats (LIFE i-NanoTool), Jose Luis Romero (FP7 NanoSafePack), Lang Tran (FP7 MARINA and Cost Action MODENA), Socorro Vazquez (FP7 Guidenano), Jesús López de Ipiña (FP7 Scaffold), Anna Costa (FP7 SanoWork) and Robert Rallo (FP7 Modern).

5.2.3. Maintenance and use of the project web site

ITENE will upload information related with updates on REACH regulation, relevant events concerning REACH implementation and chemical safety assessment of nanomaterials, as well as updates of the NanoRISK tools. New dissemination events and networking activities has been scheduled after the end of the project. Detailed information of such events will be published on the web site accordingly. The maintenance costs, including either human resources and internet domains, will be funded by ITENE using own resources.

5.3. Evaluation of the project implementation

The current section includes a complete evaluation of the project implementation, including the analysis of the methodology, technical results and dissemination activities.

5.3.1. Overall view of the project implementation

This subchapter provides information on the adequacy of the methodology applied to conduct the activities scheduled within the project, as well as the evaluation of the results achieved on the basis of the indicators of progress included in the grant agreement signed by the consortium.

Evaluation of the methodology: the methodology applied to conduct the activities was adapted to each of the actions conducted. Table 52 includes information on the success and failures identified in relevant actions.

Table 53. Analysis of the methodology applied

Action	Methodology	Successful aspects	Failure
A1	Information gathering	Large quantity of data	- Time consuming
	Questionnaires	Reliable results	- Time consuming / Need of direct phone calls
A2	Information gathering	Large quantity of data	- Time consuming
A3	Information gathering	Large quantity of data	- Time consuming
	In depth Database analysis using indicators of quality	Big quality of the data obtained. Cost effective methodology	- Need personnel with long experience in REACH regulation and effectiveness testing
A4	Questionnaires + phone calls	Reliable results	- Time consuming / Need of direct phone calls
B1	Information gathering	Large quantity of data	- Very Time consuming due to the need of analysing more than 100 reports - Need personnel with long experience in Personal protective equipment certification
B2	Chamber assembly	Very clear idea of the most design and functionalities of the chamber	- Need of more resources than initially scheduled - Need personnel with long experience in aerosol science to select proper materials and configurations

Action	Methodology	Successful aspects	Failure
B3	Aerosol generation and measurement	Cost effective considering the need of generate high concentrations of ENMs	- Need personnel with experience on the generation of airborne Nanomaterials from liquid solutions
	Evaluation of the effectiveness of personal protective equipment and ventilation systems	High accuracy of the data generated in the nanoaerosol exposure chamber prototyope	- Very time consuming due to the need of conduct more than 75 tests. - Need personnel with wide experience in aerosol measurement
B4	Development of the RMM library using visual basis and excel on-line app	Cost effective solutions: very dynamic programing language and easy to implement, limiting the amount of resources incurred	- Requires knowledge on the programming language to introduce changes in the RMM library - Time consuming in the design stage of the relational database
B5	Measurement campaign and use of predictive models	Non published data generated. New information on the concentration of ENMs available for risk assessment	- Requires knowledge and equipment to perform quantitative measurements - Time consuming in the due to the need for analysis a big amount of data.
B6	Use of adobe in design to develop the multimedia guideline	Cost effective solution to develop powerful designs in pdf, including embedded videos and interactive menus.	- Requires an external contractor due to the high expertise needed.
B7	Face to face activities	Higher interaction with stakeholders	- Time consuming
E4	Networking activities in conferences and project meeting	Higher interest of people approached	- Time consuming considering travels and meeting arrangements

Analysis of results: the results to date are in line with the indicators of progress and expected results included in the proposal. The following table depicts the status of the project concerning the results and progress indicators:

Table 48. Analysis of the results

Act.	Foreseen in the revised proposal	Achieved	Evaluation
A1	A list of representative NMs	Yes	A list of 15 ENMs were selected, including carbon based ENMs, metals, inorganic metal oxides and natural ENMs
A2	Base set of information needed for safety assessment and risk management of NMs	Yes	We have selected information on the operative conditions and RMMs used at industrial level
A3	Compendium of datasheets containing reliable values on the protection efficiency of PPE and engineering controls	Yes	We have developed several datasheets including data on the effectiveness of the types of RMMs initially defined
A4	Complete description of the specification and functionalities of the test chamber	Yes	The chamber and associated equipment was designed to allow the evaluation of the parameters defined in the action
B1	One detailed protocol for each RMM, as well as a complete report on the pros and contras of the standards evaluated	Yes	A total of 10 protocols have been developed and critically assessed, including 3 for respiratory protection, 3 for protective clothing, 2 for engineering controls (LEVs) and another 2 for administrative controls
B2	Fully operative testing chamber	Yes	A fully operative and validated testing chamber was finally achieved in May 2014. New Improvements available.
B3	A complete description of the experimental set up	Yes	A complete description of the experimental set up is available on deliverable DB3a.
B3	A complete report for each risk management measure	Yes	All the RMMs initially selected were tested following the experimental set up developed. The result were validated, obtaining correlations higher than 95 % for personal protective equipment. For LEV systems, correlations between 91 and 93 % are reported.

Act.	Foreseen in the revised proposal	Achieved	Evaluation
B4	A complete library of efficient risks management measures	Yes	A Library of Risk management measures including Personal protective equipment (PPE) and engineering controls have been designed, being available in the project web site.
B5	A catalogue of at least 10 validated workplace controls suitable for the control and mitigation of exposure and release	Yes	To date, 4 controls have been validated at industrial level, including one type of respirators, butyl gloves, Tyvek type protective suits, and canopy hoods.
B6	A complete guidance on the required measures and controls for mitigating and control the risk posed by ENMs	Yes	The structure and contents of the guide were defined last December 2014. The guide was drafted according with the responsibilities and contents decided by the consortium
C1 to C5	Monitoring of the impact on the project, including socio-economic impact, promotion of REACH fulfilment and generation of data on ENMs properties	Yes	The monitoring activities were conducted with success, including the use of dedicated questionnaires, evaluation of monitoring indicators based on extensive literature reviews and interaction with key stakeholders.
E1 to E4	Management of the project actions	Yes	The management activities, including reporting, financial management and monitoring were completed with success.
Ds	Dissemination actions	Yes	The list of actions scheduled to disseminate the project were completed, including the development of the web site and dissemination materials and the communication of the outcomes in relevant conferences and events.

The results of the project are completely available and accessible on line within the web site, an under the section “results”. The RMM library and guidance on recommended measured are being used by a large set of companies, which implies, a better implementation of REACH in the near future.

I**ndicate effectiveness of the dissemination:** the dissemination activities conducted have been focused on the dissemination of the activities conducted within the project, as well as the presentation of the results in relevant conference and events. For the purposes of evaluation of NanoRISK dissemination activities quantitative indicators and associated metrics have been set up. These targets are reviewed by the dissemination leader periodically. The progress is depicted in the table 54.

Table 54. Analysis of the dissemination actions effectiveness

Metric	Target Number	Status
Number of presentations given at externally-organized scientific and technological conferences	5	9
Number of dissemination events (co)organized by NanoRISK	3	3
Number of training workshops organized by NanoRISK	2	4
Number of attendees’ total for training workshops organized	50	96
Number of brochures distributed	50 per partner	>100
Potential readership of project newsletter via social media	20,000 per newsletter	20,000 per newsletter
Number of external nanotechnology news websites disseminating project newsletter	20	5
Total instances of lobbying at Public Authorities, International Organization and Standardization Bodies	2	1

These metrics will allow for the effectiveness of project dissemination efforts to be examined and reported upon in the Final Report for the project.

5.4. Analysis of long- term benefits

The rising production and use of materials and substances at the nanometer scale is generating both environmental and human health impacts, which are increasing the probability of human diseases and environmental pollution, with a special concern for water, soil and atmosphere as key compartments where organisms are likely to be exposed to in different ways.

REACH Regulation is the main legal instrument to protect the environment and human health from risk posed by chemicals in Europe, including those at nanoscale. Under REACH, manufacturers, importers and downstream users have to ensure that the substances they manufacture, place on the market or use, do not adversely affect human health or the environment, covering all the life cycle of the substance.

Activities undertaken on NanoRISK project for supporting the implementation of REACH will improve the protection of environment and human health through several aspects:

1. Environmental benefits

The main objective of the NanoRISK project is the improvement on the implementation of REACH Regulation for producers, importers and users of nanomaterials with the main goal of controlling and reducing health and environmental impacts by means of recompiling and testing the needed controls to ensure a high level of protection for human health and the environment across the ENMs life cycle.

Moreover, the enhancement of **knowledge** regarding information on **physicochemical, toxicological and ecotoxicological properties** of materials and substances at the nanometer scale, as well as **exposure, use and risk management measures**, will provide new data to support the risk assessment of nanomaterials, thus assuring a safe use and thus reducing environmental and human health potential impacts.

Once known the effectiveness of the risk management measures, the data obtained from the scientific literature and those obtained by real measurement will be compared and analysed, in order to select the **most efficient exposure control techniques**, ensuring that its implementation will enable a reduction of the unintentional emissions by 5 % on the basis of likely exposure scenarios in the real work place environment as well as typical source characteristics.

2. Long-term benefits and sustainability

As long term results from the NanoRISK project, it is estimated an overall reduction of unintentional emissions from the production process to the main environmental compartments, air, water and soil, by at least 5% for the exposure scenarios characterized during the project, depending on the specific measures implemented in each one.

In this regard, this reduction will be achieved through the **characterization and implementation** of **risk management measured and procedures** in the main exposure scenarios. To this end, the project is working on the following aspects:

- Information gathering on the on the effectiveness of existing controls to prevent and control the release of nanomaterials under different operative conditions.
- Definition of protection factors for each of the risks management measures, including mechanism of local exhaustive ventilation (LEV), full-face respirators, dusk mask respirators, personal eye-protection, protective clothing or protective gloves.
- In situ study of the effectiveness of the risk controls implemented in the selected case studies. To this end, expertise staff from ITENE characterize the variations on the levels of airborne nanoparticles under different ventilation conditions by means of appropriate real time measurement devices. Secondly, the PPE employed are tested by ITENE and VITO in terms of efficiency of protection against direct/indirect contact with ENPs, tests focused on the performance requirements (e.g. resistance to penetration, transmittance, filtering, etc.) of the equipment.

On the other hand, the development of multifunctional toolkit will be a starting point for the further creation of a **network platform** to close the knowledge gaps about nanomaterials impact and to develop and implement, in collaboration with scientific committees, EU policy makers and international researchers, methods of mitigation, assessment and control of risk that will mitigate risks posed by nanomaterials to the human and environmental safety.

3. Replicability, demonstration, transferability, cooperation

One of the aims of the project is to transfer the outcomes to the end users and relevant stakeholders by mean of interactive training sessions, where the attendants will have opportunity for learning how to use the RMMs. For this purpose, the NanoRISK project will support the development of standard approaches for risk assessment, enabling the comparison of results between researches and improving the reproducibility of the tests, both relevant aspects to accelerate the regulatory process.

Likewise, the **library of proven, technically feasible and economically viable** organizational measures, PPE and engineering techniques to control and reduce the risk of exposure to ENMs will be accessible to all the stakeholders and to the general public. For the completion of the library, the RMMs will have been scaled up and tested at stakeholders' facilities, to consider both the mitigation of the risk and the economical sustainability of the measures defined.

4. Best Practice lessons

The evaluation of the emissions' reduction as a result of the implementation of the selected RMMs by industrial partners and voluntary case studies will be the core of the monitoring plan to quantify the reduction of emissions from the productions sites.

The best practices implementation during the handling and use of nanomaterials will be monitored through the variations of Risk Characterization Ratios (RCR), estimating the levels of exposure and release on the basis of the efficiency of the RMMs selected, as well as in view of the best practices implemented. To evaluate the improvement, the following indicators have been considered:

- Variation > 0.5: High improvement
- 0.5 > Variation > 0.25: Medium Improvement
- 0.25 > Variation > 0.1: Low Improvement
- 0.1 > Variation > 0.05: No improvement detected

The RCR is a measure of the safety of a defined exposure scenario and its characterization is mandatory under the framework of REACH. This RCR is dependent of the concentration of the substance and the predicted no effect level in the environment (PNEC) on human health (DNEL) of the substance.

5. Innovation and demonstration value

Since the project will explore at the same time legal and policy issues, as well as scientific and technical issues, the outcomes of the project will increase the knowledge about the risk to the human health and the environment due to the use of NMs in the industry, supporting the regulatory activities with scientific data to establish new legal requirements.

Research activities are ongoing under the Research Framework Programmes and the Joint Research Centre, 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.

The project will also add value to the International Standardization since it will work on the development of methods for testing RMM against NMs by evaluating the adequacy of the published harmonized Standards from ISO, CEN, BSI and ASTM, and adapting them to the specific NM properties.

6. Job creation potential

The job creation potential of the project is anticipated due to the promotion of the use of ENMs in the nanocomposite sector. The increase in the investment on nanotechnology is directly related with a bigger number of human resources, being estimated an increase in the number of employees at European level of at least 6 persons per company, meaning 10.080 new jobs.

7. Long term indicators of the project success

Concerning long term results, the improvement on the REACH implementation will enable the mitigation of risk posed by chemicals in general, reducing the health and environmental impacts of substances at nanoscale due to a better knowledge on the authorized uses of the target ENMs and new data to support the selection of non-dangerous ENMs.

Probably the most remarkable indicator will be the abovementioned overall reduction of at least a 5 % of unintentional emissions to air, water and / or soil from production processes, reduction based on the characterization and implementation of the proven RMMs. However, another important indicator is the use and completion of the network platform to cover the gaps on the impact of nanomaterials in biological and environmental systems.