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Evaluación de la efectividad de medios de protección individual y colectiva para el control de los riesgos de nanomateriales

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NanoRISK is funded by DG Environment under the LIFE+ Programme Environmental Policy and Governance (LIFE12 ENV/ES/000178)

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1. Visión general del proyecto

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1. Visión general del proyecto

❑ Motivación del proyecto / concepto

Los objetivos y tareas planteadas en el marco del proyecto giran en torno a la necesidad de dotar a la industria de **herramientas de base tecnológica para la caracterización, evaluación y gestión de los potenciales efectos adversos en la salud humana y el medio ambiente de los nanomateriales** (NMs).

La producción y uso de NMs ha experimentado un crecimiento exponencial debido al amplio abanico de aplicaciones de la nanotecnología, incluyendo la producción de materiales y productos acabados con propiedades de alto valor añadido, incluyendo resistencia mecánica, conductividad, o efectos bactericidas, entre otras propiedades.

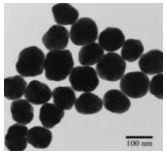
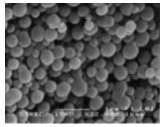
Este aspecto contrasta sin embargo con un **alto grado de incertidumbre relativo a la toxicidad e impacto ambiental de los nuevos desarrollos basados en la nanotecnología**, aspecto que ha suscitado la aparición de nuevos requisitos legales y ha limitado a su vez la inversión por parte de pequeñas y medianas empresas, disminuyendo por tanto las oportunidades de negocio y la capacidad de innovación del tejido industria.

1. Visión general del proyecto

❑ Origin of the Idea

El proyecto surge de la necesidad de promover el control de los potenciales riesgos de los NMs en vista del creciente aumento de los niveles de producción de nanomateriales y nanoproductos, y la incertidumbre actual relativa a sus propiedades toxicológicas y ecotoxicologicas.

Application de la nanotecnologia (Nanomateriales)	Nuevos productos de alto valor añadido (Nano-Composites)
MWCNTs / SWCNTs	Conductividad
Metales y Oxidos	Efectos bactericidas
Carbonatos / Silices	Propiedades mecánicas
Arcillas	Propiedades barrera

Barreras: Salud laboral e impacto ambiental

- ❑ Diversos estudios indican que la exposición a determinados NMs pueden ocasionar efectos agudos y/o crónicos en la salud humana y el medio ambiente
- ❑ Un número muy limitado de estudios aportan información sobre la efectividad de los medios de protección frente a la exposición a partículas en el rango del nanómetro

- **Falta de información relativa a los niveles de exposición y medios de protección**
- **Aumento del las disposiciones legales aplicable: REACH / CLP / Cosméticos**
- **Falta de datos accesibles relativos al perfil toxicológico de los NMs**

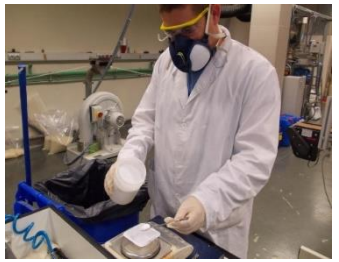
1. Visión general del proyecto

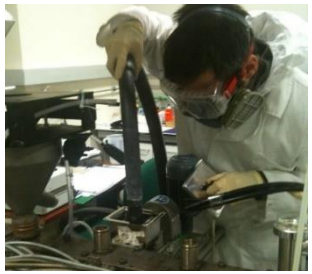
❑ Objetivos del Proyecto

De forma global, el proyecto pretende llevar a cabo la identificación y validación de equipos de protección individual (EPIs), sistemas de ventilación (LEV) y medios de contención para su uso como **medios de protección frente a aquellos nanomateriales de mayor aplicación en la industria de los nanocomposites**, incluyendo aplicaciones en envases y embalaje, automoción, construcción y electrónica.

Para tal fin, las acciones del Proyecto incluyen:

- El desarrollo de un **prototipo de cámara de ensayos** para la evaluación del comportamiento aerodinámico de nanoaerosoles y la evaluación de la eficacia de medios de protección
- El desarrollo de **protocolos estándar (SOPs)** para la evaluación de la eficacia de equipos de protección individual (EPIs) y sistemas de ventilación (LEVs)
- La **determinación experimental** de la efectividad de equipos de protección respiratoria, guantes, ropa, y sistemas de ventilación
- La **selección de medios de protección eficaces y el desarrollo de herramientas para promover su uso**, incluyendo la RMM library y la guía de uso de EPIs (cooperación con INSHT).



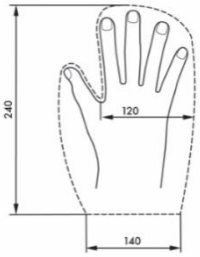


1. Visión general del proyecto

Objetivos del Proyecto

De acuerdo con la memoria de solicitud del Proyecto, y considerando las prioridades del programa LIFE, los objetivos especificos incluyen :

- Construcción de una **librería interactiva en formato Microsoft Excel** para la consulta de información relativa a la eficacia de medios de protección frente a distintos tipos de nanomateriales y operaciones de manipulación "procesos – PROCs": RMM Library
- Desarrollo y validación de un prototipo de cámara (**Nanoaerosol Test Chamber**) para la evaluación de efectividad de equipos de protección individual y colectiva frente a aerosoles en rango nanométrico en condiciones de ensayo reproducibles.
- Desarrollo de una **guía multimedia para la selección de medios de protección** adecuados frente a nanomateriales



- Mejorar la base de conocimiento relativa a los **parámetros que determinan la exposición a NMs** en el lugar de trabajo.
- Mejorar la base de conocimientos actual para **la estimación de cantidad de NMs liberada al medio ambiente** vía efluentes industriales.
- Analizar la **adecuación de las normas internacionales** (ISO/ASTM) para la certificación de la efectiviad de medios de protección.
- Definir los **escenarios habituales de exposición a NMs** en el lugar de trabajo, incluyendo condiciones operativas, niveles de exposición, niveles de exposición y medios de protección.

1. Visión general del proyecto

Objetivos del Proyecto

- Promover el desarrollo de **herramientas para la caracterización del peligro y potencial de exposición** con objeto de apoyar a la industria en el procesos de evaluación de la seguridad química en el context legal actual, principalmente REACH.
- Comunicación de los resultados del proyecto a través de los medios definidos por el programa de financiación LIFE e incluyendo la organización de talleres prácticos, seminarios y conferencias
- Promover el la **implantación del reglamento REACH** como herramienta para el control y gestión de los potenciales riesgos de los nanomateriales.

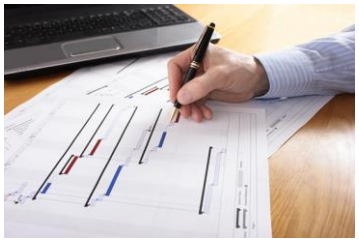
La consecución de los objetivos definidos permitirán alcanzar un **mayor grado de protección de la salud humana y el medio ambiente** frente a los potenciales riesgos de los NMs, considerando como aspecto clave la generación de nuevos datos sobre usos, exposición y efectividad de medios de protección, todos ellos clave para completar la evaluación de la seguridad química y la caracterización del riesgo en el marco de REACH.

1. Visión general del proyecto

Actividades principales

El proyecto se divide en 5 tipos de acciones, dos de ellas de **carácter científico-técnico**, una acción dedicada a la **monitorización** del impacto de las acciones del proyecto, una acción dedicada a la **comunicación y difusión** y finalmente una acción dedicada a la **gestión administrativa y técnica** del proyecto

- **A. Preparación**
- **B. Implementación**
- C. Monitorización
- **D. Difusión**
- E. Gestión



A

A.1. Selección y descripción de NMs
A.2. Recopilación de Información relativa a las condiciones de Uso, MGRs y exposición
A.3. Recopilación de Información relativa a la eficacia de las MGRs
A4. Especificaciones técnicas del prototipo de cámara de ensayo

B

B.1. Evaluación crítica de los protocolos ISO/ASTM para la evaluación de EPIs
B.2. Diseño y construcción del prototipo
B.3. Desarrollo y validación de protocolos de ensayo en la cámara de ensayos
B.4. Desarrollo de la Librería virtual de medidas de gestión del riesgo
B.5. Escalado Industrial
B.6. Guia relativa a las MGRs a aplicar para el control del riesgo
B.7. Actividades de formación

C

C.1. Definición de la Situación de Partida
C.2. Evaluación cuantitativa y monitorización de factores de protección en condiciones controladas
C.3. Evaluación de las mejoras alcanzadas a escala indsutrial
C.4. Promoción de la implantación de REACH
C.5. Evaluación del impacto socio-económico

D

- Web Site
- Brochure – Folletos
- Roll up.
- Newsletters
- Factsheets
- Videos

E

- Coordinación
- Networking
- Justificación

Business, Science & Innovation

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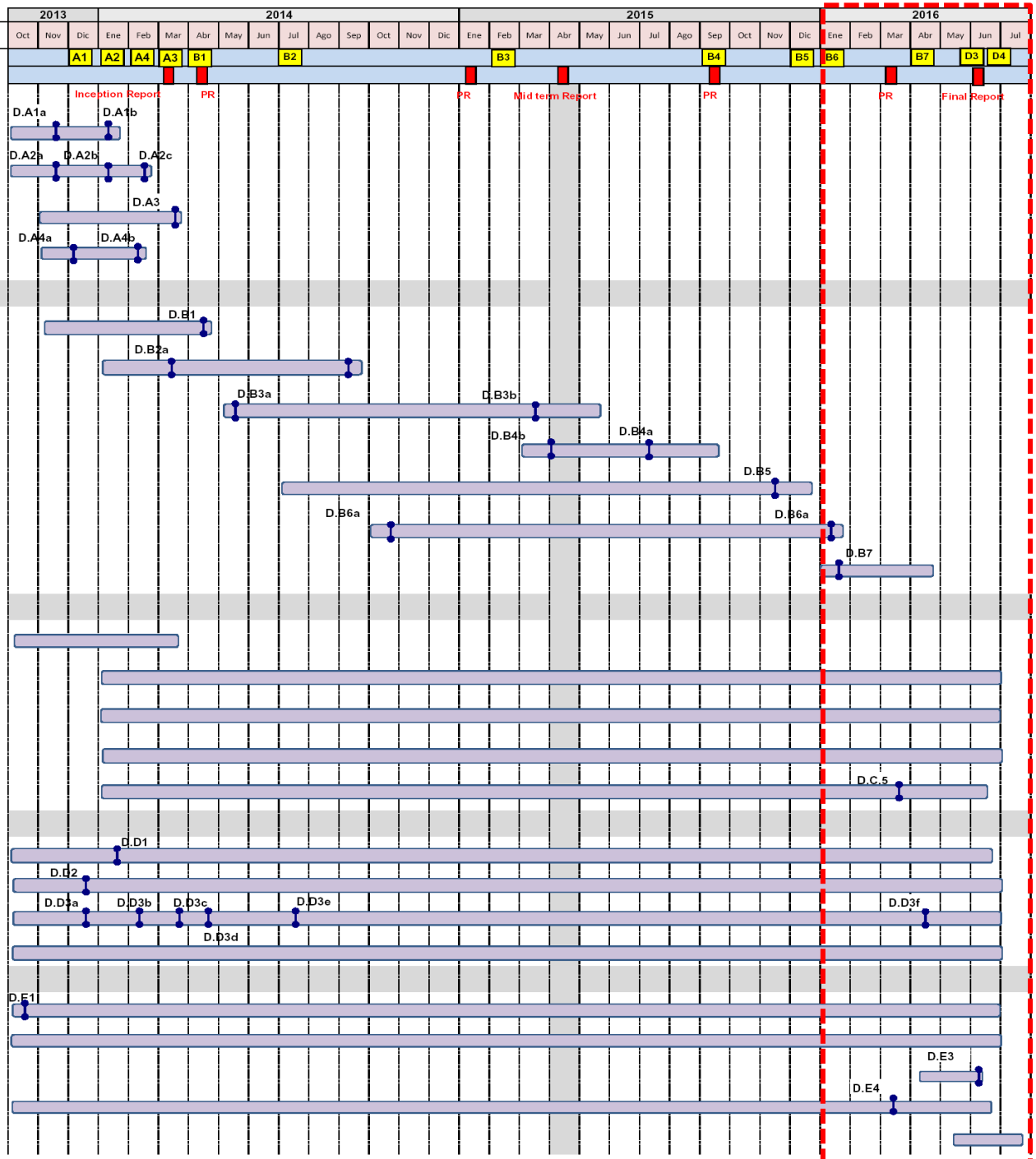
Action Number	Name of the Action
Milestone line	
Reports line	
A. Preparatory actions	
A.1	Selection of representative Nanomaterials
A.2	Information gathering on the conditions of use and risk management measures across nanomaterials life cycle
A.3	Compilation of data regarding the efficiency of risk management measures for occupational and environmental exposures
A.4	Identification of the test chamber prototype requirements for standardized testing
B. Implementation Actions	
B.1	Compilation and critical evaluation of the published standards for determining the protection efficiency
B.2	Design and construction of the test chamber prototype for demonstration activities
B.3	Development of the testing activities according to the selected approaches
B.4	Development of a Risk Management Measures (RMM) library tool
B.5	Scaling up to industrial case studies
B.6	Guidance on the required measures and controls for mitigating and control the risk posed by the target nanomaterials during its entire life cycle
B.7	Training activities for end users and stakeholders
C. Monitoring the Impac of the project actions	
C.1	Definition of the starting situation – baseline
C.2	Quantitative Assessment and monitoring of the protection factors achieved under controlled conditions
C.3	Evaluation of the improvements achieved in industrial conditions
C.4	Promotion of REACH fulfilment by implementing the LIFE nanoRISK project
C.5	Assessment of the socio-economic impact of the project actions
D. Communication and dissemination actions:	
D.1	Communication and dissemination management
D.2	Preparing and keeping the project website
D.3	Elaboration of informative material
D.4	Dissemination of results
E. Project Management and Monitoring	
E.1	Project management
E.2	Project monitoring
E.3	Financial Audit
E.4	Networking with other projects
E.5	After Life+ Communication plan



1. Visión general del proyecto

❑ Consorcio

▸ Coordinación

Instituto tecnológico del embalaje, transporte y Logística (ITENE)

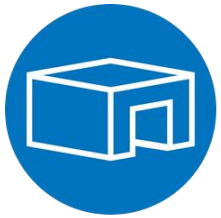
▸ Asociados:

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

1. Visión general del proyecto

Resultados esperados

- Prototipo funcional de **cámara de ensayo** para la evaluación de la eficacia de las medidas de prevención y control del riesgo (Nanoaerosol Testing Chamber).
- Librería de medidas de prevención y control del riesgo eficaces y técnicamente viables (RMM library).
- Conjunto de **10 protocolos de ensayo estándar** (SOPs) para la evaluación de la eficacia de medidas de prevención y control del riesgo, incluyendo: equipos de protección respiratoria, guantes de protección química, ropa de protección, y procedimientos administrativos.
- **Guía multimedia** para la selección de equipos de protección individual (EPIs), sistemas de ventilación (LEV) y tecnologías de tratamiento de efluentes eficaces frente a NMs.
- **Criterios de selección** de medios de protección, incluyendo balances cuantitativos de costes de implementación y eficacia frente a partículas y aerosoles de en rango nanométrico.
- Descripción completa de las **condiciones de trabajo (escenarios) en los procesos de síntesis y procesado de nanomateriales** en los sectores de referencia del proyecto: packaging, automoción, construcción y energía.



1. Visión general del proyecto

Entregables clave (acceso público vía web)

Entregables	Act.	Descripción	Publicación
Report on representative NMs	A1	Justification of the NMs selected, including market data, hazard and exposure profile.	20/11/2013
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
Activities and processes within the NMs life cycle	A2	Description of critical activities and processes across relevant stages in the life cycle	28/11/2013
Report on the OC of the RMM 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
A set of representative data on exposure levels to airborne NPs 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 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
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	Detailed analysis of the performance of selected RMMs, including total inward leakage (TIL) and average penetration factor (APF) for respirators, permeation for dermal protection, capture efficiency for ventilation, and splash protection against ENMs in solution	27/09/2015
Report on the structure, contents and functionalities of the guidance	B6	Definition of the scope of the guidance, main chapters and responsibilities, design, structure and multimedia options	15/10/2014
Report on the reduction in exposure and reléase in industrial case studies	B5	Report with detailed instructions and procedures to implement PPE and LEV to reduce and control the exposure in industrial settings	15/03/2016
Project Leaflet (x2)	D3	3-fold brochure for dissemination purposes	20/12/2013
Project Factsheet (x2)	D3	Detailed description of the project, including concept, objectives, expected results, and work plan	14/02/2014
Project Newsletter (x3)	D3	Newsletter published containing relevant results and progress of the project	20/02/2016
Notice Boards	D3	Roll-up of the project, including an overview of the main objectives and results	30/04/2014
Informative video downloadable	D3	First version of the video presenting the concept, activities and impact of the Project	29/01/2016
RMM Library Tool	B4	Edition and publication of the Interactive Library on PPE, EC and treatment tech.	15/02/2016
Final versión of the guidance	B6	Multimedia version of the guidance	15/03/2016
Trainning manuals	B7	Trainning manuals on the use of PPE and LEV against NMs	15/04/16

2. Acciones desarrolladas en el marco del proyecto

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2. Acciones desarrolladas en el marco del proyecto

❑ Avances del Proyecto (M1 – M30)

Hasta las fecha, las principales tareas deasarrolladas incluyen:

- Caracterización y descripción de las principales actividades y procesos vinculados a la producción y/o uso de NMs en el sector de los nanocomposites, y especialmente aquellos con un mayor potencial de exposición: 12 escenarios de exposición (GES) y 28 actividades que pueden dar origen a una potencial exposición en el lugar de trabajo identificadas (A1-A2)

- Descripción de los tipos específicos de EPIs, sistemas de ventilación (LEV) y procedimientos administrativos usados habitualmente para prevención y control de la exposición en el lugar de trabajo (A3)

- Definición de los principales parámetros a considerar en la evaluación de la eficacia de medios de protección, incluyendo **fuga hacia el interior y fuga total hacia el interior** en equipos de protección respiratoria, **permeacion** en guantes de protección, **resistencia a la penetración** por pulverización de líquidos o penetración de aerosoles de NMs en ropa de protección y filtros, **eficacia de captura** en sistemas LEV (A3)

2. Acciones desarrolladas en el marco del proyecto

❑ Avances del Proyecto (M1 - M30)

- Diseño y desarrollo de la cámara de ensayo de nanoaerosles en base a los requisites de ensayo y parámetros de eficacia a determinar para la certificación / validación de EPIs y sistemas LEVs (A4 – B2)

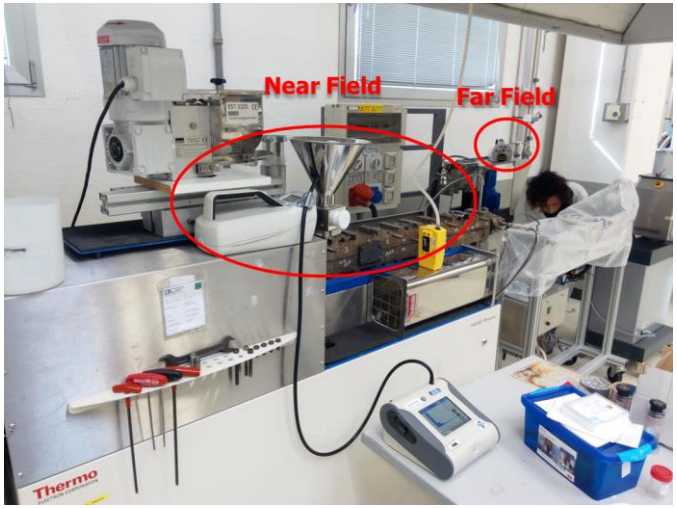
- Diseño de métodos de ensayo y optimización de la instrumentación para la evaluación de la efectividad de EPR, guantes, ropa, y sistemas de ventilación/contención (B3)

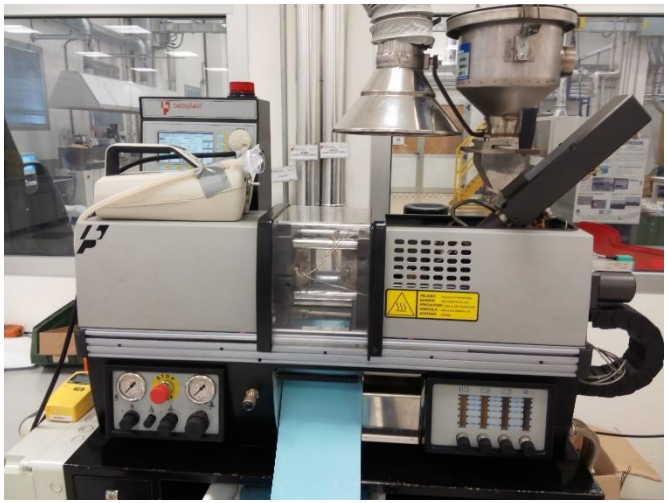
- Validación de protocolos y Evaluación experimental mediante ensayos dinámicos y estáticos en condiciones controladas (B3)

- Diseño y desarrollo de la librería multimedia (RMM Library) de eficacia de medios de protección (B4)

2. Acciones desarrolladas en el marco del proyecto

- Evaluación de la eficacia de medios de protección y niveles de exposición en procesos industriales: casos de estudio en Avanzare y CRP (B5)





2. Acciones desarrolladas en el marco del proyecto

- Diseño y desarrollo de la primera versión de la guía de uso de medios de protección para el control de los riesgos de los NMs (B6)

Contents

Parameter	Short description	Relevance to NMs
Breathability	Allowing the wearer to breathe easier is a key parameter to encourage the use of RPE	This is not a nano-specific parameter but should be considered especially for disposable mask when high levels of exposure are expected
Tightness of Strap	The fitting of the RPE is highly dependent of the tightness of the strap and the wearer behaviour	Check the tightness of all strap connections before wearing the respirator should me always considered.
Fitting	The fitting factor determines the real level of protection of common tight-fitting RPE.	The total inward leakage derived from a poor fitting of the respirators has been demonstrated to be a major cause of risk when using NMs. A proper design is hence a key research priority.
Sweating	In hot and humid conditions, wearing RPE increases heat stress, sweating and discomfort.	As in the case of bulk chemicals, standard precautions shall be considered to prevent sweat, which can cause discomfort
Ease of Decontamination	Reusable equipment should normally be thoroughly decontaminated and cleaned.	In the case of nanomaterials, special considerations shall be considered to clean the RPE used during operation. Correct Donning and Doffing Procedures are of especial relevance.

A key parameter when selecting a RPE is the **fitting factor**, identified in the table above, an defined as a means of assessing how well a respirator seals to a face. This fitting factor in measured to evaluate the effectiveness of the respirator, and depends mostly the anthropometric parameters of the face of the wearer. Research has shown that fit testing is necessary to assure that respirators are properly worn and provide a preliminary level of expected protection. It is not yet possible, however, to identify of predict with high precision which combination of facial features and respirator design characteristics will assure both initial and long-term fit.

To cope with this situation, PPE manufactures use anthropometrics studies to improve the seal of the RPE to the face. The anthropometric parameters are normally computed and parametrized by commercial computer assisted design (CAD) software. To date, there are software solutions able to compute thousands of data to improve the fitting factor of the RPE.

The use of the finite element method, widely used to model the behaviour of gases is recommended. These models allow researchers to prepare 3D representations of actual heads and half and full facepiece respirator masks. These studies has enabled the simulation of the **total inward leakage** (TIL) under relevant conditions of use and considering the relationships between respirator fit, respirator discomfort, and the geometry of faces (figure 2).

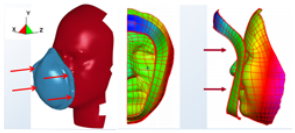


Fig.2. Simulation of the gas flow (Souce: NIOSH/NPPTL Public Meeting)

The main purpose of these studies is to enhance respirator fit and sizing procedures by improved knowledge of the relationship between human and respirator features and respirator effectiveness. A similar approach is highly recommended to evaluate the effectiveness of the face seal for nanoparticles.

2. Acciones desarrolladas en el marco del proyecto

- Estimación de los niveles de concentración de NMs en matrices ambientales de interés mediante modelización de procesos y determinación de niveles medios de exposición en base a revisiones bibliográficas (C1)

- Comunicación de los principales resultados del Proyecto a través de la participación en jornadas y la difusión de material grafico (D)

  - Página web del proyecto: www.lifenanorisk.eu
  - Trípticos (EN/ES)
  - Posters / Roll Ups
  - Videos promocionales + webinars
  - Workshops y seminarios: Sevilla / Valencia
  - Presencia en conferencias internacionales
  - Newsletters
  - Participación en redes sociales (twitter, Facebook and LinkedIn)
  - Actividades de networking
  - Publicaciones técnicas / papers

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2. Analysis of the activities completed and results

Target Nanomaterials and uses

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					
Nanoclays	High					
Nanocellulose	Controversial					

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

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2. Analysis of the activities completed and results

Target RMMs – Identified at Industrial level

	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)

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2. Analysis of the activities completed and results

- **Main results**
- NanoRISK Aerosol testing Chamber

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2. Analysis of the activities completed and results

Experimental set up + SOPs development

The experimental set-ups were developed, adapted and refined to comply with the requirements of the 10 SOPs stablished. Moreover, protocols were revisited and when necessary, adapted to the limitations of the experimental tests.

		Score				
Protocol	**RMMs**	**Amount of particles**	**Ref**	**Suitability for low solubility ENMS**	**Flow rates**	**Total**
Determination of inward leakage of NMs	Respiratory protection	10	7	5	5	**27**
Determination of total inward leakage of NMs	Respiratory protection	10	7	5	5	**27**
Determination of particle filter penetration by NMS	Respiratory protection	6,5	7	5	5	**23,5**
Determination of inward leakage of aerosols of NMs into suits	Dermal protection: protective clothes	3	7	5	5	**20**
Determination of resistance to penetration by spraying a liquid solution of ENMs	Dermal protection: protective clothes	3	7	5	5	**20**
Determination of permeation to nanoparticles in gloves	Chemical protective gloves	6,5	7	5	5	**23,5**
Determination of particle filter penetration in local exhaust ventilation	Engineering controls	3	7	5	5	**20**
Determination of fume hood effectiveness	Engineering controls	3	7	5	5	**20**
Determination effectiveness of RMMs during maintenance op.	Administrative controls	3	7	5	5	**20**
Determination effectiveness of RMMs during cleaning operations	Administrative controls	3	7	5	5	**20**

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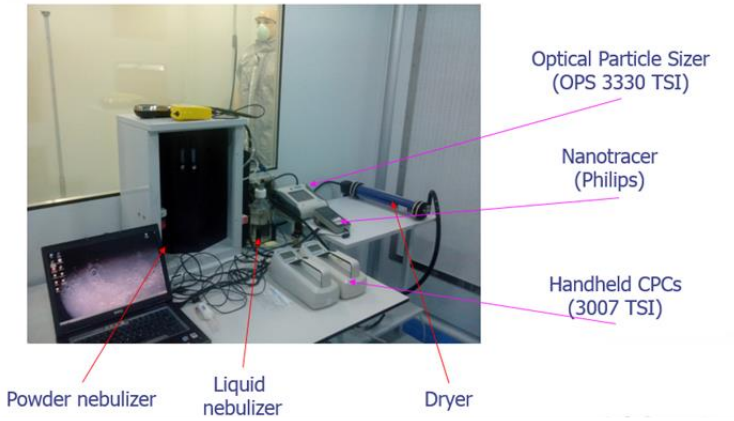
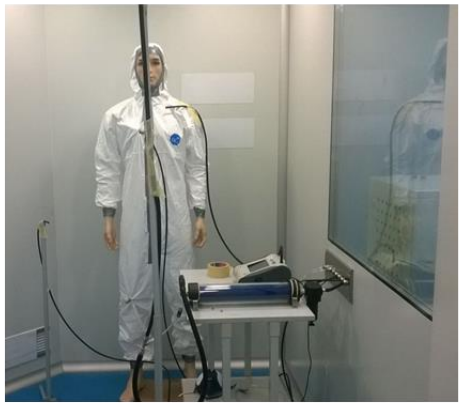
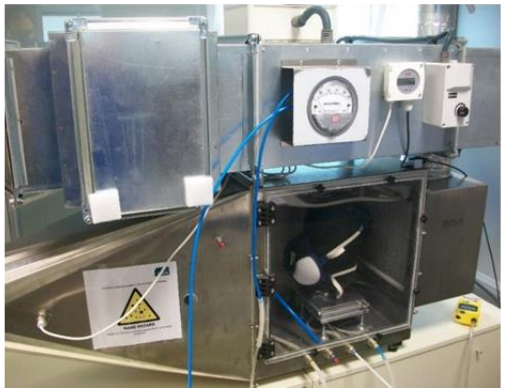
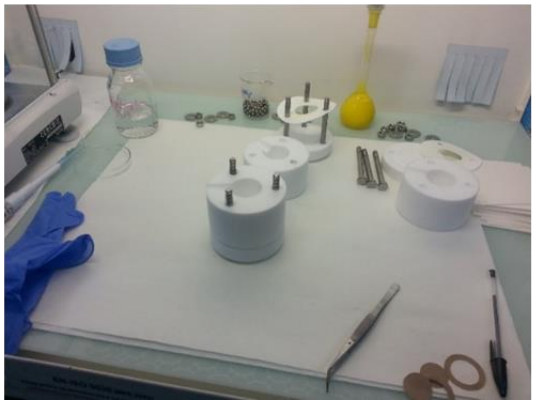
2. Analysis of the activities completed and results

- Experimental activities under controlled conditions completed









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2. Analysis of the activities completed and results

Experimental activities under controlled conditions completed

The results from the test conducted so far suggest that the control of exposure via inhalation is a key priority when dealing with NMs. In this regard, the results showed that Disposable and Half Mask Respirators provided medium performance levels of filtration efficiency against NMs.

The performance levels determined in relevant studies suggest that face seal leakage, and not filter penetration, is a key parameter to be considered when working with NMs.

The results of the evaluation of the effectiveness of chemical protective gloves and clothes showed very low penetration levels, meaning that common measures on the market are effective against NMs.

			Average Protection	
RMMs	Specifications	Performance factors	Static	Simulated
Disposable filtering half mask	Filter type P2L (Medium efficiency)	Protection achieved (reduction of NMs leakage)	79 ± 3 %	69 ± 9 %
	Filter type P3L (High Efficiency)		84 ± 3 %	73 ± 5 %
Unpowered Half mask	Filter type P2L		89 ± 5 %	81 ± 5 %
	Filter type P3L		91 ± 3 %	86 ± 8 %
Unpowered Full face mask	Filter type P2L		93 ± 3 %	90 ± 3 %
	Filter type P3L		95 ± 2 %	92 ± 6 %
Chemical protective gloves	Nitrile	Permeation protection	98 ± 1 %	91 ± 4 %
	Butyl		99 ± 1 %	96 ± 3 %
Body protection	Laboratory Coats / Pants	Protection achieved (reduction of NMs leakage)	80 ± 1 %	70 ± 4 %
	Full Body Suit (Tyvek / Saranex)		98 ± 1 %	89 ± 6 %
	Chemical Splash Suit		91 ± 5 %	85 ± 5 %
Capturing hoods (LEV)	Movable capturing hoods	Capture efficiency	70 + 5 %	64 ± 5 %

Material	Thickness (mm)	Penetration (%)
Non powder Latex	0.15	8.55
Vinyl	0.08	0.010
Non powder Vinyl	0.08	0.013
Nitrile Thin	0.07-0.09	0.040
Nitrile Thick	0.11-0.15	0.006

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2. Analysis of the activities completed and results

RMM Library completed / Guidance on – going

RMM Library Tool

PROPERTIES OF THE ENM

Chemical composition
- ○ Metal Oxides
- ◉ Nanocellulose / Nanoclays
- ○ Carbon-based nanomaterials

Shape
- ◉ 1D: Platelet
- ○ 2D: nanotubes, nanorods, and nanowires
- ○ 3D: spherical

Size Range
- ○ <10 nm
- ◉ 10 - 50 nm
- ○ 50 - 150 nm
- ○ 150 - 300 nm
- ○ > 300 nm

State
- ◉ Liquid dispersion
- ○ Dry / Powder

PROPERTIES OF THE PROCESS

Type of process (more info at Exposure Scenario sheet)

Life Cycle Stage	Exposure Scenario	Use	
Nanoparticles Production	ES 1	NP's synthesis	○
	ES 2	NP's Functionalization	○
Formulation	ES 3	Manufacture of intermediates (blending/mixing)	○
	ES 4	Formulation	○
Industrial Use. Uses of Additives in Nanocomposite Production	ES 5	As component for production of dispersions, pastes and other viscous matrices	○
	ES 6	As component for solid blends and matrices	○
Service Life	ES 7	Industrial use of nanocomposites	○
	ES 8	Professional use of nanocomposites	○
	ES 9	Manteinance/ Cleaning/Sampling	◉

Scale of the Process
- ○ Amount used < 1 kg
- ◉ Amount used > 1 kg <= 100 kg
- ○ Amount used > 100 kg

Enclosure of the Process
- ◉ Open
- ○ Closed

Time of exposure
- ◉ Punctual <=15
- ○ Media >15 min < 1 h
- ○ Continued >=1 h

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2. Analysis of the activities completed and results

Scoping visits completed

	AV	CRP	TS	AL	LATI
Respiratory protection equipment					
Disposable filtering half mask	X	X			
Unpowered Half mask	X	X	X	X	X
Unpowered Full face mask					
Body Protection					
Protective suits (Tyvek type)	X				X
Laboratory coats	X	X	X	X	X
Eye Protection					
Safety goggles (Type D (dust) and C (splash))		X			X
Receiving hoods (LEV Systems)					
Canopy hoods		X			X
Capturing hoods (LEV Systems)					
Fixed Capturing hoods	X		X		
Movable Capturing hoods			X		
Enclosing hoods (LEV Systems)					
Fume cupboard	X		X		
Horizontal / downward laminar flow			X		
Glove box (Low to High)	X	X	X	X	X

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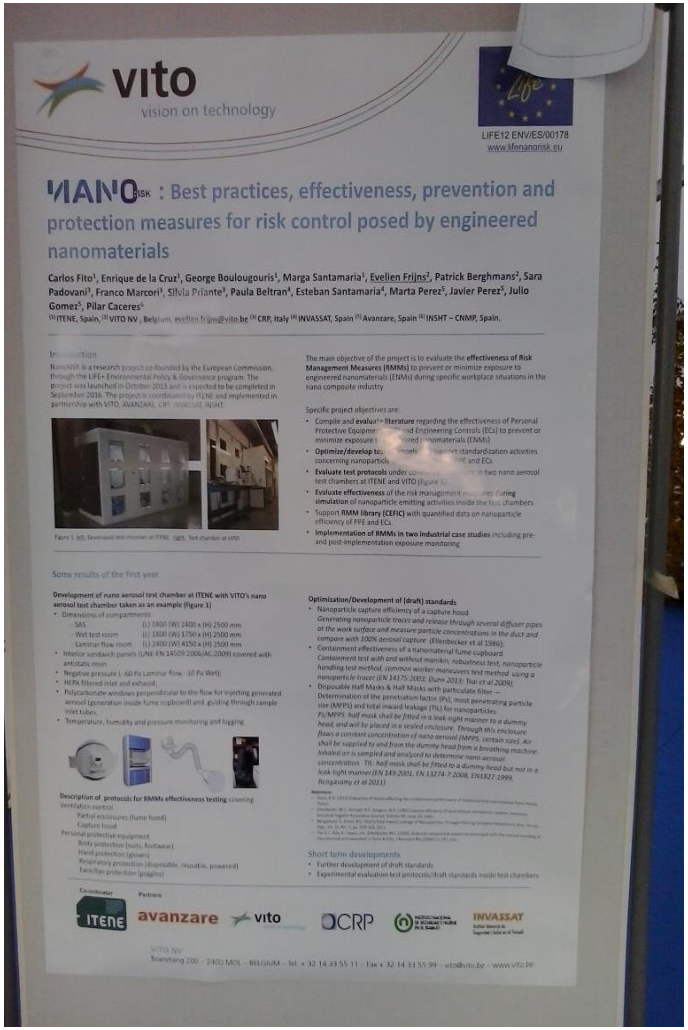
2. Analysis of the activities completed and results

Dissemination



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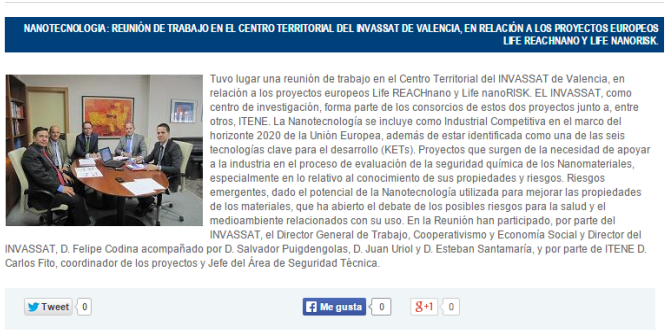
2. Analysis of the activities completed and results

Dissemination actions

Metric	Target Number	Status
Number of presentations given at externally-organized scientific and technological conferences	5	2
Number of dissemination events (co)organized by NanoRISK	3	2
Number of training workshops organized by NanoRISK	2	0
Number of attendees total for training workshops organized	50	>90
Number of brochures distributed	50 per partner	>100
Potential readership of project newsletter via social media	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	2



NANOTECNOLOGIA: REUNIÓN DE TRABAJO EN EL CENTRO TERRITORIAL DEL INVASSAT DE VALENCIA, EN RELACIÓN A LOS PROYECTOS EUROPEOS LIFE REACHNANO Y LIFE NANORISK.

Tuvo lugar una reunión de trabajo en el Centro Territorial del INVASSAT de Valencia, en relación a los proyectos europeos Life REACHnano y Life nanoRISK. EL INVASSAT, como centro de investigación, forma parte de los consorcios de estos dos proyectos junto a, entre otros, ITENE. La Nanotecnología se incluye como Industrial Competitiva en el marco del horizonte 2020 de la Unión Europea, además de estar identificada como una de las seis tecnologías clave para el desarrollo (KETs). Proyectos que surgen de la necesidad de apoyar a la industria en el proceso de evaluación de la seguridad química de los Nanomateriales, especialmente en lo relativo al conocimiento de sus propiedades y riesgos. Riesgos emergentes, dado el potencial de la Nanotecnología utilizada para mejorar las propiedades de los materiales, que ha abierto el debate de los posibles riesgos para la salud y el medioambiente relacionados con su uso. En la Reunión han participado, por parte del INVASSAT, el Director General de Trabajo, Cooperativismo y Economía Social y Director del INVASSAT, D. Felipe Codina acompañado por D. Salvador Puigdengolas, D. Juan Uriol y D. Esteban Santamaría, y por parte de ITENE D. Carlos Fito, coordinador de los proyectos y Jefe del Área de Seguridad Técnica.

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2. Analysis of the activities completed and results

Outcomes vs expected 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.
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 currently populated with data from action B3.
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 is being drafted according with the responsibilities and contents decided by the consortium
C1/ C2	Qualitative data to identify the starting point of the project regarding the REACH implementation	Yes	We have identified the starting point concerning REACH implementation and environmental pollution retrieving data from stakeholders, as well as conducting a complete study of the release of ENMs by meads of a material flow modelling tool developed by ITENE
C3	A complete plan to support the monitoring of the RMM implementation	Yes	A monitoring plan has been drafted by ITENE and presented to 5 SMEs.
D2	Web site publicly available	Yes	Web site available and updated
D3	Dissemination materials available, including leaflets, newsletters, factsheet and Roll Ups	Yes	Dissemination materials available on the web site. Printed copies disseminated by INVASSAT

3. Problems encountered

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3. Problems encountered

❑ Main issues faced

- The management of the activities in the project have been coordinated by the administrative department of ITENE and under the supervision of the project coordinator, Carlos Fito. To date, much of the problems encountered were related with the **declaration of the costs** incurred by partners, especially due to difficulties related with the cost ratios. The doubts in terms of financial reporting have been periodically consulted with the external monitoring team.

- In relation with the partnership, the members of the consortium worked in line with the responsibilities stated in the project management document and the partnership agreement.

  As reported within the inception report, an amendment to the Grant Agreement was requested in 2014 due to the withdrawal of one of the members of the consortium (ISTAS) at the beginning of the project. To solve this constraint, the management committee decided to select two relevant institutions with wide experience in dissemination activities, REACH implementation, risk management measures testing and chemical safety of chemical substances. These two organizations were INSHT and INVASSAT, both public body focused on the promotion of the safety and Health at work in Spain and the whole Valencian region.

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3. Problems encountered

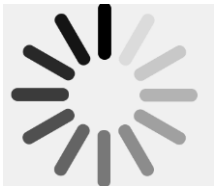
❑ Main issues faced

- Concerning financial issues, it was justified the need for increasing the cost initially allocated to develop and set up the test chamber prototype. The total cost incurred under prototype cost was finally € 38.599, which means an increase of € 18.649 over the original budged allocated under the referred cost category.

- The general progress has been discussed in 4 general assembly meetings organized so far, where all the partners were represented. The first meeting was the kick off meeting, held at the ITENE offices in Valencia on October 23th, 2013.

  A second general meeting was organized to discuss the progress and main achievements during the first 9 month of the project, being held last June 3rd, 2014. A third general meeting was organized by ITENE and INSHT-CNMP last December 3rd, 2014, in Seville (Spain). Our last meeting was organized in May 2015 in Logroño (Spain).

  No other issues shall be noted so far



3. Problems encountered

❑ Main issues faced

Besides the above, other relevant comments are depicted in the following tables.

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
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
			- 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

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Thank you for your attention ¡

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