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

Publicly Available Report

Coordinator of the Project
ITENE

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Executive Summary

The LIFE NanoRISK project is focused on the evaluation of the effectiveness of common risk management measures (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 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

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 present document contains a complete description of the activities conducted within the NanoRISK project, including detailed information of the progress s and results encountered until month 28 in each of the actions conducted.

Much of the technical activites have been completed so far, including the definition of standard operating procedures, the experimental evaluation of respiratory protective equipment, chemical protective gloves and enginnering controls, as well as the implementation of proven control in case studies.

Concering dissemination, the project has been presented in relevant conferences, including the NanoSD 2015, held in Madrid (Spain) and a join wokshop organized in the hedqueaters of the Spanish National Institute for Safety and Health at Work (INSHT) last may 2015.

1. Main Outcomes in 2015

NanoRisk project rises from the need to ensure a high level of protection of human health and the environment from the risks that can be posed by the use of ENMs. Within this context, the scheduled actions and tasks are aimed to define proven Risk Management Measures (RMMs) to prevent or minimize exposure to ENMs during the specific workplace situations of the polymer nanocomposite industry. With this aim, it has been constructed a functional test chamber prototype to support a standardized evaluation of the adequacy of PPE and ECs to protect workers from the risk posed by use of ENMs.

Up to date, some important items of the project have been achieved, as they are reported in the previous Progress report. These are:

- → Selection of representative ENMs by level of production and use in the nanocomposite industry.
- → Information gathering on the conditions of use, risk management measures and exposure data across nanomaterials life cycle
- → Compilation of data regarding the efficiency of Risk Management Measures for occupational and environmental exposures
- → Identification of the test chamber prototype requirements for standardized testing
- → Compilation and critical evaluation of the published standards for determining the protection efficiency
- → Design and construction of the test chamber prototype
- → Development of the testing activities according to the selected approaches

In this document, the activities undertaken and outputs achieved so far (Figure 1) in quantifiable terms since the last update of the project are summarized. A more detailed description of the results is provided in the deliverables developed according with the work plan.

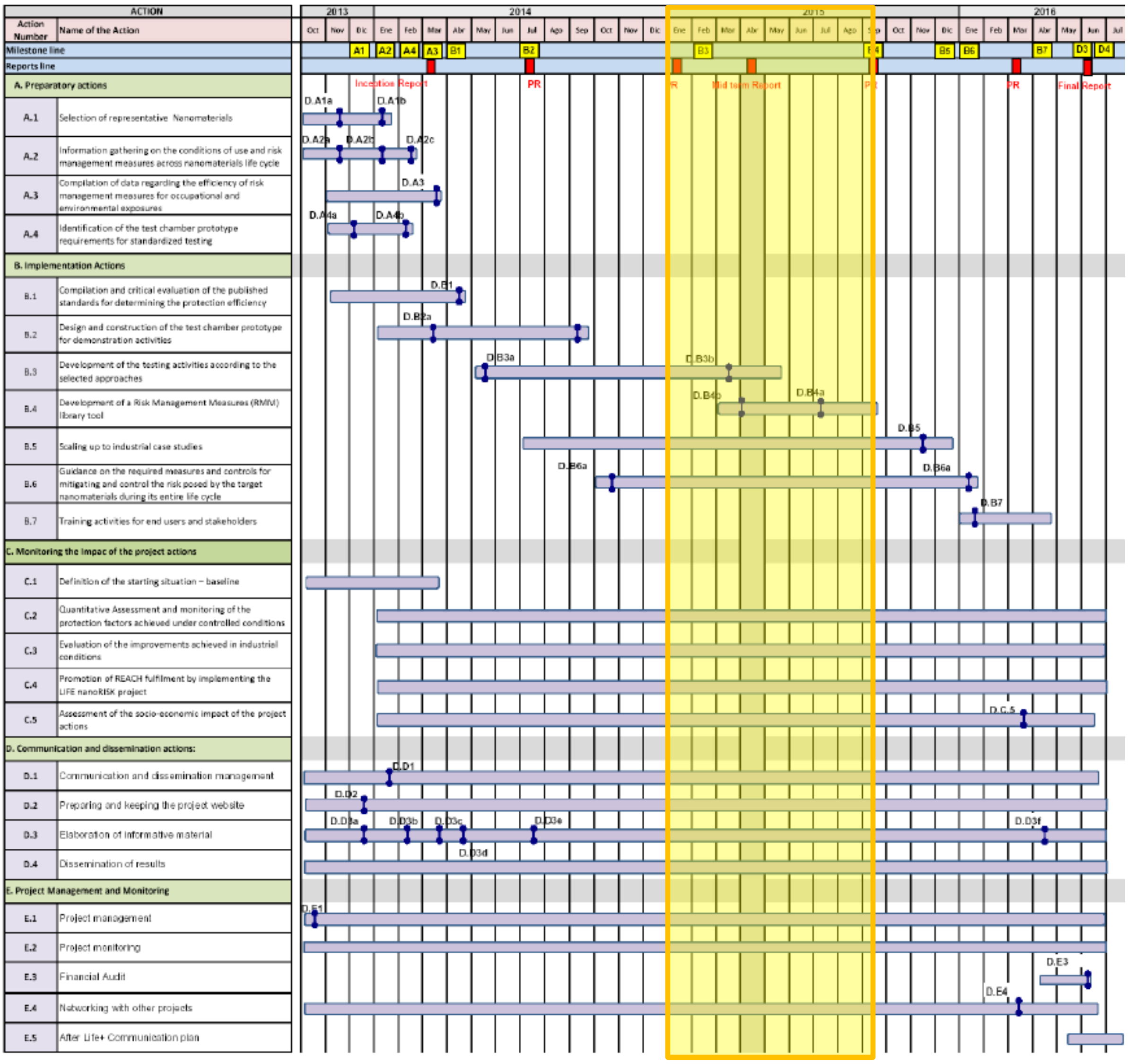


Figure 1: Activities covered within this report from the time Schedule of the Project.

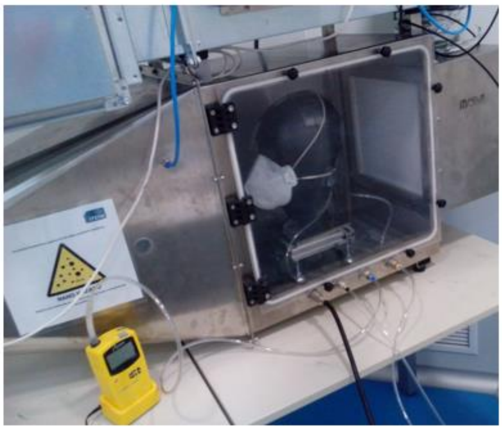
Action B3. Development of the testing activities according to the selected approaches

The main objective of this action is to assess the efficiency of existing RMMs and current testing methodologies against nanomaterials. For this purpose, experimental setups were designed to evaluate the effectiveness of the RRM, building or adapting dedicated instruments.

Some preliminary results are shown in Progress report 1, where experiments for respirators, gloves, suits and fume hoods started. Up-to-date, most of the experiments are finished and efficiencies against particles below 100 nm can be compiled in the following Table 1 to Table 6.

Table 1: Efficiency of RPE against NaCl (up) and SiO2 (bottom) nanoparticles of 35nm of mean diameter. In the middle, pictures of the setup for static (left) and dynamic (with human subjects, right) tests.

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




RPD	SPECIFICATIONS	MEASURES	STANDARD EFFICIENCY	PROTECTION (NMs)	REFERENCE PARTICLE
Half Mask	P2	Efficiency	94 %	96.26 %	SiO2
	P3	Efficiency	99.95 %	99.99 %	SiO2
	P2	Efficiency	94 %	97.67 %	SiO2
	P3	Efficiency	99.95 %	99.99 %	SiO2
	P2	Efficiency	94 %	99.98 %	SiO2
	P3	Efficiency	99.95 %	99.55 %	SiO2
	P2	Efficiency	94 %	98.12 %	SiO2
	P3	Efficiency	99.95 %	99.48 %	SiO2
	P2	Efficiency	94 %	96.26 %	SiO2
	P3	Efficiency	99.95 %	99.99 %	SiO2

Table 2: Penetration into different kinds of chemical protective suits against NaCl nanoparticles. Below, pictures of the testing activities with human subjects.

SPE	POSITION	MEASURES	STANDARD EFFICIENCY	PROTECTION (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

Table 3: Penetration into different kinds of protective gloves against NaCl nanoparticles. Below, the testing setup.

SPE	MATERIAL	MEASURES	STANDARD EFFICIENCY	PROTECTION (NMs)	REFERENCE PARTICLE
Disposable protective gloves	Nitrile Thin	I.L (%)		0.040	NaCl
	Nitrile Thick	I.L (%)		0.006	NaCl
	Vinyl	I.L (%)		0.103	NaCl
	Non powder Vinyl	T.I.L (%)		0.013	NaCl
	Non powder Latex	I.L (%)		4.64	NaCl
Reusable protective gloves	Neoprene / Natural Latex	T.I.L (%)		1.63	NaCl
	PVC	I.L (%)		3.17	NaCl
	Butyl II	I.L (%)		-	NaCl

Table 4: Protection efficiency of two kinds of laboratory goggles and testing setup.

SPE	SPECIFICATIONS	MEASURES	STANDARD EFFICIENCY	PROTECTION (NMs)	REFERENCE PARTICLE
Conventional		I.L (%)		57.79 %	NaCl
Tight-fitting goggle		I.L (%)		20.07 %	NaCl

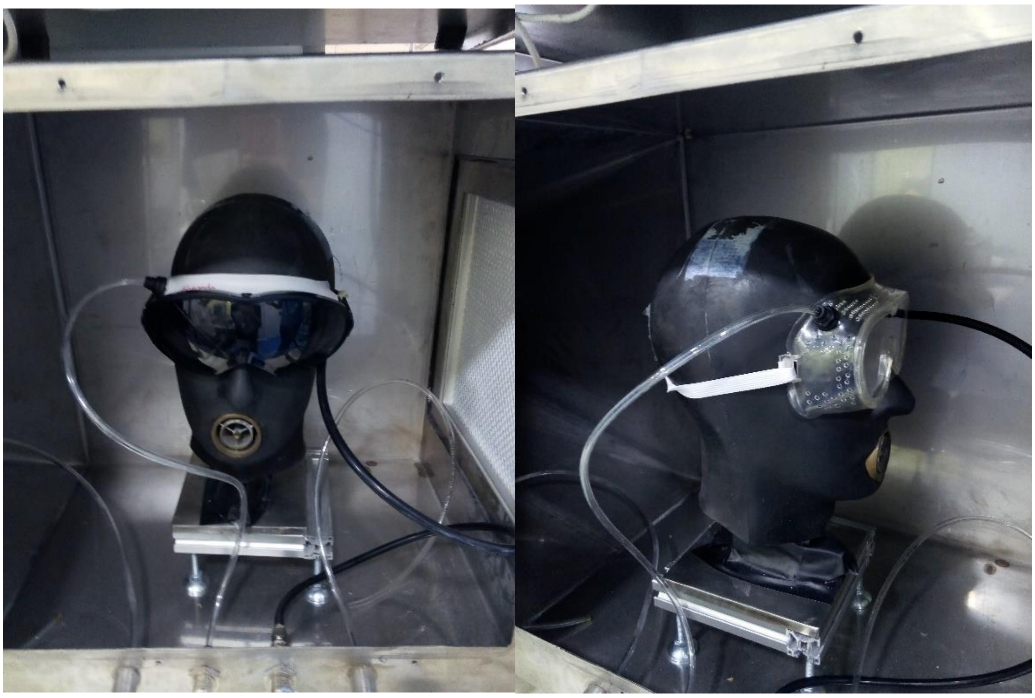


Table 5: Capture efficiency of movable hoods varies with distance and position.

TILTED CAPTURE HOOD		VERTICAL CAPTURE HOOD	
DISTANCE DIFFUSER PIPES – CAPTURE HOOD (CM)	EFFICIENCY WITH TILTED CAPTURE HOOD (%)	DISTANCE DIFFUSER PIPES – CAPTURE HOOD (CM)	EFFICIENCY WITH VERTICAL CAPTURE HOOD (%)
0	100 ± 14	0	100 ± 5
15	79 ± 4	5	79 ± 6
50	72 ± 2	20	53 ± 43
65	63 ± 5	45	82 ± 2
-	-	70	66 ± 20

Table 6: The capture efficiency of fume hoods is dependant of the area of the open sash.

Test A	21	19	21
	688	891	30
Test B	2	7	11
	953	1553	26
Test C	3	6	9
	184	1660	8

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

The aim is to develop a catalogue of Risk Management Measures (RMMs) to support the application of REACH regulation, helping in the selection of necessary workplace controls for protection against chemicals at the nanometer scale.

The RMM library is conceived as a free, downloadable and up-to-date online tool in which the effectiveness of different engineering controls, administrative controls and personal protective equipment is collected and displayed for various industrial, professional or laboratory processes to facilitate the decision on the control and the management tool to employ in each case.

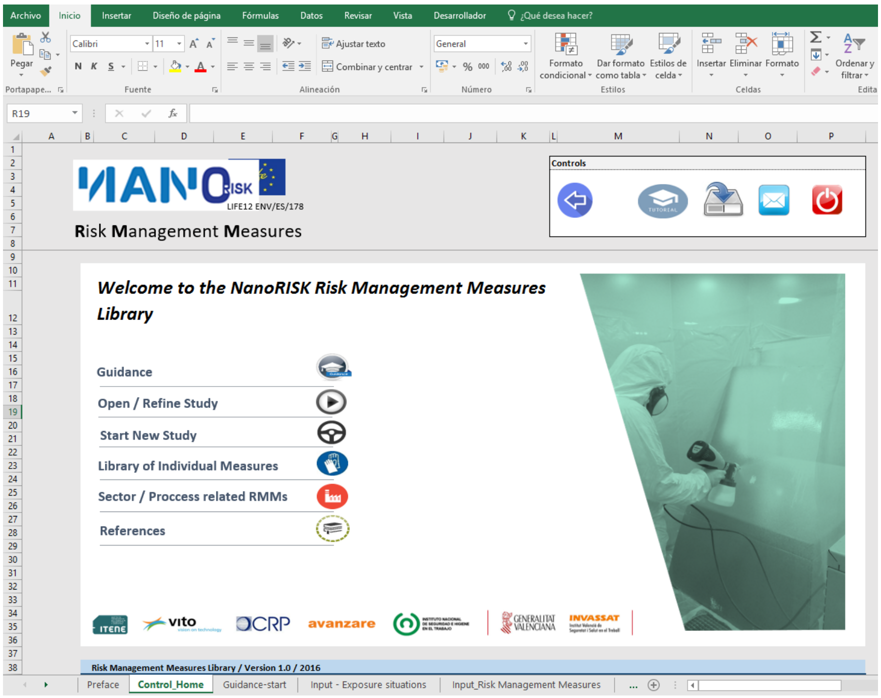
The library is based on the structure of the MGR library of CEFIC (2007). It contains a brief description of the properties of nanomaterials for which RRMs are applicable along with a list of additional RRMs that may be necessary to avoid the spread of risk to other compartments.

The library contains quantified data where possible, including default efficiency values and maximum achievable values, plus the efficiency values for each of the RMMs studied within the project.

The library can be consulted and downloaded from the NanoRISK website (http://www.lifenanorisk.eu/index.php/interactive).

Figure 2: RMM library to download from NanoRISK website.

The library is intended for use alone or as supplementary information from the guidance on the safe use of nanomaterials. It is also accompanied with a manual to help users through it.


Controls
LIFE12 ENV/ES/178
Risk Management Measures
Welcome to the NanoRISK Risk Management Measures Library
Guidance
Open / Refine Study
Start New Study
Library of Individual Measures
Sector / Proccess related RMMs
References
Risk Management Measures Library / Version 1.0 / 2016
Preface
Control_Home
Guidance-start
Input - Exposure situations
Input_Risk Management Measures


LIFE12 ENV/ES/178
Risk Management Measures Library
Controls
Guidance On Using RMM Library Tool
The RMM Library tool consists several worksheets, where the main sections are:
- Input Exposure situations
- Input Risk Management Measures Information
- Run Assessment - Results
- List of Individual Measures
- List of sectors and measures recommended
- Current references and guidelines of risk managemen measures
General Work-flow of the library
Step 1. Identify the main properties of the ENMs handled
Step 2. Select an adeaquate occupational exposure situation according with the conditions of use of the ENMs
Step 3. Describe the specific types of risk management measures used in the work place
Step 4. Get information on the estimated effectiveness of the PPE and technical measures implemented by pressing "Run Calculation". Get recommendations on the types of PPE and technical measures to be implemented by pressing "Get Recommendations"
Step 5. Print a pdf copy of the list of recommended measures
Instructions
This tools has been tailored designed to support stakeholders on the selecction of proper measures to guarantee a high level of protection to human health when working with ENMs. In detail, key stakeholders are:
- Health and safety advisors and occupational hygienists from private companies, universities and/or research organizations working with ENMs
- Workers and professional users who use ENMs as such, in mixtures or incorporated into articles in research or production processes
- Researchers from academia, non-profit research organizations and private research institutions
- External Occupational Safety and Health Consultants working with companies dealing with ENMs
Preface
Control_Home
Guidance-start
Input - Exposure situations
Input_Risk Management Measures

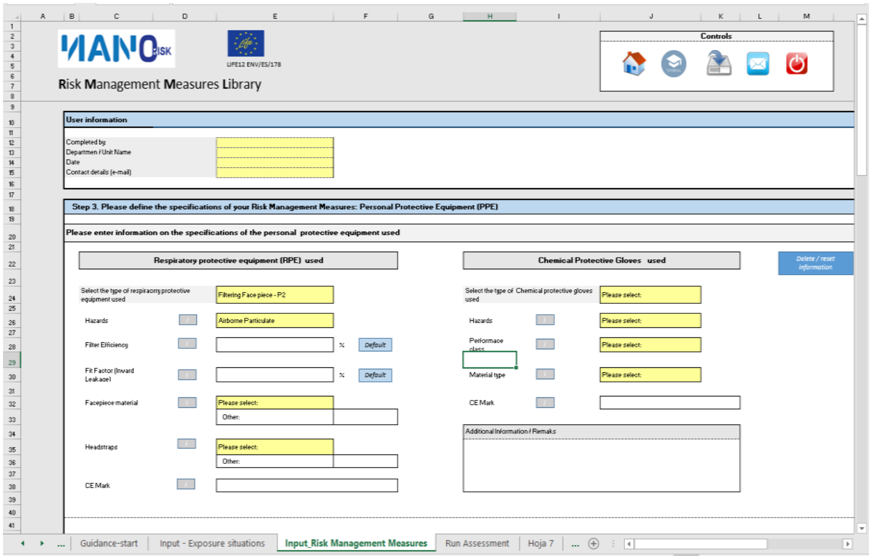


Figure 3: Some screenshots from the RMM library.

Action B5. Scaling up to industrial case studies

This action is focused on the scaling up of the tests conducted in the test chamber prototype to the real operative conditions defined in the exposure scenarios. To achieve this objective, the RMMs studied under the framework of the project will be implemented in a minimum of 5 SMEs dealing with nanomaterials, characterizing at different stages a set of indicators related to the operability and effectiveness of the RMMs implemented in the company.

To validate the RMMs effectiveness, technicians of ITENE, VITO and INSHT have visited the installations to quantitatively measure of the effectiveness of RMMs in reducing exposure and environmental emissions (Figure 4).

Figure 4: Weighing of reagents (left) and release of TiO2 slurry in bag (right)

The reduction of emissions and worker´s exposure will be monitored by studying periodically a series of indicators stablished in the present deliverable intended to measure the number of emitted nanomaterials in industrial conditions.

A monitoring plan to assess the reduction in exposure by applying the proper RMMs has been developed. It consists a stepwise tactic where a first approach of the expected exposure is carried out by dedicated questionnaires and interviews of the process to the company. The exposure scenarios are classified depending on its likehood of exposure, being all the RMMs present analyzed upon their performance in the process and their appropriateness.

From the data of effectiveness of RMMs against NMs attained in this project, the suitability of the current RMMs of the process is analyzed, and new RMMs are proposed. For example, in Figure 5 the operation of a LEV decreases the ambient concentration up to 98%.

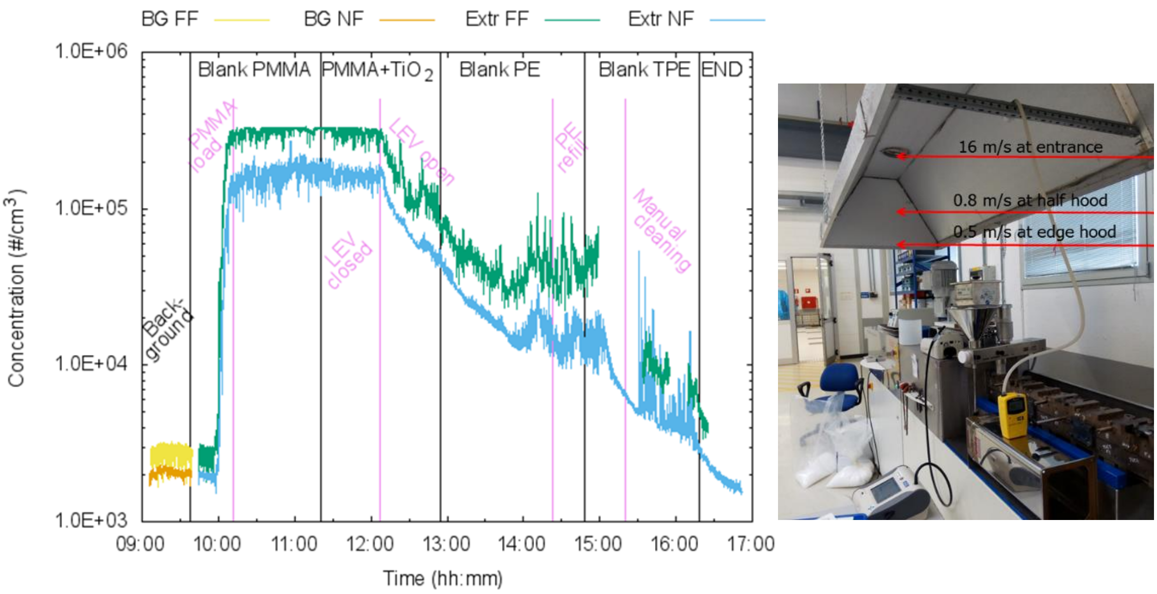


Figure 5: Comparison of concentration of particles in the Near and far Fields during extrusion of TiO2 nanoparticles recorded by the CPC with and without an extractor.

In the case of PPE, the principal factor comes from their use and fitting, thus a training is given to the wearers on how to select, use and maintain the proper PPE for the task. In Figure 6 can be seen the effect of measuring inside the face filtering mask FFP3 where it provides an efficiency above 99,78% in real working operations. Recall that a bad fitting or a misuse of the PPE can incur on a decrease of performance up to 60% or more.

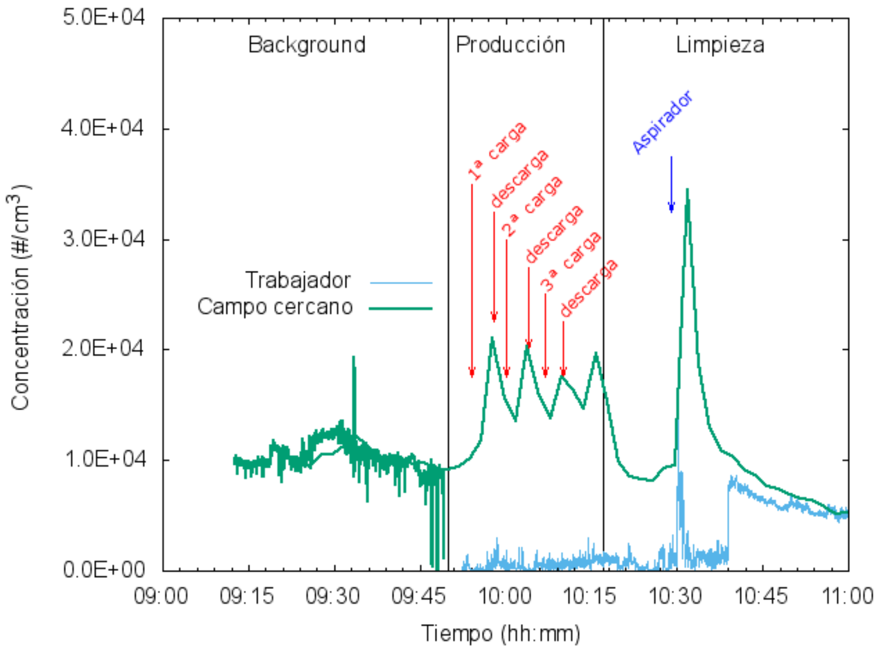


Figure 6: Particle number concentration during the production in solid medium of SiO2 and the subsequent cleaning in the near field (green line) against the concentration inside the worker's mask (blue line).

Action B6. Guidance on the required measures and controls for mitigating and control the risk posed by the target nanomaterials during its entire life cycle

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.

The guidance developed is freely accessible and can be consulted and downloaded from the NanoRISK website (http://www.lifenanorisk.eu/index.php/interactive). It contains 10 sections, as presented below:

1. Abbreviations and acronyms
2. Summary
3. Introduction: Environmental, health and safety (EH&S) issues in Nanotechnology.
4. Regulations and standards
5. Basics on Risk Management Measures: STOP principle
    5.1. Hierarchy of Safety and Health Controls

5.2. Technical measures
5.3. Organizational measures
5.4. Personal protective equipment (PPE)
5.5. Emission Control Technologies (ECT)

6. Effectiveness of common risk management measures against occupational exposure to ENMs
    6.1. Current knowledge on the effectiveness of PPE and LEVs
    6.2. Recommended testing approaches
    6.3. Protection factors and performance levels based on the studies conducted within NanoRISK
7. Recommended measures for the safe handling and control of exposure
    7.1. Recommended measures for controlling occupational exposures to ENMs
    7.2. Respiratory, dermal and eye protection selection charts
    7.3. Recommended technical measures for controlling environmental release
8. Health Surveillance and environmental monitoring
9. Instruction sheets
10. Frequently asked questions
11. Annexes

2. Scheduled activities

The next period, from January 2016 to the end of the project will focucuss on the finalization of the multimedia guidance on recommended measures, the organization and development of training sessions and the monitoring of the impact of the project.

In terms of dissemination activities, it has been planned the participation of the project in relevant conferences and trade fairs, including NanoSpain 2016 and Nanosafe 2016 to be organized in Logroño (Spain) and Grenoble (Francia) respectively.

The participatin in a workshop organized by INSHT is also anticipated.

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