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Development of a real-time information and monitoring system to support the risk assessment of engineered nanomaterials (ENMs) under REACH

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Deliverable

DA4b. First implementation plan of the project

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Summary

The activities conducted so far under the project has enabled the definition of the main specifications of the NanoMONITOR air monitoring station prototype and the data acquisition software. Both systems will be validated and implemented by end users in a list of case studies to support the generation of reliable, robust and comparable data on the concentration of engineered nanomaterials in a representative number of locations.

The present document constitutes the implementation plan of the project, containing a detailed description of the scheduled activities defined by the members of the consortium to promote the use of the products of the project by target stakeholders, with special emphasis on companies producing or using nanomaterials, as well as public bodies with interest on monitoring air pollutants.

A list of four companies have been approached to support the validation of the operational settings and functionalities of the monitoring station prototypes, including:

- Al-Farben, as producer of metal oxide nanoparticles at industrial scale, and located in Alcora, Spain.
- Tec Star, as producer of nanomaterials and ENMs based dispersion at laboratory scale, and located in Modena, Italy.
- Avanzare, as producer of graphene and ENMs based composites at pilot to industrial scale, and located in Logroño, Spain.
- Chimigraf, as downstream user or nanomaterials for ink-jet applications at industrial scale, and located in Rubí, Spain.

Four more locations have been scheduled so far, including the metropolitan area of the city of Valencia (Spain), and an industrial area. The implementation plan defined within this document includes the following locations:

- Subway station at the city centre (urban)
- High density traffic road in the city
- Industrial area in Paterna (Valencia), Spain
- Natural environment

Representative persons from the abovementioned companies and public bodies were contacted to stablish a first list of activities to be conducted in June 2017, where a beta version of both the NanoMONITOR station prototype and data acquisition software will be released.

The exact location of the air monitoring station will be presented under deliverables DB4, where a complete description of monitoring location, activities conducted and results will be provided.

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1. Scope and goal of the deliverable

The present deliverable provides a detailed description of the activities to be conducted to guarantee the implementation of the outcomes of the project by stakeholders, in particular companies dealing with ENMs and public entities with responsibilities and interest in the use of measured data for risk assessment purposes.

This document establishes a list of objectives, strategies, plans and procedures in order to promote the use of the NanoMONITOR monitoring station and the data acquisition software by target stakeholders. The development and implementation of the outcomes of the project is a dynamic process involving the following six steps:

1. Goal setting
2. Definition of areas of special interest
3. Implementation strategies
4. Evaluation and follow up

The abovementioned steps are described in detail within this document. The results of the implementation phase, including the results from the evaluation and follow up are out of the scope of this deliverable.

2. Goal setting

Goal setting provides the basis for the formulation of the implementation plan, being defined in consultation with stakeholders. The goal of the implementation plan should be consistent with the role and activities conducted by stakeholders, being also in line with the activities conducted within the project.

As stated previously, the project out comes will be implemented in case studies representing companies dealing with ENMs and public bodies and institutions with responsibilities in air quality monitoring.

The goal of the implementation plan defined considering the ideas contained in the proposal text are detailed below:

a) Goals of the Implementation plan in industrial case studies

The goal of the implementation plan in industrial case studies focusses on the **promotion of the use of the monitoring station prototype** to evaluate the concentration of ENMs during the manufacturing and downstream use of nanomaterials as such, in dispersion or embedded into a matrix, the **use of measured data for risk assessment purposes** on a regulatory basis (i.e. REACH regulation / Environmental legislation), and the use of the **data acquisition software** to improve the implementation of risk management strategies.

The specific goals of the implementation plan for companies producing and/or using ENMs are the following:

1. Install a monitoring station in four companies, including ENMs producers and downstream users. Metal oxides and carbon based materials shall be covered.
2. Cover a minimum set of 10 industrial processes involving the use of ENMs, including:
    - Synthesis
    - Weighting
    - Packing / bagging of ENMs in dry form
    - Packing of ENMs in dispersion
    - Mixing / stirring operations
    - Sonication
    - Spraying (gas)
    - Spraying (liquid)
    - Drilling
    - Cleaning
3. Evaluate the operability and applicability of the station to evaluate the concentration of ENMs in indoor workplaces
4. Evaluate the operability and applicability of the data acquisition software to improve the use of measure data on a regulatory basis, including risk assessment, reporting and risk management.

b) Goals of the Implementation plan in local authorities and public bodies / institutions

The goal of the implementation plan for non-industrial organizations focusses on the installation and implementation of the NanoMONITOR station and data adquisition software to promote the generation of robust data on the concentration of nanomaterials in urban and natural areas, supporting decision making by public authorities (i.e. air quality management / public health) and improving the availability of data to estimate the potential concentration of materials in the nanometer range in relevant areas and ecosystems (i.e. urban locations, water bodies or agricultural soil, among other).

The specific goals of the implementation plan for companies producing and/or using ENMs are the following:

1. Install a monitoring station in four locations in the Valencian Community, including indoor areas (subway station), high density traffic roads, industrial concentration areas and natural environments.
2. Integrate the data generated by the stations on the air quality data generated by the network of sensors installed by the Air Quality Monitoring data on the Valencian Community.
3. Identify hot spots where a major concentration of ENMs is expected
4. Evaluate the operability and functionalities of the data acquisition software by the end uses, including:
    - Researchers from public and/or private organizations working with ENMs
    - Safety advisors interested in data on the concentration of ENMs for risk assessment purposes, including environmental impact studies.
    - Citizens interested in being informed of the air quality of the city

3. Definition of areas of special interest

3.1. Introduction

As stated in the proposal text, the definition of the implementation locations will be conducted considering areas of particular interest due to the population exposed, the type of industrial activities conducted or the relevance of the area to provide a better understanding of the background exposure to PM0.1 particles.

Current data on the concentration of total suspended particulate matter (SMP), PM10 and PM2.5 measured by the Valencian Community Air Quality Monitoring network will be analysed in depth to define the location of a background monitoring location to act as a "control". This control station will be selected on the basis of the levels of particulate matter measured during the last 10 years, and considering the environmental conditions of the area to avoid special climatic conditions interfering the quality and representativeness of the measures.

At the time of writing areas such as the Albufera National park are of special interest. The Albufera National Park is one of the most important nature areas in the Land of Valencia. This area is corner of nature in which we can find local flora and fauna in its wildest state thanks to the strict protection against human activities.

On the other hand, one industrial areas will be selected considering the levels of production and use of ENMs, as well as the levels of PM1 and P2.5 retrieved by the Valencian Community Air Quality Monitoring network during the last 10 years. At the time of writing, the technological park of Valencia has gained attention due to the increase of companies working with ENMs, becoming the main point of use of ENMs in the Valencian Community.

Two more locations will be selected in the metropolitan area of the City of Valencia. The first location will be selected in view of the data provided by the stations measuring air pollution in high density traffic roads. The second location will consider the metropolitan transports of the City, and especially the subway, which represents a common urban indoor where the presence of particles below 1 micron is likely.

Considering industrial facilities, the selection of 4 companies manufacturing and using ENMs in quantities larger than one ton per year, including SMEs or large companies was included in the proposal text. In this regard, a set of 4 companies have been pre-selected to cover relevant ENMs and processes, ensuring the representativeness of the types of ENMs and covering the most interesting applications. The companies selected are located at different countries in Europe, ensuring the evaluation and demonstration of the applicability of the monitoring system under representative climate regions.

On the basis of the abovementioned considerations, a list of 4 companies and 4 locations have been preselected:

- Location 1. Al-Farben, as producer of metal oxide nanoparticles at industrial scale, and located in Alcora, Spain.
- Location 2. Tec Star, as producer of nanomaterials and ENMs based dispersion at laboratory scale, and located in Modena, Italy.

- Location 3. Avanzare, as producer of graphene and ENMs based composites at pilot to industrial scale, and located in Logroño, Spain.
- Location 4. Chimigraf, as downstream user or nanomaterials for ink-jet applications at industrial scale, and located in Rubí, Spain.
- Location 5. Subway station at the city centre (urban)
- Location 6. High density traffic road in the city of Valencia
- Location 7. Industrial area in Paterna (Valencia), Spain
- Location 8. "Control". Natural environment (Albufera national park or similar)

3.2. Industrial locations

ITENE, AXON and CEAM will work on the selection of areas where a release of ENMs and hence a potential exposure to of ENMs is expected. Considering the proposal text, we have pre-selected four companies currently dealing with ENMs, and located in areas under different climatologic conditions.

Table 1 contains information on the activities covered in each case study, type of ENMs used and climatologic conditions of the area, all of them parameters affecting the fate and behaviour of ENMs.

Table 1. Information of pre-selected locations

Case	Main Activity	ENMs	Process	Location	Av Tª	Av HR (%)	Precipitation (mm/year)
1	Producer of metal oxide nanoparticles at industrial scale	CuO ZnO TiO2 Fe3O4	Synthesis Weighting Packing / bagging of ENMs in dry form Spraying (gas) Cleaning	40.18910 º N -0.56030 º E	17	56	50 – 200
2	Producer of nanomaterials and ENMs based dispersion	CuO (dry) ZnO (dry) TiO2 in dispersion Paints (nano) Coating (nano)	Synthesis Weighting Sonication Packing / bagging of ENMs in dry and/or liquid form Cleaning	44.63467 º N 10.91766 º E	14	68	400 – 600
3	Producer of graphene and ENMs based composites	CNTs Graphene Graphene oxide Polymer based n-composites	Synthesis Weighting Sonication Packing / bagging of ENMs in dry form Drilling Cleaning	42.42610 º N -2.54883 º E	12	50	450 - 500
4	Downstream user or carbon nanotubes, graphene and metal oxides for ink-jet applications	CNTs TiO2 CuO Graphene Ag	Spraying (gas) Spraying (liquid) Cleaning	41.44700 º N 1.97170 º E	15	70	50 – 200

3.3. Strategic locations in the public areas

CEAM, AXON and ITENE have identified several locations of special relevance to install the NanoMONITOR monitoring station and implement the data acquisition software, considering both indications in the proposal text and reproducibility of the conditions.

To date, we have identified four strategic location covering indoor urban areas, outdoor areas in high density traffic roads, ENMs related areas and a "brackground concentration" area to support data comparisons.

Table 2 contains information on the public areas selected, type of ENMs expected and climatologic conditions of the area.

Table 2. Information of pre-selected locations in the public domain

Case	Area	Expected ENMs	Exposure routes	Exposure periods	Av Ø (nm)	Av Tª	Av HR (%)
1	Subway station	Nanocrystalline Alloys and Magnetic Nanomaterials PM0.1- PM2.5	Inhalation	Daily	200	24	60
2	High density traffic road	PM1 Fullerenes, metal oxides and metal nanoparticles	Inhalation	Daily	100	14	70
3	Industrial area in Paterna	CNTs Graphene Polymer based n-composites Metal oxides (CuO, ZnO TiO2, Fe3O4) Metals	Inhalation	Daily	60	12	50
4	Control: Natural environment	Metal oxides PM1	Inhalation	Daily		15	70

The exact location of the stations will be decided upon discussion among the members of the consortium and representative members of the organizations or institutions in charge of the management of each location.

4. Implementation strategies

4.1. Introduction

This chapter provides detailed information of the implementation strategy of the products of the project in the pre-selected locations. This strategy varies on the basis of the specific objective of each case, being in general defined considering the following steps:

1. Review meeting with authorised members of the company or organization.
2. Training on the use of the monitoring station prototype and data acquisition software.
4. Selection of the final location and installation of the station on site
5. Definition of a sampling / measurement plan and data analysis exercises
6. Follow up

The consortium will provide technical assistance for installing and connecting the systems in both the selected companies and public areas. To support the implementation, two training sessions will be conducted, being focussed on training the staff of the companies in the use of the new software application and the monitoring devices. The top management of the companies will be invited to support the commitment of the company.

The abovementioned implementation steps and approach are explained extensively in the following chapter.

4.2. Implementations steps

- **Review meeting with authorised members of the company or organization**

A face to face meeting will be organized by ITENE to explain the objectives to be achieved in each case study, define a calendar of activities to be covered and stablish responsibilities among the personal involved in the case study.

- **Training on the use of the monitoring station prototype and data acquisition software**

A training session on the features, specifications and functionalities of the monitoring station prototype and data acquisition software will be conducted. This training will be complemented with a detailed operation manual of both subsystem, as well as on line tutorials to support a proper use.

- **Selection of the final location and installation of the station on site**

The selection of the location to install the monitoring station will be agreed after a complete study of the appropriateness of the area, considering production activities, expected concentration of ENMs, security of the area, reproducibility of the conditions and potential transferability of the results.

- **Definition of a sampling / measurement plan and data analysis exercises**

A sampling plan will be defined and communicated, including instructions to operate the monitoring station and practical exercises to be conducted with the data available in the NanoMONITOR web based application.

- **Follow up**

A continuous follow up of the implementation phase is envisaged. Once a week, members from ITENE, CEAM or AXON will contact the persons in charge of the scheduled activities to identify any constraint.

4.3. Evaluation

The evaluation phase aims at demonstrating the technical viability of the outcomes of the project. The functionality of the developments will be based on the definition of a set of **indicators** to be analysed in each location where the system is tested in order to monitor the applicability and success of the methods and technologies developed.

To date, we have identified a number of indicators that will be monitored in each case study, including:

1. Connectivity of the application software installed on site with the central data base
2. Number and types of malfunctions of the application software
3. Number of error messages generated by the application when transferring data from the monitoring units and/or external databases.
4. Alarm errors communicated by the monitoring unit installed on site
5. Description of malfunctions observed by the personnel in charge of the maintenance of the monitoring systems
6. Amount of service/maintenance needed to be executed on the monitoring systems (both time and costs)
7. Amount of availability of the monitoring systems including application software (uptime)
8. Series of data provided by the system without outliers

These indicators will be analyzed in depth by the consortium to support the identification of improvements in the system. The case study will be complemented with questionnaires to analyze the effectiveness of the project to comply with the duties stablished by REACH in each company and with the industrial scalability of the system. A compendium of dedicated questionnaires will be prepared to define the main tasks related with REACH where the outcomes of the project have a strong impact.

The last activity to demonstrate the adequacy of the proposed solutions and the viability of the outcomes will be the **validation of the quality of the data reported** in each case study, including the data collected by the devices, the results of the progress indicators and the opinions collected.

The validation will be conducted by expert staff from ITENE, CEAM, AXON and TRC. An essential step will be to evaluate robustness of the system, including an in depth analysis of the alarm errors and the evaluation of the continuity of the monitoring data provided.

A second step will include the characterization of the potential damages in the environmental enclosure developed to host the monitoring devices. In this regard, due to the long-term outdoor monitoring scope of the project, the electrical connections, battery system, heat shield, solar power system, wireless data management system, as well as any other component

included, could suffer a certain degree of degradation due to environmental conditions. This evaluation will be conducted several times to detect any problem in an early stage.

The final phase will focus on the assessment of the effectiveness of the project to support the compliance with REACH and the protection of the environment. Expert staff from ITENE will analyze the reduction of the concentration of ENMs as a result of the implementation of new administrative or technical measures by the companies conducting the case studies

4.4. Scheduled task

Table 3 contains a proposed calendar of activities to be conducted.

Table 3. Scheduled activities

Case	Area	Start date	End date	Responsab.	Station id	Analysis
1	Subway station	June 2017	December 2017	ITENE	1	January 2018
2	High density traffic road	January 2018	March 2018	CEAM	4	April 2018
3	Industrial area in Paterna	April 2017	March 2018	CEAM	2	April 2018
4	Control: Natural environment	April 2017	March 2018	CEAM	3	April 2018
5	Producer of metal oxide nanoparticles at industrial scale	September 2017	October 2017	ITENE / AXON	4	November 2017
6	Producer of nanomaterials and ENMs based dispersion	November 2017	December 2017	ITENE / AXON	4	January 2017
7	Producer of graphene and ENMs based composites	January 2018	March 2018	ITENE / AXON	1	April 2017
8	Downstream user or carbon nanotubes, graphene and metal oxides for ink-jet applications	January 2018	March 2018	ITENE / AXON	Satellite	April 2017

5. Conclusions

A detailed implementation plan has been outlined in the present document. A detailed workplan will be developed in each case study in order to support the implementation and validation of the activities conducted within the project.

The transferability and reproducibility of the outcomes of the project are of prime importance to support the success of the project, being considered as critical criteria to support the implementation stage.

So far, four companies have been pre-selected to support the validation of the operational settings and functionalities of the monitoring station prototypes, including:

- Al-Farben, as producer of metal oxide nanoparticles at industrial scale, and located in Alcora, Spain.
- Tec Star, as producer of nanomaterials and ENMs based dispersion at laboratory scale, and located in Modena, Italy.
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6. Annex

List of tables

Nanomonitor Project is partially funded by the European Commission Life+ with grant agreement LIFE14 ENV/ES/000662