Advanced web tools for promoting the application of nanotechnology and the safe use of nanomaterials in the plastic sector

Project Acronym: **NanoDesk**

Project Code: **SOE1/P1/E0215**

Deliverable Title
DA6b. "EA6c. Content and impact report of the NanoDesk platform"
Coordinator and Responsible of the Document
Beneficiary

Date of preparation
22/05/2019

Nature of the deliverable
Public

Dissemintion Level

Public / Restricted / Confidential

Document Information					
Associated Task Group	GT6	Development of the nanodesk web application			
Associated Activity		Design and programming of the NanoDesk web platform, integration of the tools developed and validation of the functionality of the system			
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Rev. Nº	Date	Author	Beneficiary name
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EXECUTIVE SUMMARY

The SUDOE NanoDESK platform is an innovative tool whose ultimate goal is to promote safety during the production and use of nanomaterials and nanostructured polymeric materials, guaranteeing the safety of the final product for the consumer, and the protection of the health of workers and the environment .

This document presents an estimate of the potential impacts of the project on the industrial fabric, considering the current use of the main types of nanomaterials and nanocomposites in the plastic sector.

The impacts have been estimated based on indicators, including increased business opportunities and improved competitiveness, variation in the reduction of nano-pollutant emissions, improvements in the level of employment, reduction of occupational diseases, and reduction of the exhibition.

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1. Introduction

The SUDOE NanoDESK platform integrates under the same application tools that allow the evaluation of the potential risks of nanomaterials and nanocomposites by the technical staff of SMEs and large industries in the plastic sector.

The NanoDESK tool has been designed considering the information needs and legal requirements applicable to the industrial fabric, and including simplified tools for the search for information, the prediction of the toxicity of a material or the estimation of exposure levels during for workers, consumers, and the environment. Specifically, the tools included in the NanoDESK platform are the following:

- ✓ Support module for decision making: DSS tool
- ✓ Module for toxicity prediction: QSAR prediction models
- ✓ Module for exposure estimation in planned use scenarios
  - Industrial and professional use
  - Use at the consumer stage
  - Emissions to the environment
- ✓ Application for mass information search: Data mining tool
- ✓ Observatory of news and information on nanomaterials and their application in the plastics sector

The benefits and impacts of the Project are broken down in the framework of this document. The basic mechanics that may cause benefits to the SUODO region citizens and the nanotechnology related industry are based on the following issues:

- ✓ Access to scientific based tools to support the risk assessment of ENMs, highlighting the exposure estimation module and the decision support system.
- ✓ Generation of new data on the levels of ENMs under common industrial activities, key factor to support the selection of appropriate measures to control the release and exposure in industrial facilities.
- ✓ Establishment of the conditions of safe use, including a proper combination of operative conditions (OCs) and risk management measures (RMMs).
- ✓ Improvement of the quality of the data incorporated to safety data sheets (SDS) in order to provide the users of ENMs with the information needed for efficient risk management with regard to workers, consumers and the environment

The potential **economic impact** of the project can be differentiated into cost savings and non-monetary advantages on the market. Cost savings could be realised by using the more comprehensive information on the exposure potential to manage more efficiently the potential risks upon exposure on the own site and those along the supply chain.

Market advantages could result from the availability of better information on the type of risk management measures to be implemented, being these communicated in the exposure scenarios to be enclosed to the safety data sheets. In this sense, the compliance with REACH regulation has been demonstrated to improve the company reputation, market predictability and liability costs, all of them directly related with the financial viability and grow of the companies, especially during crisis situation.

In relation to the **environment**, the benefits include: 1) less actual damage to the environment due a to a reduction on the release of ENMs into the environment, 2) lower spending to remediate or compensate for environmental damage and, 3) lower risks of damage to the environment derived from release sources in urban areas. Inevitably, these levels overlap.

Concerning **human health**, benefits related to occupational health are described as the prevention of occurrence of occupational diseases and respective costs (curative, disabled life years and costs for employers) through the generation and communication of more and better information on the concentration of ENMs under common exposure situations, as well as on the use of proper risk management measures to maintain the levels of occupational exposure and environmental concentration below the currently available exposure levels (REL: recommended exposure levels for workers / PNEC: predicted no effect concentration in the case of environmental matrices).

Benefits related to **public health** are mainly related with a better knowledge on the presence of ENMs in commercial products such as packaging materials, cosmetics, medical devices or building products, as well as less public spending for public health damage, less incidence of public diseases, and reducing risks/exposures of the general public.

2. Impacts on the industrial fabric and the final consumer

The main impacts of the project on the EU Industry and society are described below:

- **Impacts on EU Industry**

The **project has a strong impact on the industry** to the extent that promotes the use of ENMs to develop new added value nano-enabledproducts. The possibilities for application of nanosized particles in plastic market are rapidly increasing on the basis of the current societal needs and market trends. Nevertheless, there are number of issues that warrant concern about the mass commercialization of ENMs and nano-enabled products, considering mainly technical and safety concerns.

The activities of the project are aligned with the current barriers related with the impact of ENMs on the safety of workers that limit the use of the nanotechnology at industrial levels. Similarly, the results of the project are directly exploitable by the industry, highlighting the **observatory** and the **consumer exposure model**, developed following the industrial needs and the type of information laid down on REACH regulation to perform a robust chemical safety assessment.

The abovementioned results will support the industry in the preparation of the chemical safety assessment report and **the chemical safety assessment** of ENMs under REACH, key aspects to place in the market a ENM on a regulatory basis.

The improvement in the safety of the production process and the fulfilment of a key European regulation such as the regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), food safety regulations, or the cosmetic directive will **improve the business opportunities of those SMEs affected by regulatory provisions related with ENM**. In fact, the EC recognizes that compliance with Health & Safety directives, as well the sector related regulations will play a key role in promoting economic growth and employment in the EU but also realizes that the costs of compliance for SMEs are high, then, the use of non hazardous ENMs, as well as the definition of measures to reduce exposure and release will minimize the costs to control the risks during the production process, supporting at the same time the economic growth of the SME and their competitiveness.

Moreover, improved worker and consumer safety have obvious economic benefits for the EU with respect to healthcare provision. In this sense, several studies describe business benefits in terms of savings related to occupational health due to the proven efficiency of the control measures for protecting workers from the risks related to chemical agents.

- **Impacts on EU society**

Beyond the toxicity risks to human health and the environment which are associated with first generation nanomaterials, nanotechnology has broader societal implications and poses broader social challenges. In this sense, NanoDESK tries to meet social objectives in terms of nanotechnology application, principally in terms of safety and health related to the use and commercialization of nanotechnology based products in the plastic sector.

The contribution of the project to the safety of the workers and nano-enabled plastic products placed on the market will improve the approbation of this kind of products into the society as well as a better image of the new technologies, ensuring the commercialization in the near future. The expected benefits in terms of product quality, safety and environmental respect, will be key issues to accept the changes towards the new nanostructured products, which will be better accepted by the consumers.

Simultaneously, the participation of enterprises in the project implementation and the direct application by the representative companies from the polymer based nanocomposites industry has a strong impact in the transferability and implementation of the project results, providing the

industrial stakeholders and the general public with appropriate instrumentation and knowledge to successfully select proper ENMs and control the risks posed by the use of nanomaterials.

Besides the society and EU industrial development, the project has a strong impact on the implementation of EU polices. In this regard, the project 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 and plastic products.

At this stage, the project results provide a better understanding of the risk to the human health and the environment of target ENMs, supporting regulatory bodies with scientific data to establish new legal requirements to the use of NMs in the EU industry in particular, as well as other countries worldwide in general. Similarly, the new data generated on the concentration of ENMs in plastic products supports the definition of legal requirements for the application of ENMs in products to be used by consumers, and the definition of concentration limits "thresholds values" for risk assessment purposes.

The project is aligned with the considerations expressed by the European Parliament resolution of 24 April 2009 on regulatory aspects of NMs, which explains that the use of NMs should respond to the real needs of citizens and that their benefits should be realized in a safe and responsible manner, considering the potential EHS problems.

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 manufactured Nanomaterials 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.

The project is in line with the research areas underpinning risk assessments and management in which new knowledge is more needed, bringing value to the European development of risk management knowledge by the identification of products with higher concentration of ENMs, as well as the definition of the exposure scenarios where a potential exposure to NMs is more likely, and therefore, where there is an urgent need for implementing proper measures to control the exposure, including working procedures, containment systems, ventilation and personal protective equipment.

The project has also a strong impact on the International Standardization since it works on the development of methods for sampling ENMs in complex matrices. To this end, the member of the consortium analyzed in depth the adequacy of the published harmonized Standards from ISO, CEN, BSI and ASTM, and adapting them to the specific NM properties.

- **Indicators**

As stated previously, a set of indicators were developed to support the impact analysis of the project. Economic impacts comprise the net cost to manufacturers, importers, downstream users, distributors, consumers and society as a whole. Economic impacts include for example:

- Cost of new equipment or production process necessary to work with ENMs
- Operation and maintenance costs (labour costs, energy costs, etc),

- Cost differences between different ENMs due to different production costs and purchase prices
- Design, monitoring, training and regulatory cost

We have differentiated private and social cost, focusing the analysis on private cost, understood as the costs incurred by the identified actors in relevant supply chain, in the case NMs related value chains.

On the other hand, the impacts on society are mainly related with the overall level of employment, as well as the reduction of the levels of pollutants released to the EU environment, including atmosphere, water and soils.

The specific set of indicators defined within the project, as well as the base line and expected results are depicted in table 1.

Impact Indicators	Short term	Medium term (2 year)	Medium Term (5 year)	Short term
Direct cost for regulations implementation	- 0.19	- 0.23	- 0.3	- 0.35
Increase of the business opportunities and competitiveness (Market share)	+ 0.02	+ 0.08	+ 0.1	+ 0.2
Changes in the amount of environmentally hazardous NMs releases (reduction)	- 0.03	- 0.09	- 0.2	- 0.3
Changes in the level of employment at ENMs producers and downstream users.	+ 0.01	+ 0.05	+ 0.10	+ 0.2
Insurance cost related with health damage of workers	- 0.05	- 0.1	- 0.18	- 0.25
Reduction of Occupational diseases	- 0.1	- 0.15	- 0.3	- 0.4
Public spending for public heath damage	- 0.02	- 0.05	- 0.1	- 0.15
Exposure reduction	- 0.09	- 0.15	- 0.25	- 0.35

* The table shows how much the total cost would decrease (-) and the improvement of the occupational hygiene conditions at work (+) under the assumptions about the cost of individual elements.

As can be derived from the table below, a strong impact derived from the reduction of the direct cost associated with the implementation of regulatory requirements is expected. It shall be noted also a reduction in the environmentally hazardous substances released to the environment.

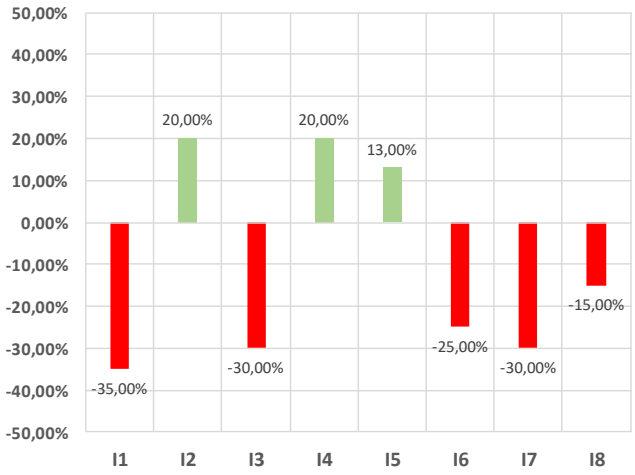

Figure 1. Representation of the socio economic impact of the project

3. Impacts on safety and health at work

Benefits related to **occupational health** are described as the prevention of occurrence of occupational diseases and respective costs (curative, disabled life years and costs for employers) through the generation
and communication of more and better information on ENMs properties and risks, the derivation of safe conditions of use and the communication of these along the supply chain via the exposure scenarios.

Table 2 depicts those indicators directly related with the benefits of the project on human health, including less spending in insurance cost, reduction of occupational diseases, reduction of public spending on public health damage and exposure reduction. Insurance and public spending have a direct economic impact, while occupational disease and exposure reduction impacts directly on the society.

Table 2. Socio-economic impact based on state of the are based assumptions

Impact Indicators	Baseline	Short term	Medium term (2 years)	Medium Term (5 years)	Long Term (10 years)	Impact
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 /m^3 (50.000 pt/cm^3)	22,75 (45.000)	21,25 (42.500)	18,75 (37.500)	16,25 (32.500)	- 35%

A less incidence of public diseases is of special interest, being mainly related with a reduction on the release of potentially toxic NMs to the environment and indoor workplaces. Moreover, these benefits are also related to the medical cost for curing worker´s diseases borne by society as a whole (through the public health system).

The most prominent link between NanoDESK and benefits for workers' health was identified as the generation and communication of new information on ENMs properties, as well as the definition of easy to use risk assessment tools, enhancing the implementation of existing workers' protection legislation. The **effectiveness of NanoDESK in reducing occupational damage was estimated in a 30 %** in the long term, being quantified in at less 1380 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 has been also estimated a reduction in at least 15 % of the public spending to compensate damage caused by ENMs on the general population, which means a maximum reduction of **€ 58 million** in 5 years. A more detailed analysis of the impact of the project on occupational health is provided in table 3. Similarly, to the estimates on the economic impacts, the quantitative appraisals are uncertain and dependent on assumptions. However, the table also makes clear that the potential benefits are substantial.

Table 3. Quantitative Impact analysis of the project on occupational health

Parameters	Assumptions	Total reduction in €	Medium term (5 years)
Cost related with health damage of workers	35 % reduction of emissions containing ENMs and 30 % reduction in occupational diseases	€ 25 – € 58 million	Skin: 4 – 8 million € / Respiratory: 5 -15 million € Eye: 1 –2 million € / Cancer: 15 – 33 million € Total: between 25 and 58 million € over 5 years
The impact of NanoDESK on Skin and respiratory diseases	Effectiveness of NanoDESK in reducing exposure: Asthma - 50%, COPD – 10 %, Dermatitis – 50% Medical Costs: 1500 – 5000 €/case	1380 cases € 2 - € 7 million	Asthma: 690 (€1.035.000 – €3.450.000) COPD: 138 cases (€207.000 – €690.000) Dermatitis: 552 cases (€828.000 – €2.760.000) Total: 1380 cases (€103,500 – €3.450.000)

*COPD: chronic obstructive pulmonary

Due to the lack of knowledge, information and data for carrying out quantified estimates of benefits from NanoDESK was compensated by making assumptions. Overestimations may occur due to too high assumptions on the NanoDESK contribution for a better health and environment protection. Nevertheless, the impact of REACH on occupational exposures to chemicals is difficult to estimate and related costs may vary across the EU. The lack of data on uses and actual exposures will be partially enhanced by NanoDESK and more information will become available on cause-effect links as well in the upcoming years.

In addition, it should be noted that a complete estimation of the benefits of the project to either occupational and public health is challenging due to the current lack of data on actual exposure and the influence of other factors on the development of a disease.

In the field of workers protection, actual values for curative costs and estimates on the average employers' costs per incident of disabled worker (lost output) are researched from data bases or other studies and summed up.

Finally, as current regulation builds on enterprises taking their responsibility for safe products, more efforts could be made to motivate enterprises by quantifying expected benefits at company level based on case studies. Furthermore, an illustration of how enterprises could integrate NanoDESK tools in their business strategies in a way that benefits would be generated, might encourage enterprises to be proactive, foster quality differentiation in the market and thus promote the implementation of regulatory requirements in their own supply chains.

4. Impacts on the industrial fabric

A big impact on the particular economies of companies dealing with ENMs is anticipated due to a reduction on the direct cost related with the implementation of regulatory requirements, which will result in a direct increase of the R&D investments, and therefore, an increase in the number of added value products available on the market.

Moreover, a 20 **% increase on the business profits** is expected due to a better image and reputation of the company, and a reduction of insurance cost related with occupational disease and environmental related taxes. The reduction on insurance cost related with occupational safety has been quantify on a 25 %, meaning € 9 and € 45 million in the short and medium term respectively.

Table 4. Socio-economic impact based on state of the are based assumptions

Impact Indicators	Baseline	Short term	Medium term (2 years)	Medium Term (5 years)	Long Term	Impact
Direct cost for regulatory compliance	€ 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%**
Insurance cost related with health damage of workers	I_6: € 180 millions	€ 171 millions	€ 162 millions	€ 148 millions	€ 135 millions	**- 25%**

A total benefit of more than € 85 million are expected in the long term (5 years) to the Industry dealing with ENMs, which means a direct benefit of roughly € 32.000 per company.

There are other potential impacts of the project, considering better conditions for innovation and less cost from penalties related with environmental emissions. In this sense, several studies (Chemsec: Surviving REACH; COM: extended IA; Danish Eco-Council: Leap forward; ECORYS – Summary Ias; UBA: benefits in selected chains; WWF: Innovation in chemicals) state that the overall conditions for innovation will be improved by REACH implementation. This relates to the development of new substances as the case of ENMs, and/or product and process optimisations.

Finally, it shall be noted that risk management at company level could benefit from NnoDESK resulting in lower expenses. The mechanism through which this would be realised is the improved information, in particular on safe handling and risk management measures.

Whether or not business benefits will be realised to a large extent depends on the way enterprises make use of new information or tools generated within the project, and how the supply of and demand for ENMs develops in the EU market. Thus, the attitudes and behaviour of the individual enterprises as well as the interaction within the supply chain will determine the extent of benefits that can be realised at enterprise level. This makes it particularly difficult to establish precise links between the project and the benefits expected at enterprise level.

In summary, a number of potential business benefits have been identified and described that could be triggered by the project. These benefits remain abstract with regard to the actual cost and resource savings that could be realised at individual and also at macro-economic level. Due to the lack and difficulties of obtaining general baseline data, business benefits could best be explored based on a case study approach

5. Project Indicators

In the life of the project, a group of 59 companies have been contacted in order to inform them of the project activities. A flow of information is maintained continues considering whether subscription to the project website and the NanoDESK platform.

Of the 59 companies with which a contact is maintained to date, **6 of them have participated in a more active way**, considering their participation in the validation of the NanoDESK platform (Xenobiotics and Coordination and Control Engineers), case studies (Intenanomat, Laurentia Technologies and Applynano), and the active dissemination of the project (Spanish Plastics Center).

The following table describes the tasks performed:

Empresas	Actividades
ProtoQSAR 2000 	ProtoQSAR is part of the project partnership, leading the development of the active structure relationship (QSAR) models within the framework of the PT3 task package and its implementation in the NanoDESK platform in the framework of the PT6 task package.
Centro Español de Plásticos 	The staff of the Spanish Plastics Center (CEP) has been especially involved in task packages 5 and T2, supporting and advising ITENE staff to identify present and future applications of nanomaterials in the plastics sector, as well as the support for the dissemination of the project in events relevant to the objectives of the project.
Xenobiotics 	Xenobiotics has actively participated in task package 3, including the validation of the results of the predictions of the activity structure relationship models (QSAR) developed. The main interest of the companies lies in the application of the QSAR models as an alternative to the in vitro models applied by the company for the provision of services.
Applynano Solutions 	Appynano has actively participated in the task package 4. In this regard, ITENE technicians have carried out a campaign to characterize the exhibition in their production plant in order to assess the degree of precision of the models.

Empresas	Actividades
Intenanomat	Intenanomat has actively participated in the task package 4. In this regard, ITENE technicians have carried out a campaign to characterize the exhibition in their production plant in order to assess the degree of precision of the models.
Coordinación y control ingenieros	CYC actively participates in work package 6, becoming involved in the periodic validation of the risk assessment module of the NanoDESK application. In this regard, CYC has been responsible for the analysis of the applicability of the models to the analysis of accident scenarios involving nanomaterials, normally embedded in polymeric matrices.
Laurentia Technologies	Laurentia, as a manufacturer of nanoparticles as such or as a mixture, has actively participated in the development of task package 4. In this regard, ITENE technicians have carried out a campaign to characterize the exhibition in their production plant in order to evaluate the degree of precision of the models.

Centro Español de Plástico - CEP

Figures 1a. Dissemination of the project on the corporate website of CEP

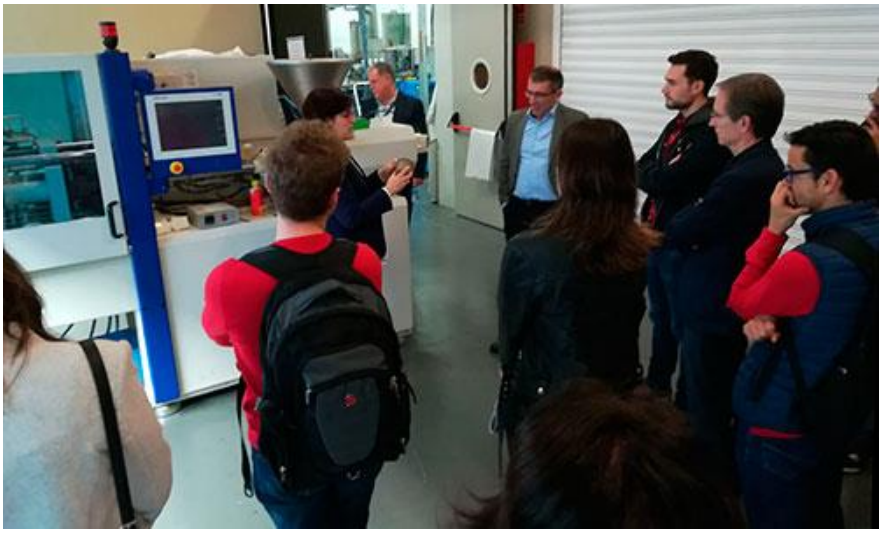

Figura 1b. Visit of Angel Lozano to ITENE

Xenobiotics

Figure 2. Left Presentation by Oscar Andreu (CEO Xenobiotics) in the framework of the project workshop. Right. Installation of measuring equipment in the Xenobiotics emission zones for the calibration of environmental models.

Applynano Solutions

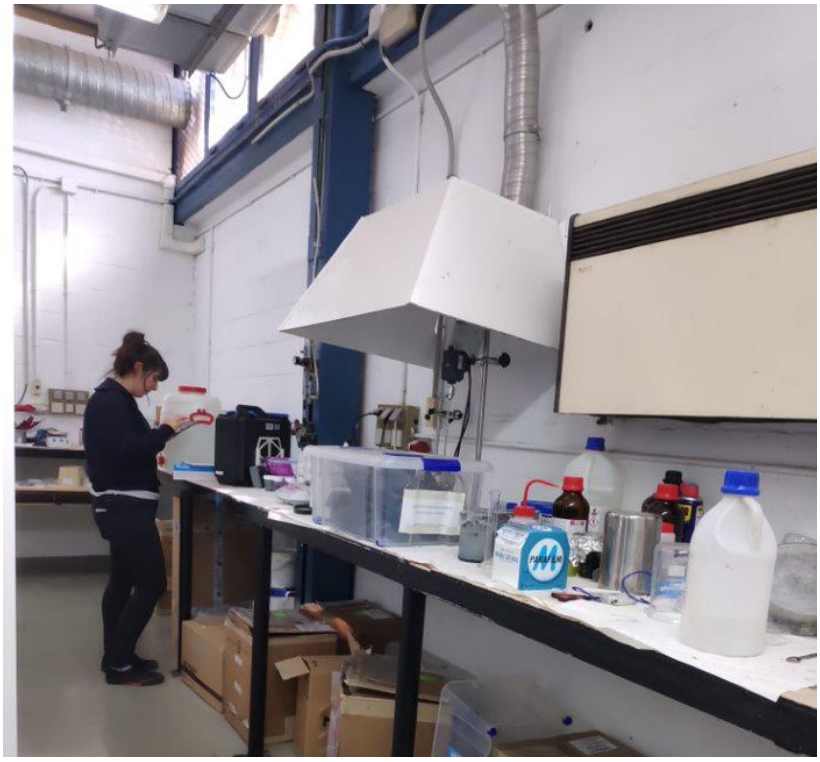

Figure 2. Preparation of equipment at the Applynano facilities (Science Park - Alicante)

Intenanomat

Figure 5. Exposure measurement campaign in Laurentia pilot plant

Laurentia technologies

Figure 6. Exposure measurement campaign in Laurentia pilot plant

Coordination and control engineers

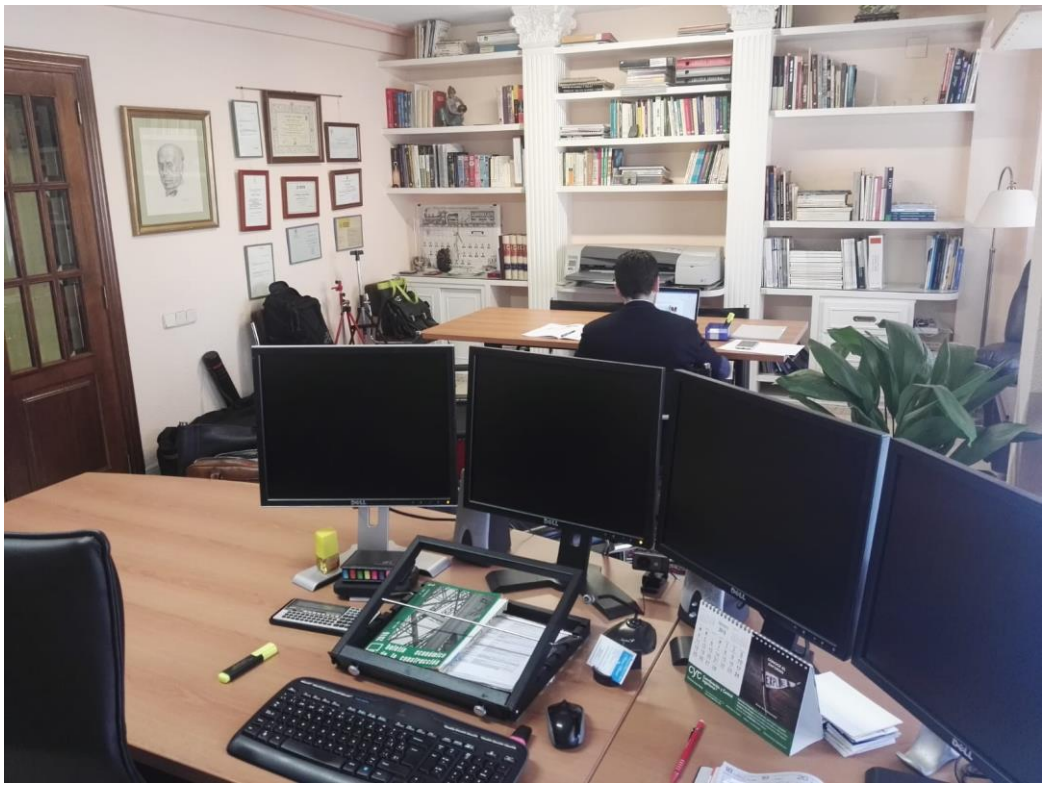

Figure 7. Project meeting at CYC facilities. Carlos Fito's picture

6. Conclusions

Nanotechnology may have direct or indirect impacts both on social and economic challenges and on products. Direct impacts would include growth of new and existing companies, job creation, new products, and wealth creation.

The impacts of the project on economy are directly linked with the benefits of the project in the safety of workers, as well as with the increase in the business opportunities due to the increase of the consumer acceptance of nanotechnology and the reduction on the lack of data to fulfil relevant policies at EU scale such as REACH regulation, CLP, food safety and safety at work.

A big impact on the particular economies of companies dealing with ENMs is anticipated due to a reduction on the direct cost related with the implementation of health and safety, as well as product related regulations, which will result in a direct increase of the R&D investments, and therefore, an increase in the number of added value products available on the market.