REACHnano

Development of a web based REACH Toolkit to support the chemical safety assessment of nanomaterials

Contract Agreement: LIFE11 ENV/ES/549 Website: http://www.lifereachnano.eu
Coordinator: Carlos Fito, Packaging, Transport and Logistics Research Center , Valencia, Spain

No.	Beneficiary name	Short name	Country
1	Packaging, Transport and logistics research center	ITENE	Spain
2	LEITAT Technological Centre	LEITAT	Spain
3	Nanotechnology Industries Association	NIA	Belgium
4	Instituto Valenciano de Seguridad y Salud en el Trabajo	INVASSAT	Spain

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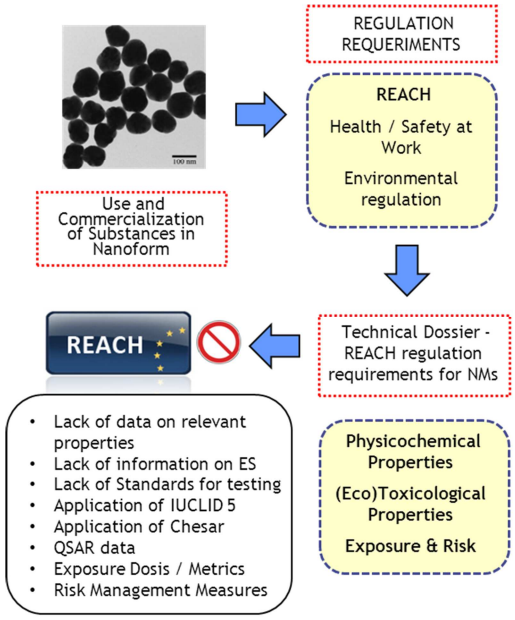
1 Summary

Within the context of REACH regulation, the main issue pertaining to the use of chemicals in whatever size, shape or physical state, is to ensure their safety to the human health and the environment, therefore, since its entry into force on 1 June 2007, **REACH plays a central role to ensure the protection of environment and health from risk posed by chemicals** and to promote sustainable development.

In this context, all available information on the substance has to be gathered and considered for the registration, however in certain cases already exits a lack of information or even standardized risk assessment methods, which make difficult the direct application of REACH regulation. This is the case of nanomaterials, which properties are often exceedingly different to those demonstrated by the bulk forms.

In order to address these major concerns and considering the priority areas of LIFE +, the **main objective of the project is to provide innovative instruments to improve the implementation of REACH when manufacturing or handling materials or substances at the nanometer scale** through the development of a web based Help Desk tool to support the risk assessment and promote the safety use of nanomaterials along their life cycle, providing the industry and stakeholders with easy to use tools to support the implementation of REACH regulation.

The toolkit to be developed within REACHnano project will take into account the needs and specifications of end-users and stakeholders, including advanced functionalities that will support industry and authorities to fulfill their main task under REACH, with special concern to those provisions aimed at ensuring high levels of human health and environmental protection such as the generation of reliable information in terms of REACH information requirements , the assessment of risk for the specific uses of the substances (i.e. exposure scenarios) and the characterization of effective risk managements measures (RMM). Moreover, this interactive web application will provide an innovative tool to share and exchange information between the scientific community and politicians, enhancing science-policy integration in support of REACH legislation.



2 Background

The use of nanomaterials is steadily increasing daily due to the new properties addressed by the nanotechnology based products. The data published show a significant increase in the production rates of the most representative nanomaterials with growth expected to achieve 2 billion jobs by 2015, being the European Union responsible for 30 % of nanomaterials manufacturing and use. In this respect, the main materials and substances at the nanometer scale currently produced in the Europe include nanopowders (metals, metal oxides, alloys), magnetic nanomaterials, carbon nanotubes (single, multi-walled), nanoceramics, nano-silica (fumed, colloidal), quantum dots (metal and semi-conducting nanocrystals) and polymer composites containing nanoreinforcements.

Such rapid proliferation results in a key environmental problem due to the fragmentary scientific knowledge of their health and environmental impacts and subsequent effects on ecosystem health. The uncertainties are extensive since the properties exhibited by substances and materials at the nanometer scale are often completely different from those demonstrated by bulk forms, affecting their physicochemical and biological behaviour, which results, in more toxic properties. Research on human and environmental toxicity (i.e. ecotoxicity) of this group of materials and substances has recently started, and draws upon existing knowledge in toxicology, ecotoxicology and environmental sciences in an attempt to predict potential future problems related to spreading of nanomaterials in the environment, notwithstanding, studies of existing nanometer-sized particles of many materials have shown adverse health effects in humans exposed, and animal studies have shown that ultrafine particles are more inflammogenic and tumorigenic than an equal mass of larger particles of similar composition.

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

The REACH regulation is the main legal instrument to protect the environment and health from risk posed by chemicals, as well as to ensure the safety use of chemicals in the European market. Since REACH deals with substances, in whatever size, shape or physical state, **substances at the nanoscale are also covered by REACH and its provisions apply**. This implies that also the safety of nanomaterials to human health and the environment should be ensured under REACH, covering their whole life cycle.

On the basis of the current situation, **activities supporting the implementation of REACH will improve the protection of environment**. In addition, the enhancement of knowledge regarding information on physicochemical, toxicological and ecotoxicological properties of materials and substances at the nanometer scale, as well as exposure, use and risk management measures, will provide new data to support the risk assessment of nanomaterials.

3 Concept and Objectives

3.1 Project Concept

The **REACHnano project deals with the enhancement of knowledge base on risk assessment of nanomaterials** through the identification and evaluation of available information under REACH requirements, as well as with the development of innovative alternatives to support the implementation of chemicals legislation, in particular REACH regulation.

The overall aim of REACHnano project is to improve the protection of environment and health from risk posed by chemicals by supporting the implementation of the REACH regulation with regard to nanomaterials, whose use raise many questions and generate concerns due to their potential health and environmental risks. On the basis of this concept, the following activities will be conducted:

a- Generation of practical information to be used in the context of REACH, including the selection of representative nanoscale materials , the identification of information sources and the characterization of the information requirements to perform the chemical safety assessment (CSA).

b- Characterization of current lack of data to prepare the REACH registration dossier by means of authorized reporting tools (IUCLID 5/Chesar)

c- Characterization of current lack of data to prepare the REACH registration dossier by means of authorized reporting tools (IUCLID 5/Chesar)

d- Design and Development of the web based REACH Toolkit

e- Promotion of REACH fulfilment by implementing REACHnano Toolkit

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3.2 *Project Objetives*

The main objective of the project is to **provide innovative instruments to improve the implementation of REACH when manufacturing or handling materials or substances at the nanometer scal**e through the development of a web based Help Desk tool to support the risk assessment and promote the safety use of nanomaterials along their life cycle, providing the industry and stakeholders with easy to use tools to support the implementation of REACH regulation. This interactive web application will provide an innovative tool to share and exchange information between the scientific community and politicians, enhancing science-policy integration in support of REACH legislation.

In detail, our key aims are:

- To develop a functional and user-friendly web based toolkit to support the implementation of REACH
- To disseminate the project results for a large community of SMEs and potential stakeholders
- To enhance the knowledge base on nanomaterials related risk and risk assessment by means of the collection, evaluation of adequacy and selection of the available information on physicochemical, toxicological and ecotoxicological properties, exposure, use and risk management measures to be provided upon registration
- To demonstrate the effectiveness of REACH regulation to protect the environment and health from risk posed by chemicals, and especially by substances at nanoscale.
- To support the monitoring of REACH compliment and its impact on risk mitigation and prevention of pollution posed by hazardous chemicals.

In summary, the **REACHnano project deals with the set-up of an innovative web application** to improve the protection of environment and health from risk posed by materials and substances at the nanometer scale through the implementation of REACH provisions, and bridge the gaps of knowledge on nanomaterials properties, hazard and exposure.

4 Overall view of the Workplan

The REACHnano project is structured in 5 main actions on the basis of the types of eligible actions under the framework of the LIFE + call.

The scheduled actions and the responsible partner are included in the following table:

Table 1: Scheduled Actions of REACHnano

WP nº	WP Title	Action Leader
Preparatory Actions		
A.1.	Selection of representative nanomaterials	NIA
A.2	Identification of information requirements to complete the CSA of nanomaterials	ITENE
A.3	Identification of information sources	LEITAT
A.4.	Identification of REACHNano Toolkit functionalities	ITENE
Implementation Actions		
B.1.	Compilation, analysis and evaluation of data to be provided upon registration of nanomaterials	ITENE
B.2	Compilation and critical evaluation of possible approaches to assess the risk posed by nanomaterials	LEITAT
B.3	Characterization of current lack of data to prepare the REACH registration dossier by means of authorized reporting tools	ITENE
B.4.	Design and Development of the web based REACH Toolkit	ITENE
B.5.	Development of complementary tools and plugins of the REACHNano Toolkit	ITENE
B.6.	Validation by application end users	ITENE
B.7.	Development of training support materials and training sessions	INVASSAT
Monitioring Action		
C.1.	Definition of the starting situation regarding REACH regulation fulfillment and environmental problems targeted by the project	NIA
C.2.	Strengthening of the knowledge base on nanomaterials properties, and environmental impacts and risk assessment	ITENE
C.3.	Promotion of REACH fulfillment by implementing REACHnano Toolkit	LEITAT
C.4.	Integrative assessment of risk characterization ratios when implementing risk management measures	ITENE

As can be derived from the table, the work plan has been split into 3 types of activities or actions and based. The overall objectives of each activity are explained below:

1. Preparatory Actions

These actions will be focussed on the generation of practical information to be used during the implementation phase, including the selection of representative nanoscale materials, the identification of information sources and the characterization of the information requirements to perform the chemical safety assessment (CSA)

2. Implementation Actions

The implementation action will be focussed on the development of the web application REACHnano Toolkit and its further validation.

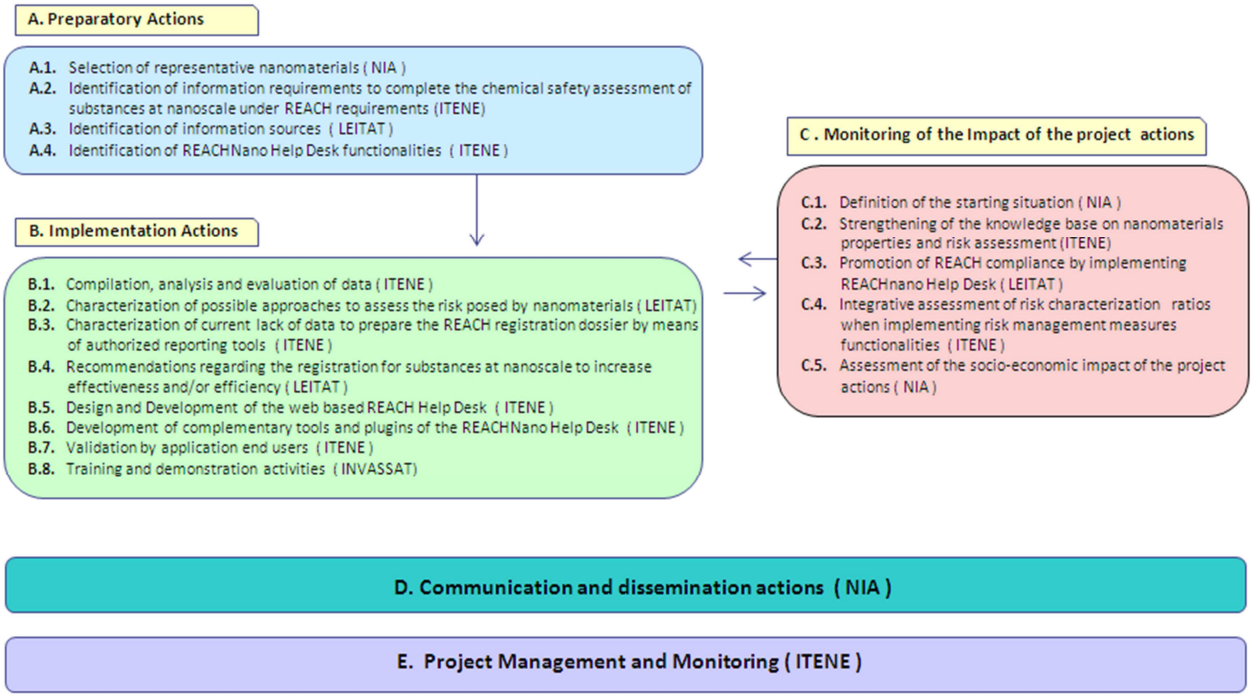
To this end, a complete compilation and evaluation of available data will be conducted to select reliable information to be used in the risk assessment process. Secondly, the current approaches and data requirements of authorized reporting tools will be analysed in depth to provide a strong basis to the further development of the web toolkit. In addition, demonstration and training activities have been considered

3. Monitoring Actions

These actions will be focussed on the monitoring of the improvements addressed by means of the project actions, as well as the adequacy of the developed means to address the specific problems and threats.

Besides the above, in order to achieve an optimal management and use of the Project across the EU, management and dissemination actions are also essential to the success of the REACHnano project.

The scheduled actions and their interdependence are shown schematically below:



5 Advances over the state of the art

Research on environmental impact has merely started, and will face major methodological obstacles regarding detection, characterization and tracing. The first is due to the small size and the complexity of the environments, and the latter to the multitude of NMs that exist and their derivatives.

In relation to the ecotoxicological properties, data on biological effects show that NMs can be toxic to bacteria, algae, invertebrates and fish species, as well as mammals. However, much of the data are limited to species used in regulatory testing and freshwater organism, and quantitative data on ecotoxicological effects are still scarce even at the single organism level. Similarly, data on potential harmful properties on ecosystems are just emerging. In this sense, ecotoxicological studies have not been performed to the level of detail that would enable a high degree of protection, nevertheless, at present, several projects are being carried out within this field (e.g. ENNSATOX, MARINA, NanoFATE, NanoReTox, NEPHH, NanoPolytox or Qnano). In addition, since 2008, the International Consortium for the Environmental Implication of Nanotechnology (iCEINT) is working to assess the potential impacts of NMs on environmental health.

In relation to the progress beyond the current state of the art, **REACHnano project will work on the identification of reliable information to be used to assess the environmental impact of nanomaterials** on the basis of REACH requirements.

In relation to the innovative approach, both **toxicological and ecotoxicological parameters will be placed in a nanomaterials inventory** that will be developed as a complementary tool of the REACHnano help desk.

Besides de above, the inventory will contain reliable information on physicochemical properties, **conditions of use** and **exposure data** that will support the development of exposure scenario and the risk characterization process, enhancing the knowledge base on risk assessment of NMs.

As a key action within the project, the data collected and validated during the previous tasks and actions will be transferred to several IUCLID files (i.e. TiO2 Nanoform.i5z), making the information available to their direct use by registrants, end users and other stakeholders.

On the other hand, the solution proposed, the **REACHnano helpdesk will be a free of charge tool**, including interactive templates to support the risk assessment of nanomaterials in their specific conditions of use.

In addition, our proposal will be designed to enable a continuous actualization, considering also the publication of on line information, latest news on REACH revisions and new findings regarding information on health and enviromental impacts.

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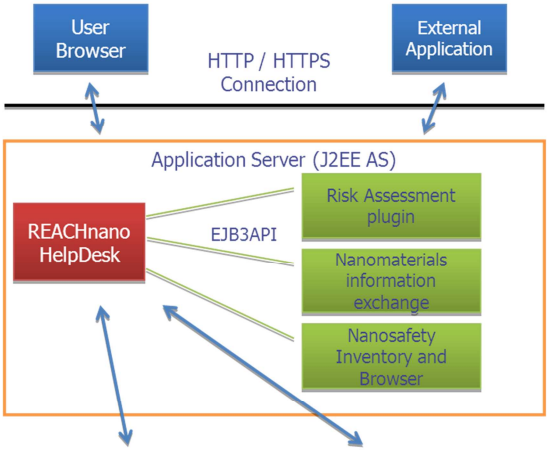
The **project will explore legal and policy issues**, as well as scientific and technical issues, that might arise in the application of the regulatory process related to the use of nanomaterials, in particular REACH regulation. At this stage, the project results will increase the knowledge about the risk to the human health and the environment, supporting the regulatory activities with reliable data to establish new legal requirements to the use of nanomaterials.

The main characteristics and software architecture of the REACHnano Tool can be split as follow:



6 Expected Results

It´s expected to produce the following results:

- Development of a web based toolkit for decision making support on risk assessment and REACH compliment (REACHNano Toolkit), when manufacturing or handling substances at nanoscale,
- Development of a set of 3 complementary tools to support the risk assessment process, information exchangeand the information search process.
- A structured compendium of free Webinars and workshops to support the training of end users and stakeholders in the use of the REACHnano help desk to promote the implementation of REACH
- A set of informative material to disseminate the project actions at a Regional, National and European level.
- A structured compendium of reliable information to be include into the chemical safety assessment report-CSR.
- A complete selection of standard testing models to be used in the risk characterization process
- A complete description of the current exposure scenarios (ES) across the nanomaterials life cycle, including a complete description of the existing operating conditions (OCs), efficient risk management measures (RMMs) and estimated exposure levels (ELs).

7 Progress to date

The project started officially on October 1st 2012 and had its kick-off meeting at the coordinator facilities on October 16.

At the moment, much of the work is concentrated on the selection of relevant nanomaterial under REACH, considering the tonnage band, sectors of use and hazardous properties as main criteria.

On the other hand, several meetings have taken place between partners to define the task under each action, especially between the technical partners ITENE and LEITAT, both involved in the characterization of the risks on the basis of the requirements laid down on REACH regulation.

Finally, the responsible partner for dissemination activities (NIA) is preparing the first brochure of the project, which will be presented jointly with the project web site.

8 Conclusion To-Date & Plan for the Future

The project is an early stage at the moment, but the Partners are working in the definition a set of representative manufactured nanomaterials in the context of REACH, taking into account the scope and exemptions of REACH provisions.

During the first period of 2013, we will identify the information needed for safety assessment and risk management of nanomaterials beyond current REACH information requirements listed in annexes VI to X, as well as any other information needed to prepare a complete dossier and fulfill other obligations such as authorisation procedures or data sharing.

A list of the main milestones to be completed during 2013 is presented below:

Milestone	Number of the associated action
Identification of reliable information resources	A.3
Selection and definition of reliable data on NMs properties	B.1
Definition of relevant testing methods under REACH	B.1
Database on Exposure Scenarios over NMs life cycle	B.1

All the activities described above will be performed with the support of the consortium partners, and relevant stakeholders and industries representatives.

The dissemination related activities will continue with the scheduled task, especially with the preparation of the project web site, which will be the key tool to disseminate the results of the project.

9 Directory

Table 2. Directory of people involved in this project.

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