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INTRODUCTION

The Central Europe project NANOFORCE started on 1st of May 2011 and ran until 31st of January 2014 (33 months). The project aims at better integrating Sciences, Industries, Finance, Management and Public Authorities for the sustainable development of nanotechnologies in Central Europe.

Nanosciences, research & development continuously improve the environmental, health and safety knowledge and performance of technologies, processes and products over their life cycles in order to avoid harm to people and the environment.

NANOFORCE follows the responsible approach towards production, development and eventual commercialisation. This means: to proactively cooperate with the legislators and the competent authorities and to adopt the values and behaviours of transparency of knowledge and prevention of benefits for workers and the consumers. Furthermore NANOFORCE wanted to foster the collaborative and interdisciplinary research on nanomaterials (in the frame of REACH regulation) and to turn the most promising laboratory results into innovative industrial applications.

NANOFORCE Central Europe partnership map

www.nanoforceproject.eu

This project is implemented through the CENTRAL EUROPE Programme co-financed by the ERDF

NANOFORCE OUTPUT BROCHURE

Responsible Use of Nanotechnology & Associated Risk Management

This project is implemented through the CENTRAL EUROPE Programme co-financed by the ERDF

NANOFORCE – State of the Art Report on Existing Safety Procedures and Nanotechnology related Legislation

The State of the Art Report on Existing Safety Procedures and Nanotechnology related Legislation provides an analysis and evaluation of the current regulations for nanomaterials in the European Union. The risks and benefits of nanomaterials are currently being assessed by many research groups, mainly because of the specific effects resulting from their shape, morphology, size, surface area, functionalization, atomic structure and particle chemistry. As part of the process of forming a legal advisory board for chemical enterprises starting up in nanotechnology, an in-depth literature review has been undertaken to illustrate the present status of legislations within the framework of the REACH regulation, also covering directives and amendments in order to identify needs and gaps within the regulatory framework.

To standardize the identification of nanomaterials and open new perspectives on risk assessment and safety regulations, a recommended definition of nanomaterials was presented by the European Commission in 2011. When entering the European market all products are subject to a standard authorization procedure guided by the EU directive on general product safety, which determines the security measures that must be applied to products prior to market placement. For the implementation of nanomaterials on the European market, industry is advised to follow the precautionary principle avoiding any possible dangerous effects on human, animal or plant health and the environment.

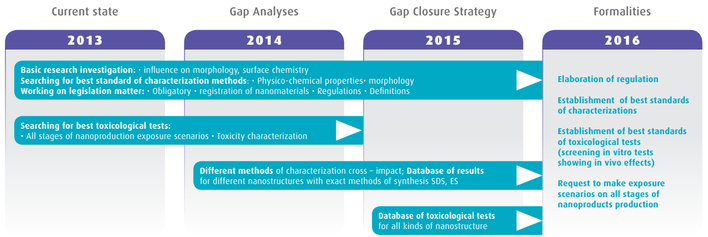
Regarding the regulatory framework for the management of chemicals, REACH is the main legislation in nanotechnology for the overall monitoring of production processes, including substances used in production and market placement of articles. The registration of chemicals manufactured in or imported to the EU, as one of the key elements of REACH, is also applicable for nanomaterials.

Regulations with relevance for nanomaterials include amongst others the following:

1.	Nanomaterials used in cosmetics must be reported to the EU Commission and additionally listed in a catalogue of products placed on the market.
2.	Food containing nanomaterials must include the nanomaterials in the labelled list of ingredients.
3.	For food additives, a change in particle size means that the additive must be considered as a different agent, requiring a new entry in the community list.
4.	For food-contact materials, nanomaterials may only be used following explicit authorization.
5.	Biocidal products using nanomaterials must be labelled as "biocidal material" with the term 'nano' in brackets.
6.	For hazardous substances in electrical and electronic equipment the precautionary principle must be applied, with additional notification provided to the EU commission. The hazardous substances must then substituted by environmentally friendly alternatives, if required.

Within REACH there are still issues to be addressed for nanomaterials on the European market; nevertheless, REACH is the most applicable regulation for nanomaterials. National legislations generally follow EU requirements, although differences can be found, depending on specific nano-initiatives of each nation. The findings of the project NANOFORCE have revealed significant needs in the standardization of the regulatory body for nanomaterials: better implementation and development of simpler and more standardized testing methods; more uniform data collection; better knowledge dissemination; and transparency of data available for stakeholders.

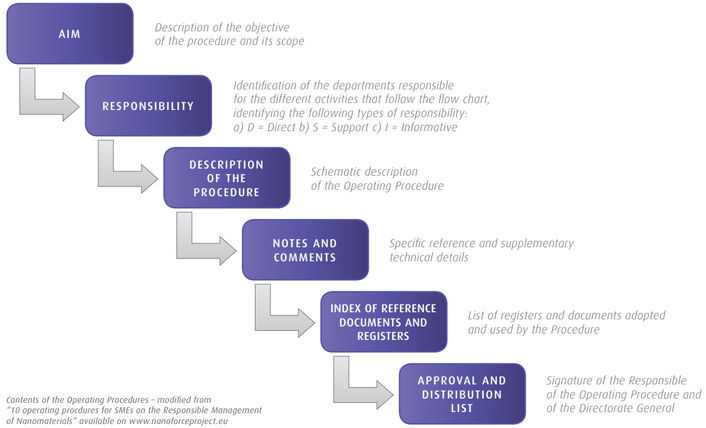
Recommendation Road Map



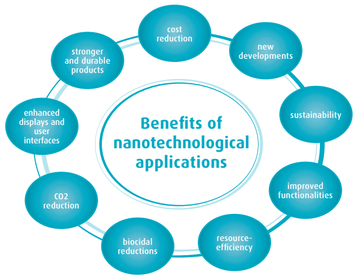
NANOFORCE Recommendation Roadmap for future Nanotechnology-R&D with respect to regulation (NANOFORCE project 2011-2014)

Guidelines for the responsible use/production of nanomaterials

Nanomaterials (natural, incidental and engineered) are used in various applications due to their specific effects resulting from shape, morphology, size including surface area, functionalization, atomic structure and particle chemistry. The use of nanomaterials can be beneficial or harmful to human and environment. It is of great interest of research and development to support the implementation of nanotechnologies in order of being able to profit from the beneficial effects. Nevertheless with great opportunity also risk might appear. Therefore a risk and benefit assessment shall be performed by a set of toxicity testing methods to ensure a safe implementation of nanotechnologies. Within the Central Europe project NANOFORCE a guideline for the responsible use and production has been set up in order to provide a comprehensive overview on the main points of interest on nanomaterials. To raise awareness on specific requirements to fulfil when dealing with nanomaterials in both research and production (with market placement) the NANOFORCE project provides information on operating procedures in nanotechnology implementation.



Contents of the Operating Procedures – modified from "10 operating procdures for SMEs on the Responsible Management of Nanomaterials" available on www.nanoforceproject.eu



In order to plan the implementation of nanotechnology in production all steps of product cycle from manufacturer, supplier, user and downstream users have to be aware of possible risks. The management of the process of production during the whole life cycle of the product needs to be ensured by early risk identification and assessment. Covering environmental, health and safety issues focus has to be laid on waste management, environmental aspects and overall life cycle assessment. Before entering the market, a prototype of the product should be made available to be tested on those aspects. Additionally prototypes can be evaluated for their marketability by the **technology rating methodology** in the NANOFORCE project. Following those principles and respecting the precautionary principle, nanotechnologies can be beneficial not only in application but also in ensuring an economic success within Europe.

Book of Recommendations for the European Commission

The European regulatory framework is growing slowly but steadily, however available regulations and guidance documents miss some details regarding nanotechnological aspects. An established legal advisory board for chemical enterprises starting in nanotechnology provides information on existing safety and nanotech related regulations within the European region including information and guidelines on endpoint measurements for nanomaterials. Within the aim of the Central Europe project NANOFORCE the general objective is to connect public and private organizations, to carry out collaborative and interdisciplinary research on nanomaterials, and to turn the most promising laboratory results into innovative applications or products.

NANOFORCE is providing a set of recommendations collected for the European Commission in order to evaluate the applicability of the available regulations in the European Union. In the light of the revision of the REACH regulation in 2014 the NANOFORCE recommendations should support the European Commission in order to evaluate the current state of guidance for research and industry on nanotechnology implementation. NANOFORCE therefore has collected samples of three nanomaterials of great interest for marketability and provided a data set of lab analysis which led to safety data sheets showing how the tested nanomaterials can be produced and professionally used conforming to safety and users guidelines. Furthermore recommendations are given on how to adapt a regular bulk material safety data sheet to the special requirements of a nano-product focusing on the correct implementation of nano-derived products and market placement.

Results are generated by standardized in vitro testing methods for human toxicity and ecotoxicological testing of nanomaterials like nano-silver, zinc oxide and titanium dioxide. A set of recommendations provided will focus on nano specific information for adaption of safety data sheets. Additionally to these recommendations the safety data sheet and exposure scenarios are examples published to show how to classify material, provide data for in depth life cycle analysis relevant for the end user and additionally provide a draft of qualitative exposure scenarios.

Safety Data Sheets and Exposure Scenarios

Within the NANOFORCE project specific characterisation and toxicological analysis of 3 nanomaterials (TiO2, ZnO, nanoAg) were carried out to evaluate their registration in the context of REACH and to evaluate their potential health and environmental hazards.

Safety Data Sheets (SDS) and Exposure Scenarios (ES) have been developed for those material. Those series of test have been carried out by scientific institutions participating in the project ensuring the comparison of results based on sound science. After performed risk assessment analysis, SDS and specific ES were elaborated to provide all safety concerns and toxicological data concerning potential risks linked to applications of nanotechnology. Furthermore these results lead to the source of the Book of Recommendations and the guideline for the responsible use/production of nanomaterials.

The knowledge gathered within the work of NANOFORCE lead to the following conclusions:

Standard tests for toxicity of materials or chemical substances are not suitable for nano materials.
New test have to be developed.
Nano-science will help to develop new tests for nano-products.
Nano-products environmental and health impacts must be evaluated case by case.
Present knowledge of nano-science tells us that in most cases nanomaterials will agglomerate and or dissolve, and not act on humans or animals as nano-objects.
Precautionary principle is to be regarded from the point of view of the possible negative impact of new regulations in the field of nanotechnology on citizens' health and safety , since they may prevent to implement important new technologies

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