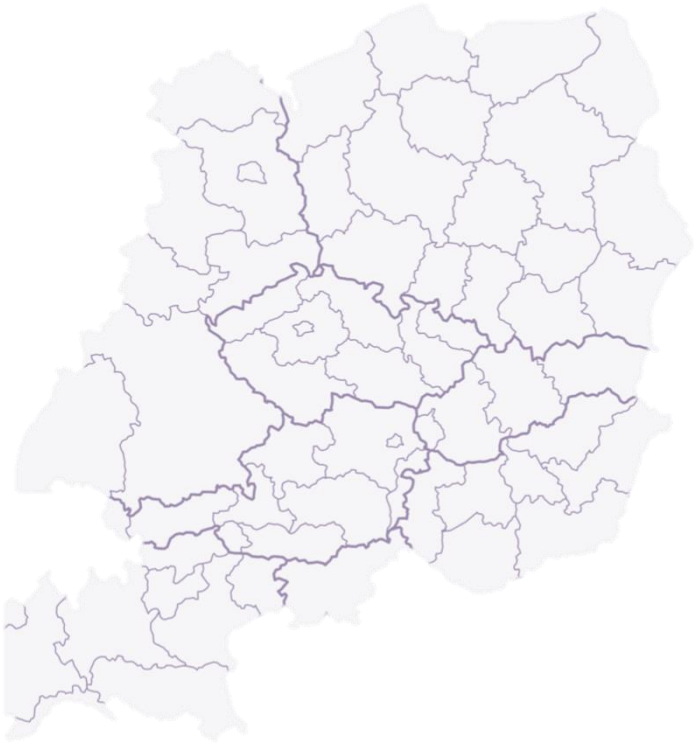
This project is implemented through the CENTRAL EUROPE Programme co-financed by the ERDF.

*"NANOFORCE"*
***Nanotechnology for Chemical Enterprises -how to link scientific knowledge to the business in the Central Europe space***



# GUIDELINES
# for the responsible use/production of nanomaterials

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# Content

# Executive Summary

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.

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.

# 1 Introduction

Despite the considerable amount of work and resources in the nanosafety domain, there are still many unanswered questions that have to be addressed to achieve a safe and sustainable development of nanotechnology in commercial applications. The general objective of the Central Europe project NANOFORCE, which is developed by national and regional chemistry associations and R&D Centres of the Central Europe area, is to foster the innovative nanotechnology-sector networks across Central Europe regions by bringing together public and private organizations to carry out collaborative and interdisciplinary researches on nanomaterials (in the frame of REACH Regulation) and to turn the most promising laboratory results into innovative industrial applications.

The main driving force of nanotechnology is the positive economic impact which is expected. Nanotechnologies have potential to bring fundamental change in whole technological disciplines, with multiple benefits and novel applications for society: *"from energy capture and storage, through water purification solutions to a new generation of lighter and stronger materials for aeronautics"* (etui - European Trade Union Institute & Ponce, 2010). The goal is to build up a framework of guidance to ensure the safe use of nanomaterials throughout the product life cycle. The benefits of nanomaterial use stand in relation to the possible side effects. Especially engineered nanomaterials (ENM) have been within the focus of risk assessment due to increasing use within applications to improve product abilities. Nevertheless one would act judgemental when formulating opinions on a standard harm deriving from ENM use. Besides the harmful possible outcomes of nanomaterial application for human and environment, results have shown certain benefits to be of advantage in means of increase health and welfare.

All attempts should start from the better use of existing results. Several initiatives, represented for instance by FP6 and FP7 projects, or the working groups and sponsorship programmes, have provided significant amount of data on different classes of nanomaterials. This data represent a valuable source of information, and should be deeply analysed to understand and identify the real knowledge gaps to be addressed in the future research and to develop a science based regulation. Another possible outcome of the analysis of these data is the generation of rational grouping and modelling approaches, which should be encouraged with the aim of focussing the testing requirements for companies producing and developing nanomaterials. Moreover, there is a huge pool of guidance documents available on the European market and the most prominent and relevant are provided by the International Organisation for Standardization (ISO) and Organisation for Economic Co-operation and Development (OECD). A list of guidance can be found in the Appendix.

# 2 Recommendations

## 2.1 Responsible Use of Nanomaterials

Effective risk communication strategies are to be developed, taking into account labelling rules and safety documents. This aspect is especially relevant for downstream users, consumers, and organizations dealing with recycling and disposal. There is an issue of communication of potential safety problems linked to nanomaterials use. For example, product safety data sheets should include all nano-relevant information, and consumers should be advised about the appropriate use of

nanoproducts, and disposal requirements. There are projects starting to deal with these issues, but results should be used to implement a nano communication strategy. NANOFORCE has carried out studies on nanomaterials (nanoAg; nanoZnO and nano$TiO_2$) which were directly provided by industry to be tested for the adaption of product safety data sheets (SDS) and exposure scenarios (ES). Recommendations for a nano SDS and information on the tests are provided within the NANOFORCE White Book of Recommendations (www.nanoforceproject.eu). To provide a guideline for the industrial application of nanomaterials, Sviluppo Chimica spa has developed a guide on "10 operating procedures for SMEs on the Responsible Management of Nanomaterials" to be downloaded at the NANOFORCE webpage www.nanoforceproject.eu. The main guidance on operating procedures can be found in figure 1.

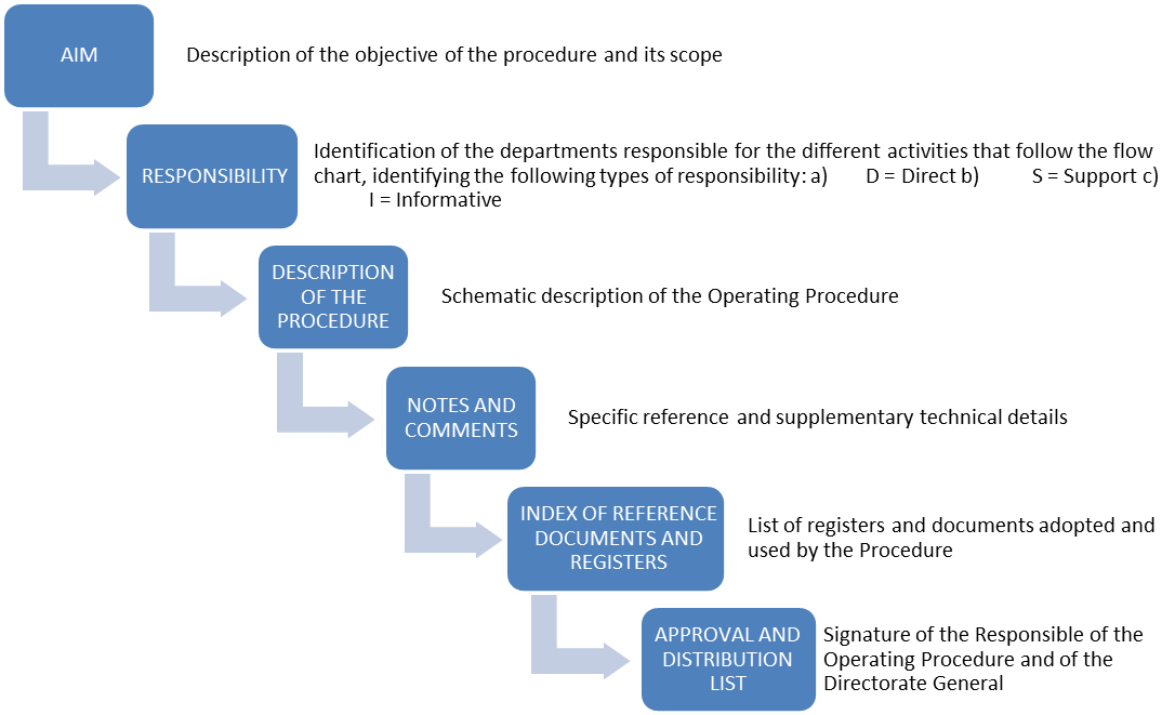


**Figure 1 Contents of the Operating Procedures - modified from "10 operating procedures for SMEs on the Responsible Management of Nanomaterials" available on www.nanoforceproject.eu**

In short summary – stakeholders should follow a principal five step approach when getting in contact with nanomaterials:

1. Verify: Am I using a nanomaterial? – Recommendation for a definition provided by the European Commission: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:de:PDF]
2. Safety Data Sheet: Collect relevant supplier and manufacturer information on the material/product and adapt SDS according to recommendations www.nanoforceproject.eu.
3. Verify: Application permission to be used (information provided by SDS) refer to www.reachhelpdesk.at
4. Exposure Scenario development: Review of the used descriptors, operational conditions and risk management measurements in the exposure scenarios (appendix of a safety data sheet)
5. Be aware: Are there specific regulations and guidelines applicable (e.g. cosmetics, biocides, food, electronic equipment…) – refer to State of the Art Report Existing Safety Procedures and Nanotech Related Legislation www.nanoforceproject.eu.

## 2.2 Research and Development

Toxicity assessment of ENM can be carried out by a variety of methods, established and/or adapted over the past decade in the frame of several research projects. An overall of 30 research projects are counted in the NanoSafety cluster, an initiative to foster collaborations between European research on emerging nanotechnologies, with different aims focusing on safety research, method development, regulatory testing, standardisation, dissemination, communication, outreach and many more (NanoSafety Cluster, Riediker, & Katalagarianakis, 2012). Within several working programs, papers and database the OECD and other research institutions and programs have provided a high volume of information to assist collaborative research within nanotechnology safe development (OECD, 2010).

As in many other fields, health and safety is mostly dependent on European legislation. Without uniform EU law any research on health and safety issues will be inadequate. Furthermore, it is an artificial grouping of materials just by its grains size and amount of nano-sized fraction. Some nanomaterials do not present new properties, but only enhanced manifestation of bulk materials of the same composition. And sometimes new property is present (e.g. nano-silver). Hence it's inappropriate to put them in one category (e.g. "metal oxides") and apply the same influence assessment methods. Therefore, until definition of nanomaterials is improved and proper methods of assessment have been chosen, it is hard to invest in research at this point just to find in several years, that obtained results are worthless.

Within NANOFORCE several working groups and joint working tables including stakeholders from industry, research, public authorities and consumer experts have been carried out in the focus of evaluating the health and safety approach of nanotechnologies. Nanomaterials are perceived as hazardous by approximately half of interviewed stakeholders, with some differences among research institutions and industry. In industry, the hazardousness is more perceived than in research institutions, and the main reasons are related to the inherent properties of the nanomaterials (size, toxicity). However, industry is also paying attention to the use of parameters to assess the hazard for workers, consumers and environment by at least thinking and being aware of exposure assessment and the need to make a case-by-case assessment. In general, exposure is not yet prevailing, neither in research lab nor in industry production areas or in the external environment. In this case, exposure scenarios, even if simple, could help to explain and prove in a scientific way why exposure is or is not happening, and could reduce unnecessary further research on toxicology of nanomaterials. One solution could be to foster the agreement to voluntary safety certification by industry, thus including at least qualitative exposure scenarios as a prerequisite.

So far, in general, the participation to toxicology projects is limited to the research institutions, and industry is only providing the material to be tested. Also the development of new tests and the validation of existing protocols are only done by research institutions, as it could be expected. Concerning safety, due to the lack of nano-specific guidelines, some big companies are working with their European industry association to develop specific guidelines, but mostly, SMEs are not able to do the same. Therefore, a national and/or regional support is required within a European framework, with the help of research centres and institutions.

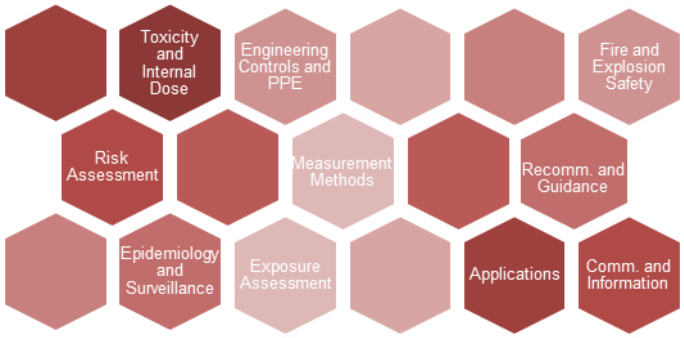


**Figure 2 NIOSH - 10 critical topic areas in nanotechnology application; modified from** (CDC & NIOSH, 2013)

In order to implement the NIOSH critical areas in nanotechnology applications (to be found in figure 2), the ITS Nano community has published a guideline on a toxicological assessment strategy to test nanomaterials on their safety. To overview data being launched by key players like the OECD and REACH guidance the "Intelligent Testing Strategies" ITS NANO has been formed. Within this project "Intelligent Testing Strategies for Engineered Nanomaterials" should be provided following the approach of physicochemical characterisation, exposure and hazard assessment to form an integrated research approach. Based on investigation several recommendations can be given (Stone et al., 2013):

- Method fidelity: Toxicity assessment of nanoparticles should include the same steps as toxicity assessment of other substances (e.g. bulk material).
- Distribution: Toxicity assessment of nanoparticles behaviour in human body and distribution has to be studied. Human cell barrier models (cell-line studies) should be used to determine the transportation, penetration and accumulation of nanomaterials.
- Exposure: Furthermore, nanomaterials used in products have to be tested on release and migration under specific conditions, identified through life-cycle analysis.

## 2.3 The Nanotech Market

A multitude of different engineered nanomaterials are already commercially available and are being used in many consumer products. A selection of the wide variety of their benefits are shown in figure 3.


**Figure 3 Benefits of nanotechnological applications**

In the long-term strategic document on research and Innovation - 'Horizon 2020' - the European Commission has suggested that nanotechnology could be one of the **key enabling technologies (KET)** for our future: *its uses will contribute to improve Europe's global competitiveness and respond to key social challenges. The safe and sustainable development and application of the nanotechnologies is therefore an important objective* (EU-Horizon 2011)[1]. Many benefits have been determined due to the great feature of nanotechnology to represent a multidisciplinary interaction of many specialised disciplines of the natural sciences.

The size of market of nanotechnologies is difficult to determine representing a main obstacle for development. In many sectors nanomaterials are already being used (cosmetics, paints and coatings, polymers) but since the EU has taken so much time to define nanomaterials and the EU's approach to them companies are reluctant to advertise or even admit that they are using nanomaterials in their products. Approximately 20% of worldwide produced goods will in some extent be based on nanotechnology until 2020 raising the global volume for products derived from nanotechnology from €200 billion in 2009 to €2.5 trillion by 2015 (Roco, 2011). Many different focus areas can be discovered due to the complexity of broad term 'nanotechnology', such as cosmetic, food, food contact material, biocidal products, plant protection products, waste, energy, bio engineering, etc. The development of *"nanomaterials, nanodevices and nanosystems is aiming at fundamentally new*

[1] http://ec.europa.eu/research/horizon2020/index_en.cfm
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0808:FIN:en:PDF
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0811:FIN:en:PDF

*products enabling sustainable solutions in wide range of sectors"* (European Commission, 2011). These new and improved products and processes will allow companies to innovate and enter new markets. 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 of *'doing your best to avoid possible negative side effects of nanotechnologies'*, and certainly avoiding any possible dangerous effects on human, animal or plant health and the environment. Nevertheless, 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. This 'precautionary principle' is laid down in Article 191(2) of the Treaty on the Functioning of the European Union, as well as in the laws of several European countries (such as Article 20a of the German Constitution). The international principle of sustainable development is also part of the 'Rio Declaration' (UNEP - United Nations Environment Program, 1992), where Principle No. 15 states: *"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."*

In the past, commercial activities could only be restricted on environmental or health grounds when it could be demonstrated that they caused – or were very likely to cause – harm. Following negative experience (from exposures to lead additives, CFCs, PCBs, Bisphenol A, mercury, etc.), it is now widely accepted that - subject to a cost-benefit analysis - risks to human health and the environment should also be averted on a 'precautionary basis' even if there is still a lack of experiments and scientific findings to show that the respective substance causes harm (Calliess & Stockhaus, 2012). In a judgment of the European Court of Justice (Commission vs. France concerning food safety) in 2010, the judges declared that the precautionary principle permits regulatory action *"where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted"*, provided that there has been "*first, identification of the potentially negative consequences for health of the proposed use of processing aids, and, secondly, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research"* (European Court of Justice, 2010).


**Figure 4 Benefits of Standardisation; modified from** (ISO, 2013)

Besides the benefits of nanoproducts, when talking about their use and production one of the most important factors to be taken into consideration is standardisation in order to be able to e.g. read across data from different research and development groups. Benefits leading from standardized procedures in nanomaterial production and analysis are shown in figure 4 and adapted according to ISO guidelines. However, to ensure the possibility to read across, a crucial step is that data are achieved with common protocols; a recently published document published by the Danish Environmental Protection Agency (The Danish Environmental Protection Agency, 2013) reviews several of the endpoints used for the regulatory registration of chemicals and the applicability of the test methods used to achieve them to nanomaterials. In addition, several ongoing research initiatives in Europe, for instance the MARINA and NANOVALID research projects, are still validating research tests, to develop SOPs to be adopted also for regulatory testing. The use of harmonised protocols is of paramount importance for the achievement of data that is comparable for the development of grouping and modelling approaches. It is important to point out that such grouping approaches can go beyond the traditional grouping according physicochemical characteristics, but should include exposure routes and toxicological behaviours. Grouping should be developed not only for nanomaterials, but also for the nano-products themselves. The goal is to assess the increased or decreased hazard given by the nano implementation during the product life cycle, and find commonalities between different products. This work would allow the performance of life cycle risk assessment (always linked to a product or a group of products) and to allow an appropriate risk management of end of life phases, and an effective risk communication.

So it is important, both for research and regulation of nanomaterials, to be more product-oriented. The mean to achieve this is the development of a testing strategy that covers the whole life cycle of the nanomaterial, hence applying a cradle-to-grave approach. As indeed highlighted into several documents and scientific papers, both the usage and wasting conditions, and the activity of environmental stressors, are able to modify the physicochemical characteristics of nanomaterials, hence potentially influencing their environmental fate, and their toxicological behaviours. Therefore, while regulation should address this issue, research in parallel should identify when modifications during the life cycle are enough to trigger the necessity of a novel risk assessment.
Concerning hazard testing, a shift in the toxicology testing is required. Toxicology testing shall indeed take an increasing advantage of 21$^{st}$ century tools, in particular High-Content and High-Throughput tools, to have a faster and more informative description of the toxicological feature of each material, with also the perspective of reducing the costs.

Nevertheless, as long as EU on one hand fosters initiatives concerning nanotechnologies and gives strong signals that nanomaterials are considered as dangerous and possibly hazardous, no one will be really encouraged to invest in them. Therefore, to overcome possible obstacles, a prototype evaluation is provided by the NANOFORCE project. Using a technology rating methodology (available on www.nanoforceproject.eu) the marketability of a product can be estimated and possible pitfalls and troubles show before risking a negative consumer perception and failure in market acceptance.

# 3 Regulations and Societal Aspects of Nanotechnologies

**Regulations: Nanotechnology in the Frame of REACH**

As result of the gradually increasing nanotechnology sector there is the necessity of a contemporary analysis of the present regulations used for nanomaterials, to outline the current situation of the nanotechnology sector, to promote international cooperation and research's coordination to overcome disciplinary boundaries, to fill the gap between more and less experienced regions and to turn investments in R&D in industrial innovations.

The recent Second Regulatory Review on Nanomaterials (European Commission, 2012), published by the European Commission in October 2012, suggests that the risk assessment of nanomaterials should still be performed on a case-by-case basis; however, while this approach still is crucial to fill several knowledge gaps that are still existing in the whole nano-risk assessment procedure, a strategy to achieve the possibility of a read-across between results achieved into different projects has to be promoted. In addition the method selection in order to test the safety of nanomaterials and/or nanoproducts should be depending on the planed use of the nanomaterials and the methods used should be well described documented and preferably standardized. Furthermore tests have to be performed on nanomaterials concerning their life cycle (Bleeker et al., 2013). Using different methods of measurements it should be taken into consideration that nanoparticles interact with environment and can change their properties (Pettitt & Lead, 2013).

Not only regulations but several guidelines with focus on needs of the good implementation of nanomaterials in products including a safe market placement are placed at disposal for consumers and producers to help ensuring the correct use of the new technology. Safety research and standardization - addressed via bottom-up approach by consolidation of national expertise - shall assist the safe implementation of nanotechnological applications and products. However, findings of NANOFORCE have shown significant needs in the standardisation of the regulatory body for nanomaterials, a better implementation and development of simple and standardized testing methods, a uniform data collection and harmonization tools for a better knowledge dissemination and transparency for data to be available for stakeholders. More information can be found in the State of the Art Report Existing Safety Procedures and Nanotech Related Legislation and further guidance is published in the NANOFORCE White Book of recommendations for the European Commission[2].

[2] download: www.nanoforceproject.eu

**Social and Ethical implications**

The awareness of nanotechnologies in daily life has increased steadily and is being shown by a recent study of the BASF Dialogforum NANO (2011/2012). One of the focal points in the discussion was the warranty of safety based on nano products for humans and the environment. Especially items that are in direct contact with the consumer are of particular interest e.g. textile products using nano-silver for anti-bacterial effects (Grobe & Rissanen, 2013).

Some consumers are concerned with possible risk that use of nanomaterials carries to environment and living organisms. This is reflected for example by cosmetics companies avoiding to advertise or even mark their products as “containing nano”. But on the other hand textile products containing nanosized silver are quite popular. It may seem that nanotechnology is more welcome when it is considered “locked” and risk of digestion or release to environment is minimal. Other factor is familiarity with the product and cement is a good example here. This product is being used for centuries and for a long time it is known, than the smaller the particles are, the better properties it presents and the best quality cement contains large amount of nanoparticles. But since we use it for long period of time, public perception of it is not as it was a nanotechnological product.

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# 5 Appendix

Standardisation is one of the key elements in research and development to provide reproducible results. The following ISO-standard- as well as OECD-guideline-searches have been conducted between July 24th to August 13th 2013.

## 5.1 ISO-Standards

The ISO has published several standardization documents to be used by companies, researcher and other stakeholders. Focusing on market needs, the ISO guidelines provide tailored information on how to safe handle nanotechnologies based on in depth expert dialogue and inclusion of multi-stakeholder opinions. Further information on the work of ISO and its benefits for the safe implementation of nanotechnologies for research and industry can be found at www.iso.org (ISO, 2013).

**ISO Standardisation Guidelines www.iso.org**

| **ISO - Standards** | | |
|---|---|---|
| **Search: "nano" (Published)** | | |
| 1 | **ISO/TC 229** | Nanotechnologies |
| 2 | **ISO/TS 80004-3:2010** | Nanotechnologies - Vocabulary - Part 3: Carbon nano-objects |
| 3 | **ISO/TS 12805:2011** | Nanotechnologies - Materials specifications - Guidance on specifying nano-objects |
| 4 | **ISO/TS 12025:2012** | Nanomaterials - Quantification of nano-object release from powders by generation of aerosols |
| 5 | **ISO/TS 16195:2013** | Nanotechnologies - Guidance for developing representative test materials consisting of nano-objects in dry powder form |
| 6 | **ISO 14577-1:2002** | Metallic materials - Instrumented indentation test for hardness and materials parameters - Part 1: Test method |
| 7 | **ISO 14577-4:2007** | Metallic materials - Instrumented indentation test for hardness and materials parameters - Part 4: Test method for metallic and non-metallic coatings |
| 8 | **ISO 9277:2010** | Determination of the specific surface area of solids by gas adsorption - BET method |
| 9 | **ISO/TS 12901-1:2012** | Nanotechnologies - Occupational risk management applied to engineered nanomaterials - Part 1: Principles and approaches |
| 10 | **ISO/TS 80004-4:2011** | Nanotechnologies - Vocabulary - Part 4: Nanostructured materials |
| 11 | **ISO/TR 14187:2011** | Surface chemical analysis - Characterization of nanostructured materials |
| 12 | **ISO/TR 11360:2010** | Nanotechnologies - Methodology for the classification and categorization of nanomaterials |
| 13 | **ISO/TR 27628:2007** | Workplace atmospheres - Ultrafine, nanoparticle and nano-structured aerosols - Inhalation exposure characterization and assessment |
| 14 | **ISO/TS 27687:2008** | Nanotechnologies - Terminology and definitions for nano-objects - Nanoparticle, nanofibre and nanoplate |
| 15 | **ISO/TR 11811:2012** | Nanotechnologies - Guidance on methods for nano- and microtribology measurements |
| 16 | **ISO/TS 80004-5:2011** | Nanotechnologies - Vocabulary - Part 5: Nano/bio interface |

| | | |
|---|---|---|
| **Search: "nano" (Under development)** | | |
| 1 | **ISO/PRF TS 80004-6** | Nanotechnologies - Vocabulary - Part 6: Nano-object characterization |
| 2 | **IEC/NP TS 80004-2** | Nanotechnologies - Vocabulary - Part 2: Nano-objects: Nanoparticle, nanofibre and nanoplate |
| 3 | **ISO/DTR 14786** | Nanotechnologies - Framework for nomenclature models for nano-objects |
| 4 | **ISO/AWI TS 80004-9** | Nanotechnologies - Vocabulary - Part 9: Nano-enabled electrotechnical products and systems |
| 5 | **ISO/AWI TS 80004-10** | Nanotechnologies - Vocabulary - Part 10: Nano-enabled photonic components and systems |
| 6 | **ISO/PRF TS 13830** | Nanotechnologies - Guidance on voluntary labelling for consumer products containing manufactured nano-objects |
| 7 | **ISO/AWI TR 18196** | Nanotechnologies - Measurement method matrix for nano-objects |
| 8 | **ISO/AWI TR 18637** | General framework for the development of occupational exposure limits for nano-objects and their aggregates and agglomerates |
| | | |
| **Total number of published ISO standards related to the TC and its SCs (number includes updates): 35** | | |
| 1 | **ISO/TS 10797:2012** | Nanotechnologies - Characterization of single-wall carbon nanotubes using transmission electron microscopy |
| 2 | **ISO/TS 10798:2011** | Nanotechnologies - Characterization of single-wall carbon nanotubes using scanning electron microscopy and energy dispersive X-ray spectrometry analysis |
| 3 | **ISO 10801:2010** | Nanotechnologies - Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method |
| 4 | **ISO 10808:2010** | Nanotechnologies - Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing |
| 5 | **ISO/TS 10867:2010** | Nanotechnologies - Characterization of single-wall carbon nanotubes using near infrared photoluminescence spectroscopy |
| 6 | **ISO/TS 10868:2011** | Nanotechnologies - Characterization of single-wall carbon nanotubes using ultraviolet-visible-near infrared (UV-Vis-NIR) absorption spectroscopy |
| 7 | **ISO/TR 10929:2012** | Nanotechnologies - Characterization of multiwall carbon nanotube (MWCNT) samples |
| 8 | **ISO/TS 11251:2010** | Nanotechnologies - Characterization of volatile components in single-wall carbon nanotube samples using evolved gas analysis/gas chromatograph-mass spectrometry |
| 9 | **ISO/TS 11308:2011** | Nanotechnologies - Characterization of single-wall carbon nanotubes using thermogravimetric analysis |
| 10 | **ISO/TR 11360:2010** | Nanotechnologies - Methodology for the classification and categorization of nanomaterials |
| 11 | **ISO/TR 11811:2012** | Nanotechnologies - Guidance on methods for nano- and microtribology measurements |
| 12 | **ISO/TS 11888:2011** | Nanotechnologies - Characterization of multiwall carbon nanotubes - Mesoscopic shape factors |

| | | |
|---|---|---|
| 13 | **ISO/TS 11931:2012** | Nanotechnologies - Nanoscale calcium carbonate in powder form - Characteristics and measurement |
| 14 | **ISO/TS 11937:2012** | Nanotechnologies - Nanoscale titanium dioxide in powder form - Characteristics and measurement |
| 15 | **ISO/TS 12025:2012** | Nanomaterials - Quantification of nano-object release from powders by generation of aerosols |
| 16 | **ISO/TR 12802:2010** | Nanotechnologies - Model taxonomic framework for use in developing vocabularies - Core concepts |
| 17 | **ISO/TS 12805:2011** | Nanotechnologies - Materials specifications - Guidance on specifying nano-objects |
| 18 | **ISO/TR 12885:2008** | Nanotechnologies - Health and safety practices in occupational settings relevant to nanotechnologies |
| 19 | **ISO/TS 12901-1:2012** | Nanotechnologies - Occupational risk management applied to engineered nanomaterials - Part 1: Principles and approaches |
| 20 | **ISO/TR 13014:2012** | Nanotechnologies - Guidance on physicochemical characterization of engineered nanoscale materials for toxicologic assessment |
| 21 | **ISO/TR 13014:2012/Cor 1:2012** | |
| 22 | **ISO/TR 13121:2011** | Nanotechnologies - Nanomaterial risk evaluation |
| 23 | **ISO/TS 13278:2011** | Nanotechnologies - Determination of elemental impurities in samples of carbon nanotubes using inductively coupled plasma mass spectrometry |
| 24 | **ISO/TR 13329:2012** | Nanomaterials - Preparation of material safety data sheet (MSDS) |
| 25 | **ISO/TS 14101:2012** | Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening: FT-IR method |
| 26 | **ISO/TS 16195:2013** | Nanotechnologies - Guidance for developing representative test materials consisting of nano-objects in dry powder form |
| 27 | **ISO/TS 17200:2013** | Nanotechnology - Nanoparticles in powder form - Characteristics and measurements |
| 28 | **ISO/TS 27687:2008** | Nanotechnologies - Terminology and definitions for nano-objects - Nanoparticle, nanofibre and nanoplate |
| 29 | **ISO 29701:2010** | Nanotechnologies - Endotoxin test on nanomaterial samples for in vitro systems - Limulus amebocyte lysate (LAL) test |
| 30 | **IEC/TS 62622:2012** | Artificial gratings used in nanotechnology - Description and measurement of dimensional quality parameters |
| 31 | **ISO/TS 80004-1:2010** | Nanotechnologies - Vocabulary - Part 1: Core terms |
| 32 | **ISO/TS 80004-3:2010** | Nanotechnologies - Vocabulary - Part 3: Carbon nano-objects |
| 33 | **ISO/TS 80004-4:2011** | Nanotechnologies - Vocabulary - Part 4: Nanostructured materials |
| 34 | **ISO/TS 80004-5:2011** | Nanotechnologies - Vocabulary - Part 5: Nano/bio interface |
| 35 | **ISO/TS 80004-7:2011** | Nanotechnologies - Vocabulary - Part 7: Diagnostics and therapeutics for healthcare |
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| **Standards under development** | | |
| 1 | **ISO/DTS 12901-2** | Nanotechnologies - Occupational risk management applied to engineered nanomaterials - Part 2: Use of the control banding approach |

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| 2 | **ISO/PRF TS 13830** | Nanotechnologies - Guidance on voluntary labelling for consumer products containing manufactured nano-objects |
| 3 | **ISO/DTR 14786** | Nanotechnologies - Framework for nomenclature models for nano-objects |
| 4 | **ISO/NP TR 16196** | Nanotechnologies - Guidance on sample preparation methods and dosimetry considerations for manufactured nanomaterials |
| 5 | **ISO/NP TR 16197** | Nanotechnologies - Guidance on toxicological screening methods for manufactured nanomaterials |
| 6 | **ISO/DTS 16550** | Nanoparticles - Determination of muramic acid as a biomarker for silver nanoparticles activity |
| 7 | **ISO/NP TR 17302** | Nanotechnologies - Framework for identifying vocabulary development for nanotechnology applications in human healthcare |
| 8 | **ISO/NP TS 17466** | Use of UV-Vis absorption spectroscopy in the characterization of cadmium chacolgate semiconductor - Nanoparticles (Quantum dots) |
| 9 | **ISO/NP TS 18110** | Nanotechnologies - Vocabularies for science, technology and innovation Indicators |
| 10 | **ISO/AWI TR 18196** | Nanotechnologies - Measurement method matrix for nano-objects |
| 11 | **ISO/AWI TR 18401** | Nanotechnology - Plain language guide to vocabulary |
| 12 | **ISO/AWI TR 18637** | General framework for the development of occupational exposure limits for nano-objects and their aggregates and agglomerates |
| 13 | **ISO/AWI TS 18827** | Nanotechnologies - Comparing the toxic mechanism of synthesized zinc oxide nanomaterials by physicochemical characterization and reactive oxygen species properties |
| 14 | **ISO/AWI 19006** | Effects of nanoparticles on cell oxidative stress |
| 15 | **ISO/AWI 19007** | Effects of nanoparticles on cell viability |
| 16 | **ISO/NP TR 19057** | The use and suitability of In Vitro Tests and Methodologies to assess Nanomaterial Biodurability |
| 17 | **IEC/CD TS 62607-2-1** | Nanomanufacturing - key control characteristics for CNT film applications - Resistivity |
| 18 | **ISO/TS 80004-1:2010/AWI Amd 1** | |
| 19 | **IEC/NP TS 80004-2** | Nanotechnologies - Vocabulary - Part 2: Nano-objects: Nanoparticle, nanofibre and nanoplate |
| 20 | **ISO/PRF TS 80004-6** | Nanotechnologies - Vocabulary - Part 6: Nano-object characterization |
| 21 | **ISO/DTS 80004-8** | Nanotechnologies - Vocabulary - Part 8: Nanomanufacturing processes |
| 22 | **ISO/AWI TS 80004-9** | Nanotechnologies - Vocabulary - Part 9: Nano-enabled electrotechnical products and systems |
| 23 | **ISO/AWI TS 80004-10** | Nanotechnologies - Vocabulary - Part 10: Nano-enabled photonic components and systems |
| 24 | **ISO/WD TS 80004-11** | Nanotechnologies - Vocabulary - Part 11: Nanolayer, nanocoating, nanofilm, and related terms |
| 25 | **ISO/WD TS 80004-12** | Nanotechnologies - Vocabulary - Part 12: Quantum phenomena in nanotechnology |

## 5.2 OECD-Guidelines

The OECD has taken up the ISO/TC 229 definition on nanomaterials – therefore the guideline documents are being established in close collaboration with the ISO standardisation body. Within several working programmes, papers and database the OECD and other research institutions and programmes have provided a high volume of information to assist collaborative research within nanotechnology safe development (OECD, 2010).

**OECD Guidelines documents**

http://www.oecd.org/env/ehs/nanosafety/publicationsintheseriesonthesafetyofmanufacturednanomaterials.htm

| **OECD Guidelines** | |
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| **No. 01 - ENV/JM/MONO(2006)19** | Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication, 7-8 December 2005 |
| **No. 02 - ENV/JM/MONO(2006)35** | Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 1st Meeting of the Working Party on Manufactured Nanomaterials, 26-27 October 2006 |
| **No. 03 - ENV/JM/MONO(2007)16** | Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de table at the 2nd Meeting of the Working Party on Manufactured Nanomaterials, 25-27 April 2007 |
| **No. 04 - ENV/JM/MONO(2008)2** | Manufactured Nanomaterials: Programme of Work 2006-2008 |
| **No. 05 - ENV/JM/MONO(2008)7** | Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de Table at the 3rd Meeting of the Working Party on Manufactured Nanomaterials, 28-30 November 2007 |
| **No. 06 - ENV/JM/MONO(2008)13/REV (This document has been updated)** | List of Manufactured Nanomaterials and List of Endpoints for Phase One of the OECD Testing Programme |
| **No. 07 - ENV/JM/MONO(2008)29** | Current Developments/ Activities on the Safety of Manufactured Nanomaterials: Tour de Table at the 4th Meeting of the Working Party on Manufactured Nanomaterials, 11-13 June 2008 |
| **No. 08 - ENV/JM/MONO(2009)6** | Preliminary Analysis of Exposure Measurement and Exposure Mitigation in Occupational Settings: Manufactured Nanomaterials |
| **No. 09 - ENV/JM/MONO(2009)10** | EHS Research Strategies on Manufactured Nanomaterials: Compilation of Outputs |
| **No. 10 - ENV/JM/MONO(2009)15** | Identification, Compilation and Analysis of Guidance Information for Exposure Measurement and Exposure Mitigation: Manufactured Nanomaterials. |
| **No. 11 - ENV/JM/MONO(2009)16** | Emmision Assessment for Identification of Sources and Release of Airborne Manufactured Nanomaterials in the Workplace: Compilation of Existing Guidance |
| **No. 12 - ENV/JM/MONO(2009)17** | Comparison of Guidance on Selection of Skin Protective Equipment and Respirators for Use in the Workplace: Manufactured Nanomaterials |
| **No. 13 - ENV/JM/MONO(2009)18** | Report of an OECD Workshop on Exposure Assessment and Exposure Mitigation: Manufactured Nanomaterials |

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| **No. 14 - ENV/JM/MONO(2009)20 (This document has been updated)** | Guidance Manual for the Testing of Manufactured Nanomaterials: OECD's Sponsorship Programme |
| **No. 15 - ENV/JM/MONO(2009)21** | Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials |
| **No. 16 - ENV/JM/MONO(2009)22** | Manufactured Nanomaterials: Work Programme 2009- 2012 |
| **No. 17 - ENV/JM/MONO(2009)23** | Current Developments in Delegations and other International Organisations on the Safety of Manufactured Nanomaterials- Tour de Table at the 5th Meeting of the Working Party on Manufactured Nanomaterials |
| **No. 18 - ENV/JM/MONO(2009)24** | Manufactured Nanomaterials: Roadmap for Activities during 2009 and 2010 |
| **No. 19 - ENV/JM/MONO(2009)45** | Analysis of Information Gathering Initiatives on Manufactured Nanomaterials |
| **No. 20 - ENV/JM/MONO(2010)4** | Current Developments/Activities on the Safety of Manufactured Nanomaterials: Tour de Table at the 6th Meeting of the Working Party on Manufactured Nanomaterials, 28-30 October 2009 |
| **No. 21 - ENV/JM/MONO(2010)10** | Report of the Workshop on Risk Assessment of Manufactured Nanomaterials in a regulatory context, held on 16-18 September 2009, in Washington D.C.,United States. |
| **No. 22 - ENV/JM/MONO(2010)11** | OECD Programme on the Safety of Manufactured Nanomaterials 2009-2012 Operational Plans of the Projects |
| **No. 23 - ENV/JM/MONO(2010)12** | Report of the Questionnaire on Regulatory Regimes for Manufactured Nanomaterials (2010) |
| **No. 24 - ENV/JM/MONO(2010)25** | Preliminary Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials |
| **No. 25 - ENV/JM/MONO(2009)20/REV** | Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First Revision |
| **No. 26 - ENV/JM/MONO(2010)42** | Current Developments/Activities on the Safety of Manufactured Nanomaterials, Tour de Table at the 7th Meeting of the Working Party on Manufactured Nanomaterials |
| **No. 27 - ENV/JM/MONO(2010)46** | List of Manufactured Nanomaterials and List of Endpoints for Phase One of the Sponsorship Programme for the Testing of Manufactured Nanomaterials: Revision |
| **No. 28 - ENV/JM/MONO(2010)47** | Compilation and Comparison of Guidelines Related to Exposure to Nanomaterials in Laboratories |
| **No. 29 - ENV/JM/MONO(2011)12** | Current Developments/Activities on the Safety of Manufactured Nanomaterials - Tour de Table at the 8th Meeting of the Working Party on Manufactured Nanomaterials |
| **No. 30 - ENV/JM/MONO(2011)52** | Regulated Nanomaterials: 2006-2009 |
| **No. 31 - ENV/JM/MONO(2011)53** | Information Gathering Schemes on Nanomaterials: Lessons Learned and Reported Information |
| **No. 32 - ENV/JM/MONO(2011)54** | National Activities on Life Cycle Assessment of Nanomaterials |
| **No. 33 - ENV/JM/MONO(2012)8** | Important Issues on Risk Assessment of Manufactured Nanomaterials |
| **No. 34 - ENV/JM/MONO(2012)13** | Current Developments on the Safety of Manufactured Nanomaterials - Tour de Table at the 9th Meeting of the Working Party on Manufactured Nanomaterials |

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| **No. 35 - ENV/JM/MONO(2012)14** | Inhalation Toxicity Testing: Expert Meeting on Potential Revisions to OECD Test Guidelines and Guidance Document |
| **No. 36 - ENV/JM/MONO(2012)40** | Guidance on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials |
| **No. 37 - ENV/JM/MONO(2013)2** | Current Developments on the Safety of Manufactured Nanomaterials - Tour de Table at the 10th Meeting of the Working Party on Manufactured Nanomaterials |