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# Nanoparticles: Aspects of Safety and Risk Management

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**Abstract**
Synthetic nanoparticles are within the scope of the existing chemical law in Europe (REACH). However, the present knowledge is not yet sufficient for the elaboration of nano-specific regulations. Many projects with the aim of completing the necessary scientific and technical basis for the assessment of nanotechnology related risks are under way. Under these circumstances voluntary safety standards by authorities or industry constitute an appropriate tool for the protection of human health and the environment.

**Zusammenfassung**
Das bestehende Chemikalienrecht in Europa (REACH) deckt synthetische Nanopartikel bereits ab. Für nanospezifische Regelungen reicht jedoch das bisherige Wissen nicht aus. Es laufen viele Projekte zur Ergänzung der wissenschaftlichen und technischen Grundlagen für eine anerkannte Risikobeurteilung in der Nanotechnologie. Freiwillige Sicherheits-Standards von Behörden oder Industrie stellen unter diesen Rahmenbedingungen ein zweckmässiges Instrument für den Schutz von Mensch und Umwelt dar.

## 1. Introduction

Nanotechnologies are characterized by a high degree of innovation dynamics. In such an environment there is often only limited or uncertain knowledge available about the effects to be expected on human health and the environment. Nano-scaled substances can display properties significantly different from those of the same substance on the micro or macro scale. Besides the dose and composition of the nanoparticles, their behaviour and potential effects are also influenced by size, particle form, surface functionalisation and charge, and aggregation tendency.

It is assumed that engineered nanoparticles can cause inflammatory reactions or even tissue alterations in human lungs. By today, there are no epidemiological studies on the health risks of nanomaterials. Studies on ecotoxicity are also only rarely available and usually cover concentrations that are not environmentally relevant. [1]

At the moment there is not only a lack of scientific knowledge for risk assessment, but also a lack of standardized testing methods and no agreement on a minimum set of characterisation criteria for nanomaterials. Consequently, there is no basis available for possible nano-specific regulations.

Against this background companies are confronted with the risk of product liability, i.e. the question who has to bear the risks resulting from the missing data base.

A limitation or exoneration of liability is always linked to the condition that a faulty part or product could not be discovered according to state-of-the-art of science and technology. It is very important that manufacturers and distributors of nanomaterials are aware of the little known risks and turn their special attention to risk management, monitoring of risk data and the global regulatory development.

## 2. Legal Regulations

Regulations serve different functions. From an authorities and consumers point of view the safety and protection of human health and the environment are of paramount importance. For companies, regulations represent on the one hand restrictions (compliance), but on the other hand they can also serve as a guideline framework (legal certainty).

Legal regulations of particular relevance are product specifications and liability claims arising from the faultiness of products. These legal regulations impose specific demands on the risk management systems of companies active in the field of nanotechnologies.

[1] Meili, C, Widmer, M. Husmann, F. (et al.) 2007. Synthetische Nanomaterialien, Risikobeurteilung und Risikomanagement: Grundlagenbericht zum Aktionsplan. Umwelt – Wissen Nr. 0721. Bundesamt für Umwelt und Bundesamt für Gesundheit, Bern, 284 S. www.umwelt-schweiz.ch/uw-0721-d

## 2.1 REACH

Regulatory frameworks for the handling of engineered nanomaterials are already existent in the European Union. They implicitly are within the scope of the European Commission (EC) ordinance REACH 1907/2006 (**REACH**: **R**egistration, **E**valuation, **A**uthorization and Restriction of **Ch**emicals) that came into force on July 1st 2007. Especially insightful are also the objectives and measures of authorities as mentioned in the considerations for the ordinance. The precautionary principle is explicitly stated there. Manufacturers, importers and downstream users have to make sure that the substances they manufacture, put into circulation and use do not adversely affect human health and the environment under reasonably foreseeable usage conditions.

REACH is applicable to chemical substances independent of whether they are present in micro, macro or nanoparticle form. Nanomaterials can, however, display unexpected properties. In the following, some elements of REACH that have a special significance for nanoparticles will be discussed in more detail:

- **Completion of the scientific knowledge about the inherent characteristics of substances:**
  This is a central concern especially in the case of novel engineered nanoparticles with special properties and an insufficient scientific database or little known health- and environmental effects. Of special interest will be studies for the assessment of nanoparticle ecotoxicity.

- **Execution of chemical safety assessments and compilation of chemical safety reports:**
  Provided an annual production of more than 10 tons per registrant, adverse effects on human health and the environment through physico-chemical properties must be determined.
  Additionally, the factors of persistence, bioaccumulation and toxicity (PBT) must be accounted for; especially in the case of insoluble nanomaterials, there are major knowledge gaps. For the categories of (very) persistent and (very) bioaccumulative (vPvB) substances, the chemical safety assessment shall include exposure assessments (including the generation of exposure scenarios) as well as a risk characterisation.

- **Forums for the exchange of substance information**:
  This instrument could play an important role for nanomaterials with an incomplete data base, e.g. in the case of different manufacturers, applications and particle sizes of a certain substance.

- **Replacement of substances of high concern**:
  Hazardous substances should be continuously substituted by less dangerous substances or technologies if economically and technically feasible alternatives are available. Examples are substances with PBT or vPvB properties, which are also expected to apply for some nanomaterials.

- **Rights and duties of stakeholders in the supply chain**:
  They include, among others, information duties, especially by the manufacturer or importer to the subsequent users and vice versa. The collected information has to be aggregated in a documentation that describes the risks associated with the production, use and disposal of a substance in a transparent and adequate way. In the case of nanomaterials where little is known about adverse effects on human health and the environment, the communication of risk management measures is of particular importance.

Basically, the legal framework conditions for nanomaterials are in place. According to the current regulation there is no special registration duty for nanomaterials as long as a conventional and therefore less fine structured version of the substance of concern is already registered. However, nano-specific adaptations of the REACH ordinance are currently subject to discussions and a working group of the EC on "nanotechnology and REACH" will start its work on July 1st 2008. It is unclear whether nanomaterials should be treated like new substances (non-phase-in substances) and therefore could only be brought on the market after a registration process according to the principle of "no data, no market", or whether nanoparticles could fall under transitional provisions like EINECS[2] listed substances (phase-in substances) do.

## 2.2 Occupational Health and Safety

There have been European Union (EU) guidelines for occupational health and safety in place for some time; especially mentionable is the Council Directive 89/391 on the introduction of measures to encourage improvements in the safety and health of workers at work and the corresponding 14th individual Directive 98/24 on the protection of the health and safety of workers from the risks related to chemical agents at work. In these regulations primarily organisational measures such as responsibilities of the involved parties in employee protection are being defined. Regarding the handling of nanoparticles it is true that there is basically no difference to the measures that have to be taken for substances of high concern, especially those that have only been partly investigated.

In 2007, the German Federal Institute for Occupational Safety and Health (BAuA) and the German Chemical Industry Association (VCI) issued a series of documents providing "guidance for handling and use of nanomaterials at the workplace". The basic principle is: Minimisation of exposition. In order to assure the lowest possible level of nanoparticle release, nanomaterials should primarily be used in the form of granulates and dispersions (substitution). In addition, dust and aerosol formation can be avoided by working in closed systems. The document also provides a flowchart for the risk assessment of nanomaterials at the workplace in the appendix, specifically for the respiratory route of nanoparticle intake. The inhalative route is commonly identified as the most relevant path for the incorporation of nanoparticles to the blood system and therefore to many parts of the body. The

[2] EINECS: European Inventory of Existing Commercial Chemical Substances

incorporation of nanoparticles via the intact skin, however, does not seem to be of equal importance.[3]

## 2.3 Food Safety

European food law is characterized by the Regulation (EC) No 178/2002. There are no special regulations for food containing nanoparticles that go beyond the general food law prescriptions. However, the use of engineered nanoparticles in food is discussed especially controversially. On the one hand this is due to the consumer's uncertainty about the actual use of such materials in food products resulting from the lack of a declaration duty. On the other hand the ingestion of nanoparticles is often perceived as being particularly problematic by consumers.

According to a report by the German Government from August 2007 on the need for adaptations of the current legislation concerning nanotechnology, the existing legal and sub-legal framework on national and EC level (e.g. the new EC chemical law REACH) already offer flexible instruments to recognize potential risks of nanotechnological developments and to react if necessary. Nanomaterials implicitly are within the scope of these regulations. The topic of "nanoparticles" is treated in the EC in the context of the consultation on suggestions for the regulation of food additives, aromas, enzymes and uniform approval procedures for such substances. Concerning the use of novel nanoscale food additives, the report states that particle size should be considered as an explicit criterion to trigger a re-assessment process. However, nano scaled particles can naturally be contained in food, e.g. milk (milk proteins, caseins), with a significant difference between such "natural" nanoparticles and many engineered nanomaterials resulting from their totally different biological degradation behaviour.

## 2.4 Liability

For this branch of law, the Council Directive 85/374 concerning liability for defective products is relevant. From this regulation results a series of duties for the producer of a product, the compliance with which consequently results in specific requirements on the management system in the companies. This also includes the duty to actively monitor a company's products. For an exclusion of liability it is among others required that the state of the art of science and technology is observed, assessed and updated. In a rapidly developing field such as nanotechnologies, a continuous monitoring therefore represents a suitable tool.

[3] www.baua.de/nn_43190/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/pdf/Leitfaden-Nanomaterialien.pdf

## 3. Programs for the Advancement of the Scientific Database

Beside risks for human health and the environment, the lack of a nano-specific legal framework can also lead to uncertainty and obstacles for the economy. The industry requires foreseeable guidelines to protect the safety of its investments. However, it is in the nature of regulations that regulators need comprehensive knowledge about the facts in order to develop these rules. While the scientific knowledge is still missing and the market volume for nano products is constantly increasing, it is especially important that these knowledge gaps will be filled, e.g. in the areas of risk research, adapted risk assessment procedures and a standardized methodology.

Against this background, there are numerous programs running on the national, supranational and international (OECD) level, aiming at the creation of the necessary framework for a responsible development and handling of engineered nanomaterials. In this context, the EC action plan for Europe 2005-2009 on nanosciences and nanotechnologies as well as several projects within the EC research framework programme can be mentioned. On the international level, relevant are among others eight projects of the OECD. These examples indicate that international collaboration in the area of human health and environmental protection is encouraged in order to develop the necessary methodology for the risk assessment of engineered nanomaterials.

## 4. Voluntary Measures for the Safe Handling of Engineered Nanomaterials

In the absence of legally binding regulations concerning the special properties of novel nanomaterials, voluntary safety standards represent a forward-looking instrument to protect human health and the environment while using the time to clarify the needs and develop the required scientific and methodological database.

Already today, several voluntary measures are being taken internationally. Some of them are more specific than others – but all of them should be looked at in the light of the precautionary principle and the industry's self-reliance.

### 4.2 Codes of Conduct (CoC)

- The EC in 2008 adapted a CoC for responsible research in nanoscience and nanotechnology. The code is based on seven principles, comprising among others sustainability, precaution and accountability and asks member nations to take concrete measures for the safe development and use of nanotechnology.
- In Germany, the "Nanokommission" (working group 3) shall in the context of the nano dialogue develop a guideline for the responsible handling of nanomaterials as well as industry-specific guidelines.
- In England, the Royal Society together with other institutions developed a code of conduct called Responsible NanoCode. Therein the participating organisations are encouraged to consider the economic and societal effects of their activities in the field of nanotechnology. Besides commercial and scientific/technical questions, ethical issues shall also be treated.

- Several individual manufacturers of nanomaterials have elaborated their own codes of conduct. An example is the one of BASF that highlights aspects of occupational and consumer safety, environment protection, transparent information and dialogue. The participation of companies in the elaboration of a scientifically well-founded database for the assessment of potential risks and the advancement of product related testing and assessment methods is regarded as being important.
- In Switzerland, the retailer's organisation (IG-DHS) in collaboration with the Innovation Society has developed the first code of conduct dealing with the handling of nanomaterials in consumer products. The signing retail companies commit to the precautionary principle and the highest possible transparency for consumers. In the light of a lack of specific legal regulations the retailers require their suppliers to disclose information on nanomaterials. Moreover, the code contains specific requirements for the risk management of manufacturers and suppliers.

### 4.3 Risk Management Systems

- CENARIOS® is the first certifiable risk management and monitoring system specifically adapted to nanotechnologies. The system has been developed by TÜV SÜD (Munich) and the Innovation Society and is already being used in practice. CENARIOS® uses the four individually combinable modules "Risk Estimation and Risk Assessment", "Risk Monitoring", "Issues Management" and "Certification" to integrate the latest findings from science and technology as well as societal, legal and market related factors into risk management. CENARIOS® is therefore especially suitable to take control of complex technology risks under conditions of high uncertainty and highly dynamic markets. The annual certification guarantees for the adaptation of the latest findings in science and technology.

- The NANO Risk Framework is a practical risk assessment guidance developed by DuPont and Environmental Defense, providing a procedure to enable the development of data profiles of nanomaterials properties, inherent hazards, and exposure potential. The NANO Risk Framework puts a strong focus on toxicity and also requires the user to perform such tests; it is therefore suitable for large companies.

### 4.4 Voluntary Reporting Schemes

- In some European countries authorities aim at collecting information from the industry on the manufacturing and use of nanomaterials (independent from REACH) on a voluntary basis. Such information would complement fundamental research and allow for data in the areas of applications, produced amounts of certain nanomaterials, protective measures in place, expositions and contaminations of the environment. Besides the British authorities there are similar approaches in Switzerland and in the U.S. By now the feedback to such voluntary reporting procedures seems to be relatively reluctant, especially due to the industry's concerns regarding the data safety of proprietary information.

With the aim of fostering the networking activities among European authorities and coordinating the approach with regard to voluntary safety measures in nanotechnology risk management, the first international authorities' dialogue took place in April 2008 in Munich. Representatives of authorities from Germany, Austria, Switzerland and Liechtenstein discussed the state and purpose of voluntary safety measures and questions of certification and declaration at the example of CENARIOS®.

There has been a far-reaching consensus that at least with the currently insufficient scientific database on the risks of nanomaterials, voluntary measures constitute a forward-looking and sensible way of dealing with the existing uncertainties. Voluntary measures are currently rated as prior-ranking, however, with the need for the assessment of their effectiveness.

## 5. Conclusion

There have been calls for a legal regulation of nanotechnology from a variety of parties. Even if the scientific and technical preconditions therefore are not available yet, adaptations and possible restrictions for nanomaterials are currently subject to investigations. The new EC regulation REACH constitutes a new and developable legislation under the scope of which also nanomaterials fall. It is expected to significantly advance the state of knowledge about the inherent properties of substances in general and therefore also of nanoparticles.

In the area of occupational hygiene certain basic rules for handling highly toxic or little known macroscaled substances may also be applied at handling nanoparticles. There have been advances in the development and testing of suitable protection devices. In the subject areas of environmental risks and risks emerging from indirect exposure of the population through the environment, there still is an immense need for coordinated action.

For the industry, risk management represents a suitable framework to responsibly handle nanomaterials in a situation characterized by incomplete knowledge and a lack of nano-specific regulations. With the risk management system CENARIOS® especially developed for dealing with those circumstances, there is a tested instrument available that takes into account scientific, technical, societal, legal and economic risks. Under the current conditions, voluntary risk management safety standards constitute suitable measures for the protection of human health and the environment.

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The Innovation Society is an international consulting company in the field of nanotechnology. It delivers professional consulting services in the areas of safe and sustainable use of new technologies, risk management (e.g. CENARIOS®), strategy development and communication.

(*): http://www.innovationsgesellschaft.ch/media/archive2/marketing_information/Flyer_OccupationalSafety_EN.pdf

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