Risiken erkennen – Gesundheit schützen

Questions and Answers on Nanotechnology

Updated FAQ of 28 August 2012

The term "Nanos" comes from the Greek and means dwarf. "Nano" is the term used for the billionth part of a metre (= 1 nanometre). **Nanotechnology** is the generic term for a wide range of technologies used in the research, development, processing and production of structures and materials measured within the nanometre scale. Nanomaterials of this kind can have completely new properties and functions. Due to the dynamic development of this key technology, production quantities are increasing which can also lead to an increased exposure situation for the population in general if nanomaterials are released from consumer products, for example. In the meantime, nanotechnology actually is being used selectively in many areas of everyday life in items such as cosmetics, foods and consumer products, without consumers being aware of this. For various product areas such as foods and cosmetics, however, specific labelling regulations have already been drawn up which are to come into effect in the foreseeable future. The object of the BfR's risk assessment is specifically manufactured nanomaterials. Whether or not unknown risks for the consumer can emanate from these new nanomaterials or products containing them has not yet been fully clarified from a scientific point of view. Furthermore, more than half of all Germans hardly know anything about nanotechnology, its uses and possible risks. The BfR has compiled selected questions and answers on nanotechnology in the following paragraphs.

What is nanotechnology considered to be?

Nanotechnology is a generic term for the development of innovative materials and applications in various natural science and technical disciplines such as physics, chemistry, biology and medicine, as well as engineering and material sciences. It deals with materials with at least one dimension smaller than 100 nanometres (nm), so called nanomaterials (see above).

With the help of nanotechnology, it is possible to develop structures, techniques and systems in which materials show completely new properties and functions. Industry, medicine, science and consumers hope that this potential will lead to beneficial applications in such areas as robotics, sensory technology, process engineering, biotechnology and medicine as well as for the further development of foods, consumer products and cosmetics.

What are nanomaterials?

According to the definition of the International Organization for Standardization (ISO), manufactured nanomaterials of organic or inorganic origin are differentiated on the one hand into three types of nano-objects which are smaller than 100 nanometres (nm) in at least one dimension:

- Spherical structures (e.g. nanoparticles and fullerenes),
- Fibrous structures (e.g. nanotubes)
- Extremely thin layers (e.g. nanoplatelets)

and into so-called nanostructured materials on the other (e.g. aggregates or compound materials containing or consisting of nano-objects of this kind).

The European Commission published a recommendation in October 2011 according to which a "nanomaterial" should be understood to be a natural material occurring or produced during processes containing particles in an unbound condition, as an aggregate or as an agglomerate, with which at least 50 % of the particles in the number size distribution have one or more

outer dimensions in the range from 1 nm to 100 nm. In special cases, the threshold value of 50 % for the number size distribution can be replaced by a threshold value of between 1 % and 50 % if this is justified by environmental, health, safety or competition considerations. This definition is to be used in future as a basic principle in all European substance directives and regulations governing the use of nanomaterials (chemicals, cosmetics, foods and feeds, pesticides and biocides). The recommendation of the Commission also provides for the possibility of establishing amendments or deviations in certain legal areas, however. A specific definition for technically manufactured nanomaterials was determined in Regulation (EU) No. 1169/2011 on the provision of food information to consumers.

On the one hand, nanoparticles can be carried into the ambient air as ultrafine dusts from natural or artificial combustion sources (e.g. volcanic ash, cigarette smoke, exhaust gases from heating systems or thermodynamic machines such as internal combustion engines) and can also be produced unintentionally in work and production processes (e.g. welding smoke).

On the other hand, nanomaterials are manufactured specifically for use in many technical areas as well as in consumer products, such as paints, cosmetics, textiles and packaging materials, as so-called engineered nanomaterials (ENM). Examples of specifically manufactured nanomaterials are nanosilver, carbon nanotubes, titanium dioxide nanoparticles or what is known as nanoclay, an aluminium silicate in nano form.

What are nanocapsules?
Organic compounds such as liposomes, micelles and vesicles, are added to foods to encapsulate other substances such as vitamins or flavourings, transport them through the body and release them at exactly the right spot. As the size of these “transport containers” is often in the nanometre range, they are also referred to as nanocapsules.

In which products are nanomaterials already being used?
It has to be assumed today that consumers come into contact with a variety of products in which nanomaterials have been processed. They are used in various ways in consumer products. For instance nanomaterials are used in food packaging, textiles, kitchen devices, varnishes and paints. They are also used in products for surface sealing and cleaning as well as in polishing agents. Nanomaterials are also used in cosmetics. Titanium dioxide and zinc oxide are used as UV filters in sun creams, for example; nanosilver is used as an antimicrobial agent in textiles and nanoclay has various applications in the food packaging sector.

According to information provided by the food industry, no inorganic materials in the nano range are currently being used deliberately in the food sector in Germany. Although silicon dioxide (SiO_2, silicic acid) with a particle size of 50 to 200 nm has already been detected in foods, it is not clear whether this was due to impurities that occur during the manufacture of nanostructured, larger-sized aggregates made of silicon dioxide, which is used as a flow aid and anticaking agent. Silicon dioxide is an authorised food additive (E 551) which, just like all other inorganic, insoluble additives, was not specially evaluated and authorised as a nanoparticle. That apart, nanomaterials can also occur naturally in foods.

The packaging industry is interested in the application of nanoparticles which are bound as fillers in plastics and varnish layers or applied as coatings to polymer surfaces (films and containers). In food packagings, nanoparticles prevent gas from penetrating the packaging or moisture from escaping. The use of nanoparticles could improve the mechanical and thermal properties of food packaging and protect food against UV light. In future, nanotechnology is to be used to develop packaging materials for foods which indicate whether the cooling chain has been interrupted or the sell-by date exceeded.

In the clothing sector, special functional textiles are being developed which make it possible to produce insulating thermal protection clothing, facilitate wet cleaning and realise sensory functions. By producing nanostructured surfaces, the water-repellent properties of textiles are to be improved with simultaneous retention of breathability. Titanium dioxide nanoparticles already provide effective protection against UV rays in textiles. Antimicrobial silver nanoparticles are already used in shoe insoles and several functional clothing textiles (e.g. sports apparel).

How are nanomaterials regulated?
There is no nano-specific regulation in the sense of a nanotechnology law. Instead, lawmakers have decided to adapt existing regulations to the new nanotechnology requirements, a process which has not yet been completed. The situation in the individual areas is currently as follows:

Nanomaterials are given explicit consideration for the first time in the new cosmetics regulation (EC) No. 1223/2009, which is to be applied in full from 11 July 2013. According to Article 16 of the EU regulation, cosmetics which contain nanomaterials must be reported to the EU Commission from 11 Jan. 2013. In addition to registration in accordance with Article 13 of the EU regulation, notification of cosmetics containing nanomaterials must also be given by electronic means six months before they are put into circulation. Comprehensive information on the nanomaterials (specification of physical and chemical properties, estimate of the quantities brought into circulation, foreseeable exposure conditions, toxicological profile and safety data) must be presented here. Cosmetics containing nanomaterials in conformance with the requirements of Appendix III, as well as nanomaterials which are authorised as colorants, UV filters or preservatives, are exempted from this.

If cosmetics contain nanomaterials, these must be listed in the list of ingredients. The name of each ingredient must be followed by the word “nano” in brackets. The marking and labelling obligation applies to all nanomaterials.

At the same time, the European Commission will check the provisions of the regulation relating to nanomaterials under consideration of scientific progress and propose amendments as necessary. The first audit report will be prepared by 11 July 2018.

In the area of **food packagings**, three different regulations apply depending on the material (e.g. paper or plastic) or function mode (e.g. intelligent materials). In addition to Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food, which has priority over all others, another regulation covers the use of active and intelligent materials in packagings. The regulation that deals with the use of plastics in packaging materials also contains a list of nanomaterials such as carbon black and titanium nitride in the meantime.

Regulation (EC) No. 258/97 (Novel Food Regulation) applies in the **food** sector. Accordingly, foods that were not used in the EU to any extent worth mentioning before the regulation came into effect (15 May 1997) and which are manufactured using a non-standard production process, such as nanotechnology, which causes significant changes to the structure or composition of the food are subject to approval. The novel food regulation is soon to be revised and it has to be assumed that more extensive regulations on foods containing or consisting of technically manufactured nanomaterials will be included in the revision.

Food additives are evaluated with regard to their health safety during the authorisation process in the form in which they are to be brought into circulation. The inorganic, insoluble addi-

tives were not especially evaluated and approved as nanoparticles, however, which means that a health assessment and approval would be required if a substance of this kind were to be manufactured and brought into circulation as a nanomaterial.

With the adoption of the food information regulation (EC) No. 1169/2011, the marking/labelling of all ingredients that exist in the form of technically manufactured nanomaterials is mandatory from 2014. They must be clearly listed in the ingredients list followed by the word “nano” in brackets.
As consumer products, textiles which do not only come into temporary contact with the human body (clothing articles) are fundamentally subject to the provisions of the Food and Feed Code. Where nanomaterials are concerned, there are no specific legal regulations for the **textiles** sector, although the treating of textiles with biocides is to be regulated from 2013 via the biocide products regulation. No regulation is currently planned for the treating of textiles with titanium dioxide as UV protection or with carbon nanotubes for harder wear and tear of the fibres. The manufacturers and distributors are responsible in terms of the Food and Feed Code and Product Safety Law, however, for ensuring that textiles treated with nanomaterials do not pose a health risk to consumers either.

The currently valid biocide regulation (98/8/EC) is to be superseded by a new EU biocide regulation in 2013. The latter basically constitutes extended demands on the data basis, safety evaluation and the labelling of nanoscale ingredients, but the new rules still have to be worked out in detail.

Nanomaterials are also to be regulated in future within the scope of the European chemicals regulation REACH. To this end, recommendations and guidelines are currently being prepared (e.g. on registration, group assessment and test data requirements).

In principle, manufacturers are obliged by the European product safety directive to guarantee the safety of their products (Art. 3 Product Safety Law). As there is no registration obligation for nanomaterials, however, the BfR does not have any reliable information on the extent to which nano products are already available on the market. Numerous product registers for consumer products in Europe also exist in several countries, but a change of thought is already taking place in some of them. France, for example, has introduced a registration obligation for products containing nanomaterials, but because the information contained in product registers of this kind is provided by the manufacturers on a voluntary basis, it constitutes an unreliable and non-uniform data basis overall. This applies to the BUND product database as well as that of the Woodrow Wilson International Center for Scholars.

The Nano Commission set up by the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) in 2006 proposed on its conclusion in 2011 that a European nano product register be built up for the purpose of making the use of nanomaterials in products traceable by the authorities. Although the BfR welcomes this advance, it currently sees various problems in the set-up of a register of this kind.

How can I tell if a product contains nanomaterials?
Consumers cannot recognise with the naked eye whether or not a product contains nanomaterials. They have to rely on a declaration which is not yet mandatory, but this is set to change in the coming years. The marking and labelling of cosmetic products containing nanomaterials is planned from 2013 and this will also apply to foods containing nanomaterials from 2014 in line with the European food information regulation.

Although several manufacturers already claim in their advertisements that their products use nanotechnology, it cannot currently be established whether they actually contain nanoparticles or other nanomaterials. ~~Marking and~~ Labelling is only practicable, however, if it is also checked whether participants are complying with the ~~marking and~~ labelling obligation. Methods for the reliable detection of nanomaterials in various products are currently being developed and evaluated by the authorities and are already available in some sub-areas.

Why are nanomaterials used in cosmetics?
Nanomaterials were taken into account for the first time in the new cosmetics regulation (EC) No. 1223/2009 which comes into effect in the EU on 11 July 2013. What has been the case up to now for UV filters and will continue to be so in future is that the decision on their inclusion in the positive list of the UV filters authorised in cosmetics will be made by the EU Commission after a risk assessment. It will be made on European level by the Scientific Committee of Consumer Safety (SCCS, formerly SCC, SCCNFP, SCCP) which advises the EU Commission. The basis for the risk assessment is formed by the Notes of Guidance.

Nanoparticles made from titanium dioxide and/or zinc oxide are to be used as UV filters in sun creams to protect the skin from UV radiation, for example. Nanotechnologically manufactured materials (so-called biocomposites) in toothpaste are intended to promote the natural tooth repair mechanism of saliva. Nanocapsules in skincare products are intended to ensure protection and the transport of active ingredients and improve the care effect. Research is being conducted into the improvement of the physical properties (e.g. transparency) of finished cosmetic products by means of nanomaterials.

Are nanomaterials used in foods?
It is being reported that nanomaterials are used as auxiliaries and additives in foods. For instance, silicic acid and other silicon-containing compounds are said to be used as anticaking agents or thickeners to prevent table salt crystals and powder-form foods from sticking together and to make ketchup pour more easily. Silicic acid is also used as a flocculant in wine and fruit juice production. It is not yet clear whether silicic acid is actually used as a nanomaterial.

Nanomaterials are also allegedly used specifically as food supplements. There are reports of the use of inorganic materials such as silicon dioxide, colloidal silver, calcium and magnesium in nanoparticle form. It is not clear whether these materials are present in foods as nanoparticles or in aggregate form. The food industry is currently developing functional foods in which vitamins, omega 3 fatty acids, phytosterols and aromas are enclosed in nanocapsules made of organic materials such as liposomes and then released at a specific spot in the body.

Are there specific health risks from nano products?
In principle, the novel properties of nanomaterials can also have negative effects on human health if released particles enter the body, distribute themselves in ultrafine quantities and accumulate in various organs. Consequently, a nanomaterial can easily have a different toxic intensity or make its way into other organs than a non-nanomaterial. Health risks cannot be excluded, especially if the materials remain in the body for a long time and have the opportunity to accumulate.

In order to estimate whether nano products constitute specific health risks, it is therefore important to know whether the nanomaterials used are bound in a matrix or are present in the product in unbound form. In particular free nanoparticles, nanotubes or nanofibres could lead to health risks due to their small size, shape, high mobility and higher reactivity.

Unbound nanoparticles could enter the human organism via three paths and develop a toxicological impact under certain circumstances: via the respiratory tract, the skin or the gastrointestinal tract. Scientists believe that the greatest risks stem from the inhalation of nanoparticles. The latest scientific findings largely rule out the possibility of nanoparticles penetrating healthy human skin. It is not yet known whether there are any risks involved in the intake of nanoparticles via the gastrointestinal tract.

Up to now, however, most nano products have consisted of nanoparticles that are enmeshed in a solid matrix or freely contained in a liquid suspension. Furthermore, nanoparticles tend to aggregate into larger unions which are generally larger than 100 nm. The toxic effects of nanoparticles linked to their small size and higher reactivity are then no longer relevant.

Has an assessment of the health risk of nanomaterials used in consumer products already been undertaken?
What has applied up to now and will continue to do so in future is that a decision on the inclusion of a substance in one of the positive lists for the ingredients, colorants, preservatives or UV filters authorised for cosmetics will be made by the EU Commission after a risk assessment has been made. It will be made on European level by the Scientific Committee of Consumer Safety (SCCS, formerly SCC, SCCNFP, SCCP) which advises the EU Commission. The basis for the risk assessment is formed by the Notes of Guidance.

Toxicological tests have already been conducted on several nanoparticles used in cosmetics. Accordingly, there has been considerable research into the behaviour on the skin of nanoparticles made of titanium dioxide and zinc oxide. Several experiments confirmed that these nanoparticles do not penetrate the healthy skin cells of humans but remain on the skin surface. They can remain on the skin for longer periods via the hair follicles (root sheaths), but do not penetrate further. Hair growth then transports them back to the skin's surface.

At the present time, however, many questions have still to be answered when it comes to assessing the health risk of nanoparticles. Very little is known about the conceivable but not proven specific toxic properties linked to nanoscalability, nor is much data available on human exposure to nanoparticles. The same applies to toxicokinetics, which deals with how they behave and how long they remain in the body. Work is currently being done internationally to identify suitable test strategies and inspection guidelines to determine possible health risks so that open methodological questions can be answered.

Has there ever been a product in which the nanomaterials caused damage to health?
So far, the BfR has not received any reports about cases in which health damage was shown to have been caused by nanoparticles or nanomaterials. The health disorders, in some cases severe, which occurred in March 2006 after the use of so-called nano sealing sprays were not due to nanoparticles or other nanomaterials according to the BfR findings.

What contribution does the BfR make to the investigation of risks caused by nanomaterials?
Together with the Federal Institute for Occupational Safety and Health (BAuA) and the Federal Environmental Agency (UBA), the BfR developed a research strategy to identify the potential risks of nanotechnology as far back as 2007 (http://www.bfr.bund.de/cm/343/nanotechnologie_ gesundheits_und_umweltrisiken_von_nanomaterialien_forschungsstrategie_endfassung.pdf)in order to outline the research requirements that exist for the assessment of possible risks and pro-

mote the development of suitable test methods and evaluation strategies. Numerous research projects have been initiated in all three involved institutions in the meantime with the result that a new edition of the research strategy to determine the possible risks of nanotechnology was published in 2012. It also contains a balance of the results of already completed projects and describes current activities in the areas of characterisation, exposure, toxicological and ecotoxological effects, as well as risk assessment and risk communication. The BfR not only conducts its own research projects, it also combines external expertise on methodical further development. In addition to this, the BfR scientists are involved in larger scale national and international joint projects and committees.

The BfR has been examining since 2006 how the subject of nanotechnology is perceived by the general public and media. A consumer conference (-> see FAQ Dialogue Process) and representative survey were conducted to record perception among the general public. The presentation of nanotechnology and its applications in the media was examined within the scope of a media analysis, with special focus on the presentation of risks vs. benefits. The estimations of the experts regarding nanotechnology were recorded in a so-called Delphi survey in which experts were questioned about the possible risks of nanotechnology in a two-stage process. It was also examined how consumers discuss nanotechnological applications in internet forums. The results of these surveys are published on the BfR homepage.

To enable a statement on whether the public attitude towards nanotechnology has changed, a survey is currently being conducted among the population along with an updated media analysis.