German Federal Institute for Risk Assessment

FAQ

13 September 2024

Nanomaterials: Tiny particles mediate manifold properties

→ Updated version of the FAQ dated 18. October 2021

The term "nanos" originates from the Greek language and means dwarf. The prefix "nano" denotes a billionth part, in this case of a metre (= 1 nanometre, nm). In general, a material is called a nanomaterial when it is in the size range between 1 to 100 nm in at least one external dimension.

Nanomaterials are a subject of the BfR's scientific risk assessment. They can be produced in numerous forms from different chemical substances. Compared to their conventional counterparts, nanomaterials have altered and, in some cases, novel properties and functions that make them interesting for many areas of application, but also deserve special attention from a regulatory perspective.

Nanomaterials are used in many areas of daily life, for example in cosmetic products, food packaging and numerous consumer goods. This is not always obvious to consumers. Specific labelling regulations apply to some product areas such as food and cosmetics.

Production volumes and the variety of forms are continuously increasing, which can also lead to increased and possibly new types of exposure for consumers, for example if nanomaterials are released from products. Whether nanomaterials or products containing them can pose health risks to consumers cannot be answered in general terms. Nanosafety research is therefore concerned with the possible risks of nanomaterials for human health and the environment.

In the following, the BfR has compiled selected questions and answers on nanomaterials.

What is nanotechnology?

Nanotechnology is a generic term for different technologies. Nanomaterials and other innovative materials can be produced using nanotechnology. The term also includes the use of nanomaterials, for example in production processes.

Nanotechnologies offer the possibility to develop structures, techniques and systems in which materials show entirely new properties and functions. It is expected that this potential will provide beneficial applications, for example in robotics, sensor technology, process technology, biotechnology and medicine, as well as for the further development of food, consumer goods and cosmetic products. Nanotechnology is therefore regarded as an important key technology worldwide.

What are nanomaterials?

The European Commission published a recommendation on the definition of nanomaterials for the first time in 2011 (2011/696/EU), which has been updated in 2022 (2022/C 229/01). The term "nanomaterial" covers materials consisting of particles in solid state, present on their own or bound as constituent parts of aggregates or agglomerates, provided that 50 % or more of the number of particles fulfil at least one of the following conditions:

- one or more external dimensions of the particles are in the size range 1 nm to 100 nm;
- the particles have an elongated shape such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm;
- the particles have a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.

This updated recommendation is intended to serve as a basis for the definition of nanomaterials in various areas of legislation. However, the Commission also allows certain amendments or derogations in specific areas of legislation, for example excluding certain materials from the scope of application of specific legislation or legislative provisions even if they are nanomaterials according to this recommendation. It may likewise be considered necessary to develop regulatory requirements for additional materials not falling under the definition of the present recommendation in the context of specific legislation.

The term "nanomaterial" is defined in the following regulations as follows:

The definition in the EU **Cosmetic Products Regulation** (EC) No. 1223/2009 was developed prior to the publication of the European Commission's first definition proposal (2011/696/EU). In the EU Cosmetics Regulation, a nanomaterial means "an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm." Materials with an internal nanostructure are, for example, nanocomposites.

The EU **Biocidal Products Regulation** (EU) No 528/2012 defines a nanomaterial as "a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm."

The EU **Novel Foods Regulation** (EU) 2015/2283 defines the term "**engineered nanomaterial**" as " any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale". Nanoscale refers to a size range between 1-100 nm.

The EU **Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals** (**REACH**, (EC) No. 1907/2006 defines in the revised Annexes (EU) No. 2018/1881 "**nanoforms" of a substance** as “a form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm, including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm."

Other regulations such as for plant protection products (EC) No. 1107/2009, food contact materials (EC) No. 1935/2004 or feed (EC) No. 767/2009 do not contain a definition of the term "nanomaterial".

What are nano-objects?

The International Organisation for Standardisation - ISO for short - distinguishes between free nanoobjects and nanostructured materials under the generic term nanomaterial (ISO/TS 8004-1:2023). Nanoobjects include nanoplatelets, nanorods, nanotubes, nanofibres, nanowires and nanoparticles. Nanostructured materials include nanocomposites and materials with a nanostructured surface.

What are nanoparticles?

Nanoparticles are nano-objects with three external dimensions between 1 and 100 nm. Nanoparticles can be produced from various chemical substances, for example gold nanoparticles, silver nanoparticles, titanium dioxide nanoparticles. The term is also frequently used for different nanoforms in order to emphasise the solid character of nanomaterials.

What are nanofibres, nanotubes, nanowires and nanorods?

Nano-objects with two external dimensions between 1 and 100 nm and the third being significantly larger are nanofibres, nanotubes, nanowires or nanorods. **Nanofibres** are fibres with a diameter of less than 100 nm. Hollow nanofibres are called **nanotubes** - carbon nanotubes are one example. Nanorods are stiff nanofibres. **Nanowires** are electrically conductive or semiconductive nanofibres.

What are nanoplatelets?

Nano-objects with only one external dimension between 1 and 100 nm and two significantly larger external dimensions are referred to as nanoplatelets. These are extremely thin layers. One example is graphene. Graphene is a two-dimensional structure made of carbon atoms, which are arranged in such a way that the resulting pattern is reminiscent of a honeycomb.

What are nanocomposites?

Composites consist of different materials and are also known as composite materials. In nanocomposites, at least one component is present as a nanomaterial.

What are materials with a nanostructured surface?

Materials are considered as having nanostructured surfaces when substructures appear on a surface whose size is in the nanoscale range. These can be either manufactured or of natural origin. The best-known example of a nanostructured surface are lotus leaves, the surface of which is covered by fine, nanoscale substructures (i.e., between 1 and 100 nm in size). Water droplets easily roll off this surface thereby removing particles of dirt. This is known as the lotus effect. This principle is now used for various self-cleaning surfaces (e.g., as paint for house walls) and is considered a prime example of technical developments inspired by nature.

What are natural nanomaterials?

Many naturally occurring structures are in the nanoscale, i.e. with at least one external dimension in the size range between 1 and 100 nm. Natural nanomaterials can be organic, inorganic or organo-metallic. In the environment, they can arise from larger structures, for example through natural combustion processes (e.g., volcanic ash) or weathering processes (e.g., of minerals), but also through the agglomeration of smaller particles (e.g., precipitates).

Apart from that, a large number of biological nano-objects exists. Many proteins, for example, are at the nanoscale. Genetic information is stored in the form of deoxyribonucleic acids (DNA for short), which are also nanoscaled with a diameter of approx. 2 nm. Foodstuffs also often contain natural nanoparticles, such as milk, which contains nanoscaled casein micelles. Micelles are spherical aggregates into which substances with both water-loving (hydrophilic) and fat-loving (lipophilic) properties spontaneously assemble.

There are also many natural materials with nanostructured surfaces. Examples include the leaves of the lotus plant.

What are bio-nanomaterials?

In contrast to natural nanomaterials, bio-nanomaterials are deliberately produced, albeit from biological molecules. Origami structures made from deoxyribonucleic acids (DNA) are a well-known example. DNA origami structures are produced from a long single strand of DNA that is folded into a three-dimensional structure. Such structures currently do not have a commercial application.

What are unintentionally produced nanomaterials?

Unintentionally produced nanomaterials are nano-objects that are formed randomly during anthropogenic, i.e., man-made, processes. This includes ultrafine dusts formed during combustion (e.g., emissions from heating systems or combustion engines, cigarette smoke). They also include particles unintentionally formed during work and production processes (e.g., during welding, grinding, milling or printing). In contrast to intentionally produced nanomaterials, unintentionally produced nanomaterials generally have a broad size distribution and often a complex chemical composition.

What is nanoplastics?

Plastic particles that are smaller than 5 millimetres (mm) are referred to as **micro**plastics.

The term **nano**plastics is widely used when the plastic particles are even smaller and have external dimensions of between 1 and 100 nm. However, the size range of 1 - 1,000 nm is also sometimes referred to as "nanoplastics".

Selected questions and answers on microplastics can be found here.

What are nanocarriers?

Nanocarriers, sometimes also referred to as nanocapsules, are nanoscale structures that are used to package and/or transport various substances. Nanocapsules often consist of organic compounds such as lipids or polymers, which are present as micelles, vesicles or liposomes. These are three-dimensional, usually roundish structures that consist of a shell of specifically orientated molecules enclosing the packaged substance. However, other structures can also serve as nanocarriers, e.g., porous silicon dioxide nanoparticles. Substances can be effectively packaged in this way and, for example, their degradation can be delayed. In addition, bioavailability can be increased as the nanocapsules are better transported across body barriers. Depending on the design, nanocapsules may release their contents immediately and completely, or they release the packaged substances slowly over a longer period of time, which can also be relevant for certain applications.

Nanocarriers have been used in medicine for many years to transport active ingredients. Some effective cancer therapies are based on this principle. The use of nanocapsules increases the uptake of the active ingredient into the tumour, so that usually less active ingredient is required leading to a reduction of undesirable effects.

Nanocapsules receive increasing interest for applications in other areas, e.g., in cosmetics, food, or plant protection products.

Which products contain nanomaterials?

Nanomaterials are used in almost every area of daily life, for example in cosmetic products, food packaging, numerous consumer goods such as kitchen appliances, but also in paints and varnishes. It can therefore be assumed that consumers come into contact with a large number of products that contain nanomaterials.

It is not always obvious, in which products nanomaterials are present. Only some areas of legislation (e.g., cosmetics, food, biocides) have labelling requirements for products containing nanomaterials.

Various websites provide information on which products (may) contain nanomaterials:

The European Union has set up a platform for nanomaterials (European Union Observatory for Nanomaterials, EUON). It provides extensive information on the use of nanomaterials in everyday life in various languages (https://euon.echa.europa.eu/en/uses).

In addition, the German knowledge platform "DaNa" also provides information on nanomaterials in various applications (https://nanopartikel.info/en/knowledge/knowledge-base/).

However, reliable information on the scope of products containing nanomaterials that are already on the market is not available. Some countries (e.g., France, Denmark and Belgium) have established national registers, but the information collected and access to it varies from country to country.

The details contained in the different sources of information are compiled with different objectives and on the basis of different sources and quality of information, resulting in an inconsistent or incomplete picture.

An example of an application of nanomaterial in various areas is titanium dioxide. Selected questions and answers on titanium dioxide (including its uses) can be found here.

What are nanomaterials used for in cosmetic products?

Nanomaterials are addressed in the EU Cosmetics Regulation (EC) No. 1223/2009. Nanoparticles can be used as UV filters in sun protection products to protect the skin from UV radiation (e.g., titanium dioxide, zinc oxide). Nanotechnologically produced materials (so-called biocomposites) in toothpastes are intended to support the natural tooth repair mechanism of saliva. In addition, numerous pigments are used in cosmetic products. Some of these are in nanoform, such as carbon black. Other pigments have a broad particle size distribution and contain a proportion at the nanoscale, such as titanium dioxide. In skin care products, nanocapsules are intended to protect and transport active ingredients and improve the skin care effect. However, only those nanocapsules that are biologically stable and do not dissolve are to be considered nanomaterials according to the EU Cosmetics Regulation.

In July 2021, the European Commission published a report on the use of nanomaterials in cosmetic products.

Current information on which nanomaterials have been notified in cosmetic products to date can be found here: https://ec.europa.eu/docsroom/documents/38284

Selected general questions and answers on cosmetic products and their health risk assessment can be found here. An FAQ on titanium dioxid can be found here.

Are nanomaterials used in tattooing products?

Tattoo inks contain pigments such as titanium dioxide, which may contain a nanoscale fraction. Selected questions and answers on tattoo inks can be found here.

Are nanomaterials used in food?

Foods consisting of or containing engineered nanomaterials are – subject to specific regulations such as Regulation (EC) No 1333/2008 on food additives – and considered novel foods in the EU. Therefore, they require a separate assessment by the European Food Safety Authority (EFSA) and authorisation by the European Commission in accordance with the Novel Foods Regulation (EU) 2015/2283. To date, there is only one engineered nanomaterial that has been authorised for use in food in the EU under Regulation (EU) 2015/2283. This is iron hydroxide adipate tartrate (IHAT) in nanoform, which has been authorised as a source of iron in food supplements since 2022 (EU 2022/1373).

Various authorised food additives have a very broad particle size distribution and particles smaller than 100 nm may be present. The proportion of nanoparticles varies and is, in some cases, between 10-30 % of the total number of particles. Synthetic amorphous silicon dioxide (SiO_2), authorised as E551, is used, for example, as a trickle aid or thickener to prevent caking of crystals of table salt and powdered foods. It is also used as a flocculant in wine and fruit juice production. Iron oxide colourants (E172), which are also available in powder form, may contain considerable quantities of nanoparticles. In accordance with the EFSA's guidance document on technical requirements for regulated food and feed, the extent to which conventional materials contain nanoscale particles must be examined as part of a risk assessment and, if necessary, this proportion must then be assessed separately, taking nano-specific requirements into account. For food additives that have already been approved and that are to be used in a form other than the previously tested and approved form, e.g., as nanoparticles, Regulation (EC) No. 1333/2008 provides for re-evaluation and, if necessary, a new authorisation is prerequisite for placing on the market.

In addition, natural nanoparticles may be present in food (e.g., nanoscale casein micelles in milk). However, these do not fall under the term "nanomaterial" according to the Novel Foods Regulation (EU 2015/2283), which only considers "engineered nanomaterials".

What are nanomaterials used for in packaging?

The packaging industry is interested in applications of nanoparticles that are incorporated as fillers in plastics and lacquer layers or that are firmly applied as coatings to polymer surfaces (foils and containers). Some nanomaterials have already been assessed by the European Food Safety Authority (EFSA) for use in plastic food contact materials and have been approved by the European Commission. The decision was based on the fact that the relevant nanomaterials cannot be released from the plastic. The approved nanomaterials serve various purposes. For example, nanomaterials can improve the mechanical or thermal properties of food packaging or protect food from UV light.

Silicon dioxide is approved as a filler and additive for food packaging made of plastic, e.g., to improve stability and reduce gas permeability. Nanoclay platelets in plastic bottles also hinder gas exchange and thus extend the shelf life of beverages.

What are nanomaterials used for in textiles?

Special functional textiles are being developed for the textile sector such as insulating thermal protective clothing, as well as those that facilitate water-based cleaning or implement sensory functions. The creation of nanostructured surfaces aims to improve the water-repellent properties of textiles, while at the same time maintaining breathability. Titanium dioxide nanoparticles are already used in textiles as protection against UV radiation. Antimicrobial silver nanoparticles are used in shoe insoles, socks, bedding and some functional clothing textiles (e.g., sportswear). In addition, new production processes have recently been introduced. For example, nanofibers with very high specific surfaces (surface-to-volume ration) can be manufactured using electrospinning, a manufacturing process, which generates nanostructures from solutions, suspensions, or molten materials using a strong electric field.

How are nanomaterials regulated?

The legislator has decided to adapt existing regulations to the new requirements for nanomaterials. This process of adapting existing product-specific regulations has not yet concluded.

Not all products are regulated by their own legal regulations. However, all manufacturers are obliged by the European Product Safety Directive and from December 13 2024 by the Regulation (EU) 2023/988 on general product safety to guarantee the safety of their products.

How can I find out whether a product contains nanomaterials?

Consumers cannot always recognise whether products contain nanomaterials. In some product areas, labelling is mandatory to provide information about the nanomaterials contained in the product.

These areas include since 2013 cosmetic and biocidal products. Since 2014, foods containing nanomaterials must be labelled in accordance with the EU Food Information Regulation.

For products without specific labelling regulations consumers cannot judge whether these products actually contain nanomaterials.

In order to effectively implement and monitor the labelling obligation, suitable detection methods are required. Methods for the reliable detection of nanomaterials in various products are currently being developed and evaluated. Methods are already available in some areas.

Do nanomaterials pose specific health risks?

In general, the focus of the BfR's scientific risk assessment are intentionally produced nanomaterials. The basic principles of a health risk assessment also apply to nanomaterials: possible health hazards (harmful effects) and actual exposure must be considered. Due to the broad application in different products, the uptake pathways via the respiratory tract (inhalation), via the digestive tract (oral) and via the skin (dermal) are to be considered.

Compared to conventional materials, nanomaterials have altered and, in some cases, novel properties/functions. This raises questions that the BfR specifically examines in its risk assessment. However, often there still is a lack of data on the long-term effects of nanomaterials in the organism.

The following questions are of interest in the context of an assessment: Do nanomaterials enter the organism more easily and therefore exhibit a different distribution in the body (toxicokinetics) than non-nanoscale materials? Do the nanomaterials remain longer in individual organs (biopersistence) so that they can accumulate and thus cause damage to health? Do nanomaterials pose a risk of inflammatory reactions due to their large specific surface area (surface-to-volume ratio), which can lead to organ damage?

Further information:

- Health risk assessment of nanomaterials

Which nanomaterials in consumer-related application areas were already assessed?

Risk assessments have been carried out for a large number of nanomaterials used in cosmetic products. An overview of the assessments can be found on the website of the EU Commission's Scientific Committee on Consumer Safety (SCCS) (https://health.ec.europa.eu/scientific-committees/scientific-committee-consumer-safety-sccs/sccs-opinions_en).

The European Food Safety Authority (EFSA) has assessed nanomaterials used in plastics that come into contact with food. The assessments are published in the EFSA Journal. The approved nanomaterials are listed in Annex I of the corresponding Regulation (EU) No. 10/2011.

The European Food Safety Authority (EFSA) has also assessed Iron hydroxide adipate tartrate (IHAT) in nanoform in accordance with the Novel Food Regulation (EU) 2015/2283, which has been authorised by the European Commission as a source of iron in food supplements since 2022 (EU 2022/1373).

Substances whose nanoforms are relevant for consumer products were also assessed under the overarching EU chemicals regulation REACH.

Has there ever been a product that caused adverse health effects due to the presence of nanomaterials?

To date, the BfR is not aware of any case in which nanomaterials present in a consumer product were proven to have caused adverse health effects.

Research into nanomaterials: What strategy are the federal authorities pursuing?

As early as 2007, the BfR, together with the Federal Institute for Occupational Safety and Health (BAuA) and the Federal Environment Agency (UBA), developed a joint research strategy to identify the potential risks of nanotechnology. The aim was to describe the research needed to assess possible health risks and to promote the development of suitable test methods and assessment strategies (http://www.bfr.bund.de/cm/343/nanotechnologie_gesundheits_und_umweltrisiken_von_nanomaterialien_forschungsstrategie_endfassung.pdf).

The research strategy was evaluated in 2013 together with the National Metrology Institute of Germany (PTB) and the Federal Institute for Materials Research and Testing (BAM) and updated in 2016 for nanomaterials and other advanced materials.

The strategy contains a summary of the results of completed projects and describes ongoing activities in the areas of characterisation, exposure, toxicological and ecotoxicological effects, as well as risk assessment and risk communication.

Which research topics on nanomaterials are currently being investigated at the BfR?

The BfR has been involved in many different aspects of nanosafety research for many years. It participates in numerous national and European third-party funded projects.

The BfR third-party funded projects are listed on the BfR website in section "Research on nanotechnology: detection, toxicology, risk assessment and risk perception". Many of the projects that have already been completed dealt with the establishment and adaptation of test methods or with the targeted investigation of selected nanomaterials such as nano-silver, nano-cerium dioxide, nano-silicon dioxide and nano-titanium dioxide.

Current research projects in the field of food safety deals with the intake of engineered nanomaterials or mixtures containing nanoparticles via the intestine, with transport and cellular effects, primarily in the intestine and liver. Substances such as food colourings, food supplements, feed, pesticides or nanoplastic polymers of various food-relevant materials are being investigated.

Current main research areas in the field of chemical safety include the establishment of so-called New Approach Methodologies (NAMs) in order to improve the prediction of the toxicological potential of nanomaterials. Another focus is on investigating nano-specific mechanisms of action in order to develop new test and assessment methods on this basis.

In the area of tattoo inks, the solubilities of various pigments in relevant media (e. g., sweat simulant) are currently being investigated at the BfR in order to support predictions about their distribution in the human body.

In the consumer-related area, investigations are also being carried out into the emission of (nano)particles in additive manufacturing processes, such as 3D printing.

The EFSA-funded network project NAMS4NANO is an ongoing research project in which several BfR departments are involved. The overarching aim is to gain a more profound understanding of the opportunities, challenges and remaining uncertainties when using NAMs in the risk assessment of nanomaterials.

The BfR also participates in European and international committees in the ongoing adaptation of guidelines and guidance documents governing the testing of nanomaterials.

Further information:

- BfR research on nanomaterials

Further informationen on BfR website for nanomaterials

Health risk assessment of nanomaterials:
https://www.bfr.bund.de/en/health_risk_assessment_of_nanomaterials-30439.html

BfR research into nanomaterials:
https://www.bfr.bund.de/en/nanomaterials_research-10431.html

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry for Food and Agriculture (BMEL). It advises the Federal Government and the States ("Laender") on questions of food, chemical and product safety. product safety. The BfR conducts its independent research on topics that are closely linked to its assessment tasks.

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