Nanomaterials FAQ

FAQ dated 18 October 2021

The term “nanos” comes from the Greek and means dwarf. The prefix “nano” denotes a billionth part, in this case of a metre (= 1 nanometre, nm). In general, a nanomaterial refers to a material with one or more external dimensions in the size range between 1 and 100 nm.

Specifically manufactured nanomaterials are the subject of the BfR's risk assessment. They can be produced in numerous forms from various chemical substances. Compared to conventional materials, nanomaterials have altered and, in some cases, even novel properties and functions that make them interesting for many areas of applications. However, this also requires special attention from a regulatory perspective.

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

Production volumes and the variety of forms are constantly increasing, which can also lead to an increased and possibly new type of exposure for consumers if nanomaterials are released from products, for example. It’s not possible to give a general answer whether nanomaterials or the products containing them pose health risks for consumers. Nanosafety research therefore deals with the potential risks of nanomaterials for human health and the environment.

The BfR has compiled selected questions and answers on nanomaterials in the following.

What Is Nanotechnology?

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

Nanotechnologies offer the possibility to develop structures, techniques and systems in which materials show completely 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 in further development in food, consumer goods and cosmetic products. Nanotechnology is considered therefore as an important key technology worldwide.

What Are Nanomaterials?

The European Commission published a recommendation on the definition of nanomaterials in October 2011. The recommendation served as the basis for defining the term in various European regulations. In doing so, the Commission has provided the opportunity to define amendments or deviations in individual legal areas. Therefore, definitions in the various legal areas may (still) differ in their detail.

According to the **Recommendation of the European Commission on the Definition of Nanomaterials (2011/696 / EU)**, a nanomaterial may be a natural, incidental formed by processes or specifically manufactured material. It must contain particles where for at least 50% of the particles in the number size distribution, one or more external dimensions is in the size range 1 and 100 nanometres (nm). It is irrelevant whether particles are present individually in unbound state, as an aggregate or as an agglomerate. An aggregate consists of strongly bound particles. An agglomerate is a collection of weakly bound particles. In specific cases, the number size distribution threshold of 50% may be replaced by a threshold between 1% and 50% , where warranted by concerns for the environment, health, safety or competitiveness.

In addition, fullerenes, graphene flakes and single-walled carbon nanotubes with one or more external dimensions below 1 nm are also considered as nanomaterials. Fullerenes consist of carbon atoms which, with a high degree of symmetry, e.g., arranged in pentagons or hexagons, form a hollow, closed structure that is reminiscent of a ball. 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. Single-walled carbon nanotubes are tubes made of carbon atoms, which can also be thought of as rolled up graphene.

The definition in the **EU Cosmetics Regulation** (EC) No. 1223/2009 was drawn up before the European Commission's definition recommendation was published. It defines a nanomaterial as "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.

In the EU **Biocide Regulation** (EU) No. 528/2012, a nanomaterial means *"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"*

In the EU Regulation on **Novel Foods** (EU) 2015/2283, the term "**engineered nanomaterial**" is defined 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 to 100 nm.

The revised annexes (EU) No. 2018/1881 of the EU **Regulation for the Registration, Evaluation, Authorisation and Restriction of Chemical Substances** (**REACH**, (EC)) No. 1907/2006 defines the "**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."*

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

What Are Nanoobjects?

The International Organisation for Standardisation (ISO) differentiates within the generic term nanomaterial between free nanoobjects and nanostructured materials (ISO/TS 8004-1:2015). Nanoobjects include nanoplatelets, nanorods, nanotubes, nanofibres, nanowires, and nanoparticles. Nanostructured materials include nanocomposites and materials with a nanostructured surface.

What Are Nanoparticles?
Nanoparticles are nanoobjects with the three external dimensions between 1 and 100 nm. Nanoparticles can be produced from various chemical substances, e.g., gold nanoparticles, silver nanoparticles, titanium dioxide nanoparticles. The term is often used as a catch-all for various nanoforms in order to emphasise the solid character of nanomaterials.

What Are Nanofibres, Nanotubes, Nanowires and Nanorods?
Nanofibres, nanotubes, nanowires and nanorods are nanoobjects featuring two external dimensions between 1 and 100 nm with a significantly larger third external dimension. **Nanofibres** are fibres with a diameter of less than 100 nm. Hollow nanofibres are called **nanotubes** - such as carbon nanotubes for example. **Nanorods** are rigid nanofibres. **Nanowire**s are electrically conductive or semiconducting nanofibres.

What Are Nanoplatelets?
Nanoplatelets are nanoobjects with only one external dimension between 1 and 100 nm and two significantly larger external dimensions. 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?
Nanocomposites are composite materials that contain nanomaterials embedded in a matrix.

What Are Materials with a Nanostructured Surface?
The best-known example of a nanostructured surface are lotus leaves, the surface of which is covered by fine, nanoscale structures (i.e., between 1 and 100 nm in size). Water droplets 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 house paint) and is held up as the definitive example of technical developments inspired by nature.

What Are Natural Nanomaterials?
Many naturally occurring structures are nanoscale, i.e., with at least one external dimension between 1 and 100 nm in size. Natural nanomaterials may be organic, inorganic or organometallic. In the environment, these can arise from larger structures, e.g., through natural combustion processes (e.g., volcanic ash) or weathering processes (e.g., from minerals), but also from the agglomeration of smaller particles (e.g., precipitates).

There is also a large number of biological nanoobjects. For example, many proteins are nanoscale. Genetic information is stored in the form of deoxyribonucleic acids (DNA), which are also nanoscale with a diameter of approx. 2 nm. Foods also often contain natural nanoparticles, such as milk, which contains nanoscale casein micelles.

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

What Are Bio-Nanomaterials
In contrast to natural nanomaterials, bio-nanomaterials are specifically manufactured, but from biological molecules. A well-known example are origami structures made from deoxyribonucleic acids (DNA). DNA origami structures are made from a long single strand of DNA that is folded into a three-dimensional structure. Such structures do not currently have any commercial application.

What Are Unintentionally Produced Nanomaterials?

Unintentionally produced nanomaterials refer to randomly created nanoobjects in anthropogenic, i.e., man-made, processes. This includes the ultra-fine dusts that arise during combustion (e.g., exhaust gases from heating systems or internal combustion engines, and cigarette smoke). In addition, it also includes particles that arise unintentionally in work and production processes (e.g., during welding, grinding or milling). In contrast to specifically manufactured nanomaterials, unintentionally produced nanomaterials usually have a broad size distribution, frequently accompanied by a complex chemical composition.

What Is Nanoplastic?

Plastic particles that are smaller than 5 millimetres (mm) are called **micro**plastics. Nanoplastic refers to plastic particles that are even smaller and have external dimensions between 1 and 100 nm (nanometres). Microplastics can be produced intentionally (primary microplastics) or arise unintentionally in the environment through weathering processes (secondary microplastics). Secondary microplastics are often created by mechanical forces such as wind or waves, additionally accelerated by sunlight (UV ageing). Numerous studies exist on the formation and occurrence of microplastics in the environment. In contrast, very few studies deal with the occurrence or development of nanoplastics. Therefore, only a limited amount of reliable knowledge about nanoplastics exists. The particles can consist of different polymers, e.g., polyethylene (PE), polypropylene (PP), polyvinyl chloride (PVC) or polystyrene (PS). They usually have a wide size distribution and are often irregularly shaped. In addition, they may have bound environmental chemicals.

What Are Nanocarriers?

Nanocarriers, sometimes also called nanocapsules, are nanoscale structures that are used for packaging and/or transporting 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, mostly round structures, which consist of a shell of specially aligned molecules enclosing the packaged substance. However, other structures can also serve as nanocarriers, e.g., porous silicon dioxide nanoparticles. This packages and protects substances effectively against degradation. In addition, bioavailability can be increased because the nanocapsules are better transported across barriers in the body. Depending on the design, nanocapsules either release their contents immediately and completely or release the packaged substances slowly over a longer period of time, which can also be relevant for certain applications.

In medicine, nanocarriers have been used to transport active ingredients for many years. Some very effective cancer therapies are based on this principle. The use of nanocapsules improves the absorption of the active ingredient by the tumour, so that usually less active ingredient is required leading to a reduction of undesirable effects. The Covid-19 mRNA vaccines, which are also packaged in nanocapsules, represent another example of this.

Nanocapsules are becoming increasingly interesting for applications in other areas, e.g., cosmetics, food and pesticides.

Which Products Already Contain Nanomaterials?

Nanomaterials are now used in almost all areas of daily life, for example in cosmetic products, food packaging and numerous consumer goods such as kitchen appliances, as well as in paints and varnishes. It can therefore be assumed that today’s consumers come into contact with a large number of products that contain nanomaterials.

However, it is not always clear which products contain nanomaterials. Products containing nanomaterials are subject to labelling requirements only in some areas of law (e.g., for cosmetic products, foodstuffs and biocides).

Information on which products (may) contain nanomaterials is available from various websites:

The European Union has set up an observatory for nanomaterials (the "European Union Observatory for Nanomaterials", EUON). It offers extensive information on the use of nanomaterials in everyday life (https://euon.echa.europa.eu/en/uses).

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

The internet hosts numerous databases with information on products containing nanomaterials, such as the BUND product database (https://www.bund.net/themen/chemie/nanotechnologie/nanoprodukte-im-alltag/nanoproduktdatenbank/).

However, no reliable information exists on the scope of products containing nanomaterial that are already available on the market. Some countries (e.g., France, Denmark and Belgium) keep national registers, but the information collected and access to it varies from country to country.

The details contained in the different sources of information is compiled with various objectives and on the basis of differing sources and quality of information, leading to an inconsistent or incomplete picture.

What Are Nanomaterials Used for in Cosmetic Products?
Nanomaterials are covered by the EU Cosmetics Regulation (EC) No. 1223/2009. In sun protection creams, nanoparticles are used as UV filters to protect the skin from UV radiation (e.g., titanium dioxide, zinc oxide). Materials produced using nanotechnology (so-called biocomposites) in toothpaste are supposed to support saliva's natural tooth repair mechanism. In addition, numerous pigments are used in cosmetic products. Some of them are in nanoforms, such as carbon black. Other pigments have a broad particle size distribution and contain a nanoscale fraction such as titanium dioxide. In skin care products, nanocapsules are supposed to protect and transport active ingredients and improve efficacy. However, according to the EU Cosmetics Regulation, only nanocapsules that are biologically stable and do not dissolve can be regarded as nanomaterials. Research is being carried out into improving the physical properties (e.g., transparency) of finished cosmetic products using nanomaterials.

In July 2021, the European Commission published a report on the use of nanomaterials in cosmetic products:
https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:52021DC0403&from=EN.
Current information on which nanomaterials have so far been notified for use in cosmetic products can be found here: https://ec.europa.eu/docsroom/documents/38284

Are Nanomaterials Used in Food?
Foods that consist of or contain engineered nanomaterials are considered novel foods in the EU, except as otherwise provided specific regulations such as Regulation (EC) No. 1333/2008 on food additives. Novel foods require approval in accordance with the Regulation

on Novel Foods (EU) 2015/2283. So far, within the framework of Regulation (EU) 2015/2283, no intentionally produced nanomaterials have been approved for use in food in the EU.

Various approved food additives have a very broad particle size distribution and these particles have been found to be smaller than 100 nm. The proportion of nanoparticles varies and is, in some cases, between 10 to 30% of the total number of particles. Approved as E551, synthetic amorphous silicon dioxide (SiO_2) is used as a flow aid or thickener, for example, and prevents caking of common salt crystals and powdered foods. It is also used as a flocculant in wine and fruit juice production. 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 reassessment and, if necessary, a re-approval process as a 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 Regulation on Novel Foods (EU 2015/2283), which only take into account "engineered nanomaterials".

The food industry is currently working on functional foods in which vitamins, omega-3 fatty acids, phytosterols and flavourings are enclosed in nanocapsules made from organic materials, such as liposomes, in order to release them in the body in a targeted manner.

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. Nanomaterials can, for example, 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 in Textiles for?
Special functional textiles are being developed for the textile sector such as insulating thermal safety clothing, as well as those that facilitate water-based cleaning or implement sensory functions. The creation of nanostructured surfaces improves the water-repellent properties of textiles, while at the same time maintaining breathability. Titanium dioxide nanoparticles are already used in textiles as effective protection against UV radiation. Antimicrobial silver nanoparticles are used in shoe insoles, socks, bedding and some functional clothing textiles (e.g., sportswear). In addition, there have recently been new types of production processes. For example, nanofibres with very high specific surfaces (surface to volume ratio) 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 been completed.

Not all products are regulated under their own legal regulations. However, in principle all manufacturers are obliged by the European Product Safety Directive to guarantee the safety of their products (Section 3 of the Product Safety Act).

How Do I Know if a Product Contains Nanomaterials?
Consumers cannot directly identify whether products contain nanomaterials. A declaration is currently compulsory in some areas of application.

Since 2013, it has been compulsory to label cosmetic products containing nanomaterials. Compulsory labelling of nanomaterials in biocidal products has also been in force since 2013. Since 2014, food containing nanomaterials has to be labelled in accordance with the European Food Information Regulation.

Since the declaration only covers a few product areas, it is currently not possible for consumers to assess whether those products without labelling requirements actually contain nanomaterials.

In order to effectively implement and monitor the labelling requirement, suitable detection methods are required. Methods for 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?
The BfR's risk assessment is geared towards specifically manufactured nanomaterials. The basic principles of a health risk assessment also apply to nanomaterials: possible health hazards (harmful effects) and the actual exposure must be considered. Due to their broad use in different products, due consideration will be given to exposure routes via the respiratory tract (inhalation), via the digestive tract (oral) and via the skin (dermal).
Compared to conventional materials, nanomaterials demonstrate altered and, in some cases, new properties/functions. This gives rise to questions that the BfR specifically addresses in its risk assessment:

Do nanomaterials get into the organism more easily and are they, therefore, distributed differently in the body (toxicokinetics) than non-nanoscale materials? Do the nanomaterials stay longer in specific organs (biopersistence) leading to accumulation and associated health issues? Due to their large specific surface area (surface to volume ratio), do nanomaterials pose a risk of inflammatory reactions that can lead to organ damage?

Additional Information: Health risk assessment of nanomaterials

Which Nanomaterials Used in Consumer Products Have Already Been Subject to Health Risk Assessments?
Risk assessments were carried out for a large number of nanomaterials that are used in cosmetic products and have been notified for this purpose or which must be approved in accordance with the EU Cosmetics Regulation. The website of the Scientific Committee on Consumer Safety (SCCS) provides an overview of the assessments (https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions_en#fragment2).

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.

Substances for which nanoforms are relevant for consumer products (e.g., zinc oxide) were also assessed within the framework of the overarching EU Chemicals Regulation REACH.

Has a Product Ever Caused Damage to Health Due to the Nanomaterials It Contained?
So far, the BfR is not aware of any case in which it can be shown that damage to health was caused by nanomaterials contained in a consumer product.

Research on Nanomaterials: What Strategy are the Federal Authorities Pursuing?
In 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 requirements for an assessment of 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 continued in 2016 for nanomaterials and other advanced materials.

The strategy contains a summary of the results from projects that have already been completed 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 Studied 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 can be found on the BfR homepage (https://www.bfr.bund.de/de/drittmittelprojekte_des_bfr-192984.html) - under the heading "Nanotechnology research: Evidence, Toxicology, Risk Assessment and Risk Perception". Many completed projects dealt with the development and adaptation of test methods or with testing of selected nanomaterials such as nano-silver, nano-silicon dioxide and nano-titanium dioxide.

Current research projects in the field of food safety deal with the intestinal uptake of nanomaterials, transport and cellular effects, mainly in the intestine and liver. They examine substances such as food colourings, food supplements or nanoplastic polymers.

Current research in the field of chemical safety focuses on the establishment of methods to improve the predictability of the toxicological potential of nanomaterials. Another focus is on the investigation of nano-specific modes of action in order to develop respective test and assessment methods.

In addition, studies are carried out on emissions of additive manufacturing processes in consumer-related applications, such as 3D printing. For this purpose, single-particle analysis methods are being developed to determine the uptake and distribution of nanomaterials in various tissues.

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

Additional Information: BfR research into nanomaterials

About the BfR

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