Verband der Mineralfarben-industrie e. V.

Comparative Compilation of relevant nano definitions in different regulations and their corresponding consequences

In recent years, legislation has focused increasingly on nanomaterials. The supposed increased risk to humans and the environment, which is often associated with the reduced particle size, prompted some regulations and ordinances to make specific demands on the use of such materials. Pigments and fillers often fall under the chosen definitions because they show their best properties with correspondingly small particle sizes - without being intentionally a nanomaterial. Even if the properties of the pigments and fillers concerned have not changed significantly, the specific regulations often mean considerable additional work.

The variety of product-specific regulations often results in different consequences for the same product, depending on the application. For example, no uniform definition for a nanomaterial has been found within EU legislation to date. For consumers, the alleged discrepancies that arise as a result are incomprehensible and weaken the trust in a comprehensive risk assessment and appropriate risk management. But also on the part of the industry, it is often difficult to understand the various requirements, especially in the area of downstream users close to end customers.

The following compilation is intended to provide an initial overview of the nano-definitions implemented in the various EU regulations and their differences, as well as - according to our interpretation - the resulting consequences for the products concerned. National regulations, such as nano registration registers, have not been taken into account in this overview. The compilation does not claim to be complete and will be updated and expanded as necessary. The legal basis for all matters is always the corresponding legal text.

Contact:

Verband der Mineralfarbenindustrie e. V.
Dr. Heike Liewald

liewald@vdmi.vci.de

The Verband der Mineralfarbenindustrie e. V. represents German manufacturers of inorganic (e. g. titanium dioxide, iron oxides), organic and metallic pigments, fillers (e. g. silica), carbon black, ceramic and glass colours, food colourants, artists' and school paints, masterbatches and products for applied photocatalysis.

The VdMi is listed in the Lobbying Register for the Representation of Special Interests vis-à vis the German Bundestag and the Federal Government (Lobbyregister des Deutschen Bundestags, number R000760) as well as in the Transparency Register of the EU Commission (number 388728111714-79).

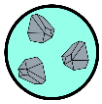
Verband der Mineralfarben-industrie e. V.

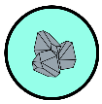
Legend of the used pictograms

 = Natural material

 = Incidental material

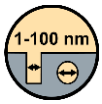
 = Manufactured material

 = Particles in unbound state

 = Aggregate or agglomerate

= 50% or more in the number size distribution

= Diameter of an external dimension in the size range 1-100 nm



= Diameter of an internal dimension in the size range 1-100 nm

 = Insoluble or biopersistant

= Nano properties even with structures > 100 nm

 = Fullerenes, graphene flakes and SWCNT

Mainzer Landstraße 55
60329 Frankfurt

www.vdmi.de
info@vdmi.vci.de

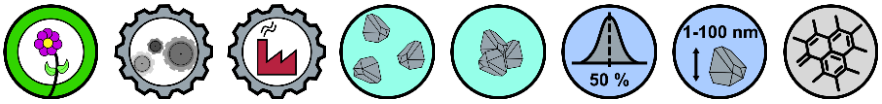
Telefon: 069 - 2556 - 1351
Telefax: 069 - 2556 - 1250

Definition of a nanomaterial – recommendation of the EU Commission

Publication: 14th June 2022 (2022/C 229/1)

Come into force: ——

The EU Commission published a recommendation of a nanomaterial definition in 2011.



'Nanomaterial' means a **natural, incidental or manufactured** material consisting of solid particles that are present, either on their own or as identifiable **constituent particles in aggregates or agglomerates**, and where **50% or more of these particles in the number-based size distribution** fulfil at least one of the following conditions:
(a) one or more external dimensions of the particle are in the size range **1 nm to 100 nm**;
(b) the particle has 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;**
(c) the particle has a plate-like shape, where **one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm**.

In the determination of the particle number-based size distribution, particles with at least two orthogonal external dimensions larger than 100 µm need not be considered.

However, a material with a specific surface area by volume of < 6 m^2/cm^3 shall not be considered a nanomaterial.

Consequences: **no direct consequences**

The definition is intended to be used as a reference to determine whether a material should be considered a “nanomaterial” for legislative or political purposes. Therefore, it only serves as a template for the nano-definitions implemented in the individual regulations and thus does not have any direct consequences for individual products.

Mainzer Landstraße 55
60329 Frankfurt

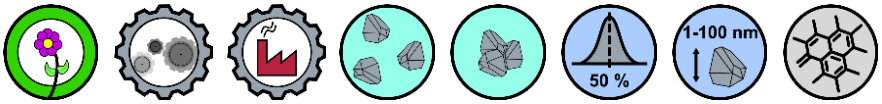
www.vdmi.de
info@vdmi.vci.de

Telefon: 069 - 2556 - 1351
Telefax: 069 - 2556 - 1250

Supplement to REACH Regulation (1907/2206) to include nanoforms

Publication:	3rd December 2018 (EU 2018/1881)
Come into force:	23rd December 2018
Application since:	1st January 2020

Since 1st January 2020, nanoforms must be recorded separately in registration dossiers. The definition of nanoform is based on the EU recommendation but introduces another, new term.



On the basis of the Commission Recommendation of 18 October 2011 on the definition of nanomaterial (1), a nanoform is 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.

Consequences: **Separate recording of nanoforms in registration dossiers**

Each nanoform must be described by the following phys. chem. properties and differentiated from other nanoforms (Annex VI, subsection 2.4.2-2.4.5):

- Particle size and particle size distribution
- Specific surface area
- Form, secondary structure (assembly structure), crystallinity
- Describtion of the surface treatment

The hazard, exposure and risk assessment must be done individually for every nanoform and set of similar nanoforms, respectively. In this process, several nano specific aspects have to be taken into account:

- Dustiness
- Dispersion stability
- Increased inahaltion toxicology
- Further study demands possible

Mainzer Landstraße 55
60329 Frankfurt

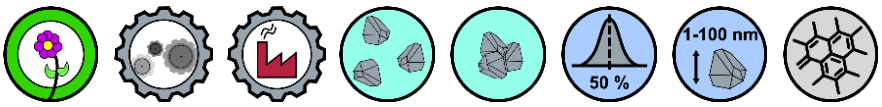
www.vdmi.de
info@vdmi.vci.de

Telefon: 069 - 2556 - 1351
Telefax: 069 - 2556 - 1250

Regulation on medical devices

Publication:	5th May 2017 (EU 2017/745)
Come into force:	25th May 2017
Application since:	26th May 2020 (with exemptions)

The nano definition of the Regulation on medical devices corresponds to the EU recommendation but does not foresee the possibility to lower the threshold.



> 'nanomaterial' means a **natural, incidental or manufactured material** 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**;
>
> Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall also be deemed to be nanomaterials;

Consequences: **Special requirements in the authorization due to higher classification**

The Regulation stipulates that when using nanomaterials, special attention should be paid to reducing the risk of particle penetration, especially if the product does not only come into contact with intact skin. Therefore, a separate classification rule applies in the presence of nanomaterials (Rule 19):

- Insignificant potential for internal exposition → medical device class IIa
- Low potential for internal exposition → medical device class IIb
- Medium or high potential for internal exposition → medical device class III

Thus, higher requirements in the authorization apply. As there is no longer the possibility for an assignement to the medical device class I, the conformity assessment must be carried out by an independent testing and certification body and can no longer be carried out by the manufacturer.

Mainzer Landstraße 55
60329 Frankfurt

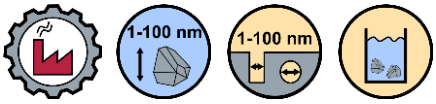
www.vdmi.de
info@vdmi.vci.de

Telefon: 069 - 2556 - 1351
Telefax: 069 - 2556 - 1250

Regulation on cosmetic products

Publication:	22nd December 2009 (EG 1223/2009)
Come into force:	11th January 2010
Application since:	11th July 2013 (with exemptions)

As the Regulation on cosmetics introduced a definition for nanomaterials before the EU recommendation was published, the definition deviates significantly from definitions introduced later.



'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**;

Consequences: **Special information and labelling requirements**

In principle, every component of a cosmetic product meeting the definition of a nanomaterial must be labeled as such in the ingrediants list by adding the indication „(nano)". Additionally, further information must be provided in the notification.

Cosmetic products with nanomaterials which are authorized as colourants, UV light filters or conservatives (Article 14, entries in Annex IV, V or VI) only need to be notified according to Article 13 and the required information on the nanomaterials need to be provided.

- Simple notification according to Article 13
  - IUPAC name and descriptors according to Number 2 of the preamble to the Annexes II to VI
  - Predictable exposition conditions

However, this does not apply if nanomaterials in accordance with the requirements of Annex III (List of Restricted Substances) are used or if there is no explicit authorization for the nanomaterial in accordance with Article 14. In these cases, the cosmetic product with nanomaterial must be notified in accordance with Article 16.

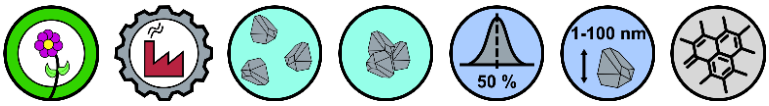
- Notification according to Article 16
  - IUPAC name and descriptors according to Number 2 of the preamble to the Annexes II to VI
  - Particle size and phys. chem. properties
  - Quantity estimation
  - Toxicological profile
  - Predictable exposition conditions

If there are any concerns, the commission can request an opinion from the Scientific Committee on Consumer Safety (SCCS).

Regulation on biocidal products

Publication:	27th June 2012 (EU 528/2012)
Come into force:	17th July 2012
Application since:	1st September 2013

The nano definition of the Regulation on medical devices corresponds to the EU recommendation but does not foresee the possibility to lower the threshold.



‘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**.

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials.

Consequences: **Separate approval, labeling requirements and special information requirements in the application for active substances**

Unless expressly mentioned, the active substance approval of a substance does not include nanomaterials. Therefore, these require a separate approval in which the risks to human, animal and environmental health are assessed. A simplified authorization procedure is excluded (Article 25).

If a biocidal product contains a nanomaterial, it must be identified on the label with the addition “(Nano)” each time it is mentioned. Possible nano-specific risks must be indicated.

Additional information on the methodology must be given in the application for the active substance:

- Reason for the suitability of the measurement methods used or any necessary changes made
- Principles for the evaluation of biocidal products (Annex VI) need to be adapted and supplemented by technical guidelines to take into account the latest scientific information

In addition, the report of the member states on the implementation of the Biocide Regulation must contain information on the use of nanomaterials in biocidal products and their potential risks.

Mainzer Landstraße 55
60329 Frankfurt

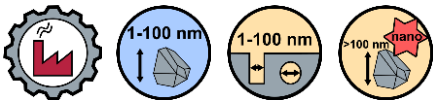
www.vdmi.de
info@vdmi.vci.de

Telefon: 069 - 2556 - 1351
Telefax: 069 - 2556 - 1250

Novel Food Regulation

Publication:	11th December 2015 (EU 2015/2283)
Come into force:	31st December 2015
Application since:	1st January 2018 (with exemptions)

The nano definition in the Novel Food Regulation is limited with regard to the origin of the nanomaterial but leaves other criteria much more open than the EU recommendation. For example, there is no clear upper limit for the size of the affected structures.



‘engineered nanomaterial’ means 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**.

Properties that are characteristic of the nanoscale include:
(i) those related to the large specific surface area of the materials considered; and/or
(ii) specific physico-chemical properties that are different from those of the non-nano-form of the same material.

Consequences: **Special information requirements in the permit application**

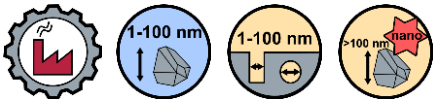
All materials falling under this definition are considered novel foods and are therefore automatically subject to this regulation.

In the application for approval, a justification for the suitability of the measurement methods used or any necessary changes made must be stated.

Regulation on provision of food information

Publication:	22nd November 2011 (EU 1169/2011)
Come into force:	12th December 2011
Application since:	13th December 2014 (with exemptions)

The Food Information Regulation refers directly to the nano definition implemented in the Novel Food Regulation (EU 2015/2283).



‘engineered nanomaterial’ means 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**.

Properties that are characteristic of the nanoscale include:
(i) those related to the large specific surface area of the materials considered; and/or
(ii) specific physico-chemical properties that are different from those of the non-nano-form of the same material.

Consequences: **Labeling in ingredients list**

Ingredients falling under the definition of technically produced nanomaterials must be clearly listed in the list of ingredients and marked with the addition "nano".

Mainzer Landstraße 55
60329 Frankfurt

www.vdmi.de
info@vdmi.vci.de

Telefon: 069 - 2556 - 1351
Telefax: 069 - 2556 - 1250