

Nano-Regulation in the EU

brief overview

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Definition

European commission (2011) **Recommendation on the definition of a nanomaterial** (2011/696/EU)

According to the Recommendation a "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 nm - 100 nm.

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.

By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

http://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm http://ec.europa.eu/environment/chemicals/nanotech/faq/questions_answers_en.htm



Adopted in 2013

New rules for the use of nanomaterials in cosmetic products

Colorants, preservatives and UV-filters, including those that are nanomaterials, must be explicitly authorised. Products containing other nanomaterials not otherwise restricted by the Cosmetics Regulation will be the object of a full safety assessment at EU level if the Commission has concerns. Nanomaterials must be labelled in the list of ingredients with the word "nano" in brackets following the name of the substance, e.g. "titanium dioxide (nano)".

The regulation on cosmetic products defines "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

http://ec.europa.eu/growth/sectors/cosmetics/legislation/index_en.htm http://ec.europa.eu/growth/sectors/cosmetics/products/nanomaterials/index_en.htm



EU cosmetics regulation



Name and address of a responsible person for compliance with the rules. Clear outline of obligations Pictogramme indicating the date of minimum

the date of minimum durability

or

period when product is safe after opening

Nano

ON THE LABEL

All nanomaterials are to be indicated in the list of ingredients. Their names are followed by "nano" e.g. Titanium Dioxide <nano>

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EU cosmetics regulation (1223/2009)



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Adopted in 2013

Nanomaterial definition in the regulation on biocidal products:

'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.

A dedicated risk assessment is needed when a nanomaterial form of an active or nonactive substance is used in a biocidal product. Such biocidal products must also be labelled and indicate the name the nanomaterial followed by the word "nano" in brackets. However, the simplified procedure for authorisation introduced in the BPR is not applicable for nanomaterials.

http://echa.europa.eu/regulations/biocidal-products-regulation http://echa.europa.eu/web/guest/regulations/biocidal-products-regulation/nanomaterials



EU Food Labelling Regulation (1169/2011)





http://ec.europa.eu/food/safety/docs/labelling_legislation_infographic_food_labelling_rules_2014_en.pdf



Department of Environmental Geosciences

EU Food Labelling Regulation (1169/2011)

Adopted in 2014

The regulation on the provision on food information to consumers defines "engineered nanomaterial" as

'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:

- 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 nonnanoform of the same material;

http://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation/index_en.htm



REACH \rightarrow **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals

entered in force in 2007

Companies producing or importing chemical substances in volumes of 1 ton/year or more have to register the substance with the European Chemicals Agency (ECHA) and provide a dossier with safety data \rightarrow "no data, no market"

Nanomaterials are covered under REACH because they fulfil the definition of a chemical substance. There are guidance documents on how to include information on nanomaterials in REACH registration.

Commission launched a comprehensive REACH Implementation Project on Nanomaterials (RIPoN) in 2009 to provide advice on key aspects of the implementation of REACH with regard to nanomaterials concerning Information Requirements and Chemical Safety Assessment.

http://ec.europa.eu/environment/chemicals/nanotech/reach-clp/ripon_en.htm http://ec.europa.eu/environment/chemicals/nanotech/reach-clp/index_en.htm





Nano-Norms-Nature Research platform (University of Vienna) <u>https://nano-norms-nature.univie.ac.at/</u>

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EU Horizon 2020, NanoFASE project





