Facts on Nano Discussion in the Pigment and Filler Industry

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Pigments and fillers are used to colour and structure the surfaces of almost all objects in our daily lives. They consist of small particles and are insoluble in the application medium (e.g. paints, varnishes and plastics) and therefore firmly bound in it.
Pigments and fillers were not invented as part of nanotechnology but existed for centuries or are the result of industrial research work over the last hundred years.

If the recommendation of the EU-Commission concerning a definition on nanomaterial of 10 June 2022[1] is applied to pigments and fillers, then a large quantity of traditional pigments and fillers would be considered as nanomaterial and is included in the statistics for nanomaterials.

In Europe approximately 100 companies produce pigments and fillers synthetically. These companies, around 75% of which are SMEs, produce a revenue of nearly 8,1 billion euro and are home to 23.000 employees. One third of the pigments and filler market is in Europe.

Definition and measurability

Various definitions have been developed within the framework of standardisation bodies, e.g. ISO. They all have an assigned size between 1 nm and 100 nm for nanomaterials in common, even though there is no scientific justification for these limits. The most important definition in Europe is the recommendation of the EU-Commission of 10 June 2022 (herein after referred to as the “Commission definition”), even though it has no legal relevance for the time being. The Commission definition replaces the original definition from 2011.
According to the Commission definition a nanomaterial is described as ‘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:

- One or more external dimensions of the particle are in the size range 1 nm to 100 nm;
- 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;
- 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.’

An alternative definition is presented by the American authority EPA.[2] There a new property due to the particle size compared to the common substances is needed next to the particle size in general.

ASTM E 2456-06 is only considering 2 and 3-dimensional nanoscale particles as nanomaterial.

[1] Commission Recommendation 2022/C 229/01 of 10. June 2022 on the definition of nanomaterial
[2] http://www.gpo.gov/fdsys/granule/FR-2015-04-06/2015-07497

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With the inclusion of aggregates and agglomerates in the Commission definition numerous pigments and fillers will be nanomaterial by definition.

In a project with the JRC the European association Eurocolour has conducted an extensive reality check regarding the applicability of the current measurement methods for pigments and fillers available in practice. [3]

The main results are as follows:

- Considerable expertise and solid knowledge of the substance to be analysed are necessary to obtain meaningful results when measuring particle size.
- Sample preparation (especially dispersion) is crucial to carry out a valid and representative determination of the particle size distribution.
- Based on the findings of this project it is not possible to recommend a single method to identify nanomaterials based on the Commission definition.

The practical decision if a material is classified as nanomaterial or not depends mainly on the following:

- The requirement for a number size distribution makes the use of electron microscopy unavoidable in most cases.
- The inclusion of agglomerates and aggregates which are built of parts with a dimension smaller 100 nm, excludes the use of automatic image counting in practice.
- The severely limited number of particles recorded and evaluated as a result of this also makes it difficult to select a sample that is representative of the material.

This means that a single analysis is associated with high personal requirements. At the same time, these very specific requirements mean that the manufacturers' previous, sometimes very extensive knowledge of particle size can only be used to a limited extent.

Hazard profile of pigments and fillers

Toxicity

As part of the REACH registration of industrial chemicals, experimental data for the majority of pigments and fillers have been compiled or newly collected. Since 2020 it has been necessary take nanomaterials into consideration for the REACH dossier (See REACH and Nano section).
Furthermore, studies are being conducted to fulfil registration requirements outside of the EU. In addition, a lot of data has been published in specialist literature. The European chemicals legislation [4] requires companies to use existing data together, search for relevant information in public databases and check the data to ensure that it is sufficient and reliable. The amount of experimental data has been increased in the last years due to research, ongoing registrations as well as request for studies by authorities and evaluations of substances.

As mentioned in the introduction many pigments and fillers fall under the Commission definition for nanomaterials. In general, these substances have been marketed in the same or equivalent quality for decades.
A considerable amount of data on toxicity of these materials especially on safety and environmental assessment has been generated long before the discussion on nanomaterials and their supposed risk.

[3] *JRC Technical Reports „ Basic comparison of particle size distribution measurements of pigments and fillers using commonly available industrial methods"* http://publications.jrc.ec.europa.eu/repository/handle/JRC92531

[4] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Solids with dimensions in nanometre scale are in the rarest of cases new and innovative substances. Nonetheless, publications on some newly developed nanomaterials have raised fears that exposure to such materials could lead to “nano-specific” toxic effects. For this reason, nanomaterials are repeatedly being considered as critical both in connection with exposure at the workplace and when used by the consumer in articles and mixtures.

A survey on research findings on nano safety summarises a variety of studies in science and industry over the last years. No results on technical nanomaterial being the reason for concern have been found with some expected derogations for fibrous or soluble materials. [5] Although the focus of studies in the last decade was on nano safety no nano specific toxic effect could be found in animal model systems. Until today there is no evidence on the hazard of particles abruptly changing between particle <100 nm (threshold value for nanomaterials) and > 100 nm (bulk goods). [6] Inhalation studies conducted specially with various inorganic and organic pigments also failed to identify any „nano-specific“ hazards. [7]

Classical materials which have been on the market for a long time, like pigments and fillers, do not change their assessment of risk to safety and the environment just because they are now included in the Commission definition and are therefore considered as nanomaterials. The substances studied so far theoretically already fulfil the current nanomaterial definition at the time of the study. Therefore, nano-specific toxic properties are already included in these tests.

Pigments and fillers are generally practically unsolvable in water and octanol. In most cases the value measured is < 1mg/l. In addition are pigments and fillers considered as chemically inert. As it is required for substances to be solvable in aqueous (e.g. in the gastrointestinal tract) or lipophilic media (e.g. lipid membranes) to be absorbed in relevant quantities into the organism, it is unlikely for pigments to become systemically bioavailable after oral, dermal or inhalation exposure. [8] As for all materials consisting of inhalable dusts, inhalation is considered as the most important route of exposure.

Compared to soluble particles, insoluble particles are mainly transported back into the mouth and coughed up via the self-cleansing mechanism of the lungs (Mucociliary clearance). Absorption of solid particles into the body via the lungs is only considered by absorption of solid particles into the cell (Phagocytosis) by the so-called phagocytes of the immune system. However, the amount absorbed in this way can be considered negligible.

The phenomenon that inert particles, when inhaled in sufficient large quantities, lead to a collapse of the normal excretory processes of the lungs has been demonstrated in small laboratory animals. Whether and to what extent these findings can be transferred to humans is controversial

[5] H.F. Krug, *Nanosafety Research – Are We on the Right Track? Angew. Chem.* **2014**, *126* 2 – 19 (*Angew. Chem. Int. Ed.* **2014**, *53*, 2 - 18); (http://dx.doi.org/10.1002/anie.201403367).

[6] K. Donaldson, C. A. Poland. *Nanotoxicity: challenging the myth of nano-specific toxicity. Curr. Opin. Biotechnol.* **2013**, *24*, 724 – 734; http://dx.doi.org/10.1016/j.copbio.2013.05.003.

[7] T. Hofmann, L. Ma-Hock, V. Strauss, S. Treumann, M. Rey Moreno, N. Neubauer, W. Wohlleben, S. Gröters, K. Wiench, U. Veith, W. Teubner, B. van Ravenzwaay, R. Landsiedel, *Comparative short-term inhalation toxicity of five organic diketopyrrolopyrrole pigments and two inorganic iron-oxide-based pigments*, *Inhalation Toxicology,* **2016**, 28(10), 463-479; http://dx.doi.org/10.1080/08958378.2016.120069

[8] Stratmann, H., Hellmund, M., Veith, U., End, N., & Teubner, W. (2020). Indicators for lack of systemic availability of organic pigments. *Regulatory Toxicology and Pharmacology*, *115*, 104719; https://doi.org/10.1016/j.yrtph.2020.104719

and has been discussed in expert workshops and is still being evaluated by various working groups and experts. [9, 10, 11]

Based on the animal findings, general exposure limits for inert inhalable dust apply in many countries.

In Germany the threshold concentration for the alveolar fraction (A-Dust) is 1,25 mg/m^3 at a density of 2,5 g/cm^3. The inhalable fraction (E-Dust) has a threshold of 10 mg/m^3 at the workplace. [12]

For Nanomaterials a lower threshold of 0,5 mg/m^3 (alveolar fraction) at a density of 1,5 g/cm^3 with a mass fraction of 20% of bio persistent and non-fibrous nanomaterials without specific toxicity is recommended. A limit value of 1,25 mg/m^3 at a density of 2,5 g/cm^3 or higher (alveolar fraction) of low mass fractions is recommended for downstream user processes. [13]

Exposure and bioavailabilty

Fine and very fine particles tend to form together to larger agglomerates. The finer the particle the more they show this behaviour. Breaking up those formed agglomerates takes considerable energy and a medium to transfer the necessary sheer forces to the particles. The achievable dispersion state and, consequently, the particle size distribution strongly depend on the medium in which the particles are contained. With the use of strong sheer forces in liquid media existing agglomerates can be broken up into primary particles, aggregates and smaller agglomerates. Surface active substances and binder systems are additionally needed to prevent re-agglomeration and to stabilize the dispersion. In airborne systems, the transfer of strong shear forces and, consequently, the breaking up of existing agglomerates are usually not possible at all or only to minor extent. This reflects in the results of workplace measurements. [14,15,16]

There is also frequently voiced concern that once inhaled, nanomaterials could release nanoparticles, which, due to their small size, may reach areas of the human body otherwise not accessible to conventional substances, so that they cause damage. Newer studies show that no breakdown of nanomaterial aggregates and agglomerates, with a release of nanoparticles, is happening inside the lungs. If anything, research points to the opposite. In lung fluid, nanomaterials come together to form even bigger agglomerates.

[9] Driscoll KE, Borm PJA. Expert workshop on the hazards and risks of poorly soluble low toxicity particles. Inhal Toxicol. 2020 Feb;32(2):53-62. doi: 10.1080/08958378.2020.1735581. Epub 2020 Mar 9. PMID: 32149535.

[10] Stratmann H, Wohlleben W, Wiemann M, Vennemann A, End N, Veith U, Ma-Hock L, Landsiedel R. Classes of organic pigments meet tentative PSLT criteria and lack toxicity in short-term inhalation studies. Regul Toxicol Pharmacol. 2021 Aug;124:104988. doi: 10.1016/j.yrtph.2021.104988. Epub 2021 Jul 2. PMID: 34224799.

[11] ECETOC Technical Report No. 122 ISNN-2079-1526-122, 2013; TR 122 - Poorly Soluble Particles / Lung Overload - ECETOC

[12] *Technische Regeln für Gefahrstoffe (TRGS) 900 „Arbeitsplatzgrenzwerte“,* **Ausgabe: Januar 2006, Fassung 12.06.2023**.

[13] *TRGS 527 “Tätigkeiten mit Nanomaterialien”*, **Januar 2020**

[14] *Nanoparticle exposure at nanotechnology workplaces: A review,* Thomas AJ Kuhlbusch, Christof Asbach, Heinz Fissan, Daniel Göhler and Michael Stintz, *Particle and Fibre Toxicology* **2011**, 8:22; http://dx.doi.org/10.1186/1743-8977-8-22.

[15] Kuhlbusch TAJ, Neumann S, Fissan H. **(2004).** *Number Size Distribution, Mass Concentration, and Particle Composition of PM1, PM2.5, and PM10 in Bag Filling Areas of Carbon Black Production. J Occup Environ Hyg* ***1****,* 660-671; http://dx.doi.org/10.1080/15459620490502242.

[16] Kuhlbusch TAJ and Fissan, H **(2006).** *Particle characteristics in the reactor and pelletizing areas of carbon black production." J. Occup. Env. Med* ***3***, 558-567; http://www.tandfonline.com/doi/10.1080/15459620600912280.

Maier et al. [17] came to the conclusion that lung surfactant does not promote the disaggregation of titanium dioxide aggregates or agglomerates. Creutzenberg et al. [18] investigated the fate of three different aggregates (including carbon black) after uptake in the lungs and found a tendency of nano-scaled particles to form larger size agglomerates following deposition and interaction with cells of the respiratory tract.

The German NanoCare-Project [19] studied and compared the behaviour of nine different nanostructured materials in presence and absence of lung fluid. The results indicate that contact with the serum or lung liquid does not result in nanomaterials breaking up into smaller sized units, rather the opposite is happening.
In the NanoCare-Project complete lung fluids were used and therefore, the results are representative of the actual lung environment.

In case of pigments and fillers being the fine particle mater, the particles are bound in a matrix in the final application – e.g. in printing inks, paints and coating (after curing) or plastics. Usually, these particles cannot be released from the matrix. [20,21]

Studies on the release of nanomaterials

Release from coatings and plastics

The end user usually only comes into contact with pigments and fillers indirectly via objects which are coated or coloured. In this case fine and nanoscale dispersed particles are bound into a solid matrix. The exposure of the end user with pigment and filler nanoparticles is therefore largely ruled out. Which was shown by scientists of the TU Dresden for the constant use of products (Ageing). [22]

Under controlled conditions coatings and pigments – which contained different fine particulate organic and inorganic pigments – were exposed to artificial weathering influences simulation everyday weather over several years. Next, the samples were exposed to several types of mechanical stress. The results show: Often, pigmented coatings and plastics are more stable to weathering influences and mechanical stress than non-pigmented ones.

After mechanical stress on surfaces, no free pigment nanoparticles were found. Neither in the airborne state nor in the abrasion. As detected under the microscope the pigment nanoparticles remain firmly bound in the matrix fragments (coatings or plastics) or are agglomerated in bigger structures. Consequently, an exposure of consumers to pigment nanoparticles could be largely excluded, also in permanent use or in the ageing of products.

[17] Maier, M., Hannebauer, B., Holldorff, H., & Albers, P., *Does Lung Surfactant Promote Disaggregation of Nanostructured Titanium Dioxide?, J. Occup. Env. Med.* ***48***, 1314-1320; http://dx.doi.org/10.1097/01.jom.0000215405.72714.b2.

[18] Creutzenberg, O., Bellmann, B., Korolewitz, R., Koch, W., Mangelsdorf, I., Tillmann, T., & Schaudien, D., *Change in agglomera tion status and toxicokinetic fate of various nanoparticles in vivo following lung exposure in rats, Inhalation Toxicology, Vol. 24, No. 12*, pp. 821-830.

[19] *39 NanoCare* **(2009)** Health *Related Aspects of Nanomaterials- FinalScientific Report,* http://www.nanopartikel.info/files/content/dana/Dokumente/NanoCare/Publikationen/NanoCare_Final_Report.pdf.

[20] *Emission von Nanopartikeln aus ausgewählten Produkten in ihrem Lebenszyklus*, Dr. Thomas Kuhlbusch, Carmen Nickel, *UMWELTFORSCHUNGSPLAN DES BUNDESMINISTERIUMS FÜR UMWELT, NATURSCHUTZ UND REAKTORSICHER HEIT*

[21] *Expositionsermittlung bei der Herstellung oder Verwendung von Nanomaterialien (Pulver, Lacke, Kompositwerkstoffe),* Daniel Göhler und Michael Stintz, *Nano-Tagung der Sächsischen Arbeitsschutz Konferenz,* **19. April 2012,** Dresden

[22] FRiNano Projekt: *Nanoparticle release from nanocomposites due to mechanical treatment at two stages of the life-cycl*e, Daniel Göhler, André Nogowski, Petra Fiala and Michael Stintz **2013** *J. Phys.: Conf. Ser. 429 012045*

Release from incineration plants

Modern flue gas plants are very effective. In testing at a waste incineration plant (iwhti the Federal Environment Agency/UBA project on the incineration of nanomaterial-containing wastes) no significant increase in the titan concentration was found in the purified flue gas.
It is worth noting that the added quantities of nanoscale TiO_2 (0,28% Ti) were above the concentration of 0,2% Ti measured in household waste.

Release from wall paints for exterior use („NanoHouse“) [23]

In weathering test an extremely low release of TiO_2-Nanoparticles was found for wall paints for exterior use. This means that the particles are firmly bound in the matrix. [24]

Migration of nanoparticles when used in consumer articles

Pigments and filler are widely used in plastics, coatings and inks which are in contact with foodstuffs. It must be ensured that these do not transfer to the foodstuffs.

As many pigments and fillers are considered as nano under the Commission definition the question, whether nanoparticles can migrate from plastics or inks and transfer to foodstuffs, is becoming more and more relevant.

Migration studies from plastic [25,26] as well as theoretical considerations [27,28] show that the migration of particles bigger than 2 – 3 nm can be ruled out. Due to the described strong agglomeration tendency of very small particles and the prevailing dispersion conditions, free particles in the size of 1 to 3 nm practically do not occur in plastics. This was also shown by comparative election micrographs. It can therefore be stated that nanoparticles cannot transfer from plastics to foodstuffs. [29]

Corresponding migration studies from printing inks did also show that there is no migration of nanoparticles [30]. Since the dried and hardened ink film is a polymer matrix that firmly encloses all pigments and fillers it contains, it was concluded that no particles from printing inks are transferred to foodstuffs.

There was also no migration of nanoparticles of zinc oxide (Nano, with and without surface treatment) found in plastics. [31]
The migration of carbon black on various food contact materials was also extensively investigated. There it was found that Carbon Black does not migrate from plastics or rubber into foodstuffs. The

[23] Life Cycle of Nanoparticle-based Products used in House Coating | NANOHOUSE | Project | News & Multimedia | FP7 | CORDIS | European Commission (europa.eu)
[24] Al-Kattan et al., *Environ. Sci.: Processes Impacts*, **2013**, 15, 2186)
[25] *Migration von Nanopartikeln*, Johannes Bott, Horst-Christian Langowski und Maria Wagenstaller, *FORUM WISSENSCHAFT TWB*
[26] *Scientific Opinion: Statement on the safety assessment of the substance silicon dioxide silanated, FCM Substance No 87 for use in the food contact materials; EFSA Journal* **2014**; 12(6):3712
[27] *Migration potential of nanomaterials in food contact plastics*, Angela Störmer, Johannes Bott & Roland Franz, *1st Joint Sympo sium on Nanotechnology, Fraunhofer* – BfR, Berlin**, 5.-6. March 2015**
[28] *A model study into the migration potential of nanoparticles from plastics nanocomposites for food contact*, Angela Störmer, Johannes Bott & Roland Franz, *Food Packaging and Shelf Life 2(2) 73-80* **(2014)**
[29] *Critical review of the migration potential of nanoparticles in food contact plastics*, A. Störmer, J. Bott, D. Kemmer, R. Franz, *Trends in Food Science & Technology* **2017**, *63*, 39-50
[30] *Analysis of the migration behaviour from printing ink layers of printed food packaging into the food*, Matthias Henker, Michael Becker, Sarah-Lisa Theisen and Martin Schleß, *DEUTSCHE LEBENSMITTEL-RUNDSCHAU, 109. Jahrgang* **April 2013**
[31] *Scientific Opinion on the safety evaluation of the substance zinc oxide, nanoparticles, uncoated and coated with [3-(methacryloxy)propyl] trimethoxysilane, for use in food contact materials, EFSA Journal* **2015**;13(4):4063

influence of mechanical stress on migration was also tested. There no migration of carbon black from food contact materials was found either. [32,33]

REACH and Nano

The EU-Commission determined in their Second Regulatory Review on Nanomaterials that REACH is the best place for the risk management of nanomaterials. [34] Nanomaterials are fundamentally regulated in the European chemical regulation REACH and therefore, no changes of the main text of the regulation are necessary.

At the end of 2018, changes to the REACH-Regulation for additional registration of nanomaterials were published. (EU 2018/1881). As a result, responsible companies need to characterize all nanoforms of a substance available and list them separately in the registration dossier of the substance and take them into account, since 1 January 2020. A nanoform is defined by the Commission definition from June 2022. The majority of registration dossiers that have since been updated with regard to nanoforms at the European Chemicals Agency ECHA are dossiers concerning pigments and fillers (as of 31 March 2023: of 167 substances with at least 113 lead dossiers from manufacturers of pigments and fillers).

In addition to the material identity nanoforms are characterized by particle size, specific surfaces, morphology, and surface treatment.

Changes to REACH Annex II in June 2020 require nanoforms, if necessary, to be indicated in the safety data sheet since 1 January 2023. Nanoforms need to be listed in the safety data sheet if they are classified or part of the reason for the classification. The listing can be done in section 1 with the addition “contains nanoform” or in section 3 together with other classified substances. Further additional information on solids or mixtures can be indicated in section 9. A non-classified nanomaterial does not need to be listed or specified.

ECHA extended their guidance documents on “information requirements and chemical safety assessment” (IR&CSA) as well as “Best practices on how to prepare registration dossiers that cover nanomaterials” with nanospecific additions. [35] In addition, ECHA has already requested more data on nanomaterials than is permitted in the context of substance and dossier evaluation. [36]

Nano product register

Registers of nanomaterials have been implemented in EU and non-EU countries over the last years. In the REACH-relevant legal area France, Belgium, Denmark, and Sweden have established their own registers. As an official EU register is not existing, information on nanomaterials from the national registers, among others are collected and published by ECHA on the European Union Observatory for Nanomaterials (EUON). [37] In addition to these registers reporting systems for nanomaterials have been established in the US, Canada, Norway, and Switzerland.

[32] *Migration of nanoparticles from plastic packaging materials containing carbon black into foodstuffs*, Johannes Bott, Angela Störmer & Roland Franz, Food Additives & Contaminants: Part A, **(2014)** 31:10, 1769-1782, DOI: 10.1080/19440049.2014.952786

[33] *Investigations into the Potential Abrasive Release of Nanomaterials due to Material Stress Conditions-Part A: Carbon Black Nano-Particulates in Plastic and Rubber Composites.* Bott, J.; Franz, R, *Appl. Sci.* **2019**, *9*, 214. https://doi.org/10.3390/app9020214

[34] eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:52012DC0572&from=EN

[35] https://echa.europa.eu/-/reach-guidance-for-nanomaterials-published

[36] vgl. Entscheidung des Board of Appeal zu TiO_2 https://echa.europa.eu/documents/10162/a3beed31-ab30-dcf1-1f86-7467f6b09a20 und SAS https://echa.europa.eu/documents/10162/02fb4c79-dcfd-ecc7-a474-b28781c202b0; https://echa.europa.eu/documents/10162/84c38038-4636-ec10-e9a0-6b961cac34b8

[37] https://euon.echa.europa.eu/

Most nano product registers are justified by the legislator with transparency for authorities and consumers about quantity and type of nanomaterials on the market, with the goal to react fast if new hazards emerge. On EU-level no data was seen but the necessity to compile available data in a comprehensible way. Therefore, the EU Observatory for Nanomaterials was established as information platform.

The design of the registers in the individual countries varies greatly. This starts with different definitions for nanomaterial in every country and continues with exemptions for the reporting obligations. Because of this the same substance could be a nanomaterial in one country but not in another. Specially regulated applications like cosmetics and foodstuffs can also have different nano definitions through which a registered nanomaterial is no nanomaterial under these regulations. These inconsistencies between the national registers have a great impact on the EU-ON, as it is not designed as a register but reflects unfiltered and without prior verification, the information collected in the French and Belgian national registers as well as the REACH registration dossiers and cosmetic inventory. The information published via EU-ON should therefore be treated with caution. As a result of the situation described above, the statement as to whether a product is a nanomaterial or whether it contains any, loses its general validity and must be decided on case-by-case basis. [38]

The first one to introduce a nano product register was France. They used the Commission definition from 2011 with an exemption for naturally occurring nanomaterials. The entries in the register are annually evaluated by the authority. However, the available reports to date are not very informative and essentially only provide a list of substances.

The Belgian law defines nanomaterials based on the Commission definition as well. It differentiates between registered substances and mixtures as well as articles and complex products for which registration is required. The Belgian register is in force since 1 January 2016 for substances and 1 January 2018 for mixtures. Unlike France where nanomaterials are registered for the previous year, nanomaterials need to be registered for the following year in the Belgian register. Furthermore, downstream users like professional and industrial users must be named as well.

The nano product register in Denmark only includes mixtures and articles which are intended for sale to the private end consumer and where the nanomaterials can be released or where they release CMR or environmental hazardous substances.
The Danish register has been in force since 30 August 2015.

Norway has a register of hazardous substances in which "nano" is listed as an additional specification. However, a nanomaterial is not considered as hazardous per se.

Sweden expands its chemical register on the 1 January 2018 with a reporting obligation for nanomaterials. Pigments are considered as derogation as the benefit of additional data is considered to be relatively low compared to the effort involved in registration. [39]

In addition to the different definitions and data requirements of the various registers, the quantities from which a substance must be registered as a nanomaterial varies. For the French and Belgian registers, a quantity of 100g per year is sufficient to start a registration. In the Swedish and Norwegian registers, a quantity of 100kg per year is required.

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[38] Suche nach Nanomaterialien - European Observatory for Nanomaterials (europa.eu)

[39] Summary and supplement to the impact assessment in the Swedish Chemical Agency´s report 10/15 (Kel Rapport 10/15) prior to notification to the EU Commission (Notification No 2017/227/S)

Outside the EU area, only new substances (not yet included in the national inventories) are subject to notification. VdMi provides interpretation aids for nano registers, which are updated regularly. [40]

Nanomaterials in consumer products

Even with the Commission definition from 2022 there is still the problem of different sector specific nano definitions. A declared objective of the Commission is to harmonize these different definitions with their definition. It should be emphasized that the term „nanomaterial" is solely a categorization of a material based on the size of its constituent particles. The term cannot be linked directly to hazard or risk. [41]

Cosmetics Regulation

The current Cosmetics Regulation (EU) Nr. 1223/2009 defines nanomaterials as "an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions. Or an internal structure, on the scale from 1 to 100 nm". [42] Formulations containing nanomaterials according to the definition of the Cosmetics Regulation need to be notified 6 months before being put on the market by the producer. Colourants need to be registered in Annex IV of the regulation. Based on the current definition only one substance is registered as nanomaterial in the Cosmetics Regulation. The planned revision of the Cosmetics Regulation is expected to adapt the Commission definition; therefore, significantly more substances will be considered as nanomaterial.

Nanomaterials used as colourants must be listed separately in Annex IV. This procedure is shortened for substances already listed in Annex IV. Fillers or pigments which are not listed in Annex IV must undergo a separate registration. This process will take more time and resources. It is unclear when the new definition will be implemented in the regulation. At the earliest, end of 2024, can be expected.

Biocide Regulation

In Regulation (EC) No 528/2012) nanomaterials are defined by the Commission definition from 2011. However, for authorization of nanomaterials in biocide products an extended authorization procedure, with special nanomaterial suitable tests, is necessary.

Furthermore, active substances that are not explicitly approved do not include nanomaterials. Labelling of all nanomaterials is also necessary. The labelling is therefore similar to that of the Cosmetics Regulation.

Food Information Regulation and novel food

In food legislation, the definition of nanomaterials is set out in the Novel Food Regulation (EU) 2015/2283. This regulates all novel foods that have not been consumed to a significant extent in the EU before 15 May 1997. Nanomaterials are specifically defined as engineered nanomaterial. These are defined as "any intentionally produced materials 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. Characteristic nanoscale properties

[40] VdMi intern document: VdMi_Interpretationshilfe_Nanoproduktregister

[41] Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR Scientific Basis for the Definition of the Term "nanomaterial", doi:10.2772/39703

[42] Regulation (EC) No 1223/2009 of the European Parliament and Council of 30 November 2009 on cosmetics products

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include those related to specific surface area of the materials considered or/and specific, physico-chemical properties that are different from those of the non-nanoform of the same material." [43]

The labelling of engineered nanomaterials in foodstuff is regulated by the Food Information Regulation. There is a reference to the engineered nanomaterials definition in the Novel Food Regulation. Accordingly, novel food additives, like pigments and fillers which fulfil the criteria of engineered nanomaterials, need to be labelled as "[nano]" on the food label. In addition, the European Food Safety Authority (EFSA) required a nano-specific assessment for the re-evaluation of food additives that meet the definition of an "engineered nanomaterial" or contain a fraction of small particles. [44], [45] Since the definition of particles in the guidance on "small particles" is much broader than in the definition of engineered nanomaterial, considerably more substances are affected.

The definition for engineered nanomaterials in the Novel Food Regulation is currently being revised by the Commission. A first draft of this revision was published as part of a public consultation. In this draft a criterion for solubility in water was presented.

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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).

[43] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001

[44] Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health, EFSA Journal 2021;19(8):6768, doi: 10.2903/j.efsa.2021.6768.

[45] Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles, EFSA Journal 2021;19(8):6769, doi: 10.2903/j.efsa.2021.6769.