Verband der Mineralfarben-industrie e. V.

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Position Paper of the Pigment and Filler Industry in the Nano Discussion

The Recommendation of the EU Commission on the Definition of Nanomaterial has major impacts on pigments and fillers, because a lot of colour pigments and fillers currently on the market fall under this definition and, consequently, under nano-specific regulations – even though these pigments and fillers have been in use for a very long time.

On 3rd December 2018, Adaptations of the REACH-Regulation introducing the registration of nanomaterials were published (Regulation (EU) 2018/1881). Thereby, the term 'nanoform' was defined. This describes the form of a substance which falls under the recommendation of a nanomaterial definition. Therefore, all nanoforms of a substance on the market must be characterized accordingly by the companies and treated separately in the registration dossier since 1st January 2020. This leads to a significant additional effort for the pigments and fillers industry as the characterization requirements on products already used for a long time increase und additionally the registration of different nanoforms might be necessary.

Pigments and fillers serve for the colouring and surface structuring of numerous daily life objects. They consist of small particles which are insoluble and firmly bound in the application medium. Pigments and fillers are nothing new. They have been in existence for many millenia, e.g. in rock and cave paintings. Today, pigments and fillers are found in a wide range of applications from automobile paint to bricks.

The EU Commission's definition of "nano" is based solely on the particle size of the material. The definition explicitly does not consider whether the material pose any risk or hazard. Thus, the assumption that nanomaterial generally represents a hazard is inappropriate, as proven by numerous studies over the past decades.[1]

Definition and measurability

According to the Commission's Definition[2] which was revised the last time on 10th June 2022 the particle size (1-100 nm) is the decisive criterion for a nanomaterial. Therefore, a nanoform is present if ≥ 50 % of the particles show a diameter in the range of 1-100 nm. This turns many pigments and fillers into nanomaterials per definition – while concrete requirements are lacking for how to verify this in practice. Since the publication of the first definition in 2011, public authorities and the stakeholder industries have been searching intensively for a straightforward and workable solution in order to enable a decision on whether there is a nanomaterial or not.

[1] D. M. Brown, H. J. Johnston, B. Gaiser, N. Pinna, G. Caputo, M. Culha, S. Kelestemur, M. Altunbek, V. Stone, J. Chandra Roy, J. H. Kinross, T. F. Fernandes, *NanoImpact* **2018**, *11*, 20-32. M. Delaval, W. Wohlleben, R. Landsiedel, A. Baeza-Squiban, S. Boland, *Arch. Toxicol.* **2017**, *91*, 163-177. T. Brzicova, J. Sikorova, A. Milcova, K. Vrbova, J. Klema, P. Pikal, Z. Lubovska, V. Philimonenko, F. France, J. Topinka, R. Rossner Jr., *Toxicology in Vitro* **2019**, *54*, 178-188. E. Joonas, V. Aruoja, K. Olli, A. Kahru, Science of The Total Environment 2019, 647, 973-980. A. Spengler, L. Wanninger, S. Pflugmacher, Aquatic Toxicology 2017, 190, 32-39.

[2] Recommended Commission's definition of a nanomaterial, status June 2022: "'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."

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Building on long-standing expertise in the pigment and filler industry, we demonstrated in a project together with the Joint Research Centre (JRC) that no universally accepted method exists for making this decision.[3]

Hazard profile of pigments and fillers – Toxicity

Like for all substances in powder form, inhalation is the toxicologically relevant uptake route for pigments and fillers. This is relevant for industrial workplace exposure. By way of technical and organisational protective measures, inhalation of pigments and fillers is reduced to a minimum in production and processing. Another possibility for reducing dust exposure in processing is the use of ready-made dispersions.

It is frequently claimed that after their uptake in the body, agglomerates or aggregates might release individual nanoparticles. More recent studies in this area indicate that there is no disintegration of aggregates or agglomerates – with a release of nanoparticles – in the lungs. The attractive forces between the particles are too strong for breaking up e.g. in the lung fluid.[4]

So far, there has been no indication of nano-specific toxicity in the comprehensive testing regarding toxicity of nanomaterials.[5] Thus, for classic materials like pigments and fillers which have been on the market for a long time the assessment of hazards concerning safety and environment does not change fundamentally – simply because today many of these materials are considered to be nanomaterials. Nevertheless, the effort for manufacturers of nanomaterials increases, since the legislature unjustifiably and blanketly considers these to be dangerous and therefore enforces nano-specific requirements in regulations.

Studies on the release of nanomaterials from paints and plastics

Numerous studies (e.g. the study FRiNano[6]) showed that in particular pigments and fillers that were firmly bound in a matrix did not release any free nanoparticles, not even under mechanical stress or weathering. For this reason, it makes no sense to address such firmly bound pigments and fillers in connection with nano.

Migration of nanoparticles from consumer articles

Pigments and fillers are frequently used in plastics, coatings, and printing inks that come into contact with food. Here, it must be ensured that there is no migration to the foodstuff.

[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] Maier, M., Hannebauer, B., Holldorff, H., & Albers, P., *Does Lung Surfactant Promote Disaggregation of Nanostructured Titanium Dioxide?, Journal of Occupational and Environmental Medicine, Vol. 48, No. 12,* **December 2006**, pp 1314-1320.

[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).

[6] 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.*

Based on studies on migration from plastics[7,8] and on theoretical considerations[9,10] it was possible to demonstrate that particle migration can be excluded for particles sized over 2 to 3 nm. No migration of nanomaterials was observed in relevant studies with printing inks, either.[11]

Consequently, also in these respects, we see no basis for special restrictions by the legislator for nanomaterials. More transparency could be brought about by informing consumers about nanomaterials not being linked with higher risk generally.

REACH and Nano

We agree with the statement made by the EU Commission in the so-called *Second Regulatory Review on Nanomaterials*[12] that *"REACH sets the best possible framework for the risk management of nanomaterials".* The corresponding amendments of the REACH Annexes published in December 2018 give the legal frame for the recording of nanomaterials. Since 1st January 2020, 149 substances[13] with a nanoform have been registered by European manufacturers. The majority of these belong to the group of pigments and fillers (at least 97 substances or 65 %[14]).

Besides the substance identity, a nanoform is characterized by its particle size, specific surface area, morphology, and surface treatment (see REACH Annex II, Subsection 2.4). However, the information requirements proposed by ECHA in form of a Guidance document exceed the legal text by far and are therefore lacking a legal basis like discussed at length in our position paper concerning the characterization of nanoforms.[15] Additionally, the demanded analytical methods are partly difficult to apply and lead to inaccurate results for real pigment and filler samples due to lacking measurement routines. Nevertheless, none of the studies carried out so far have pointed to a potential, nano-specific danger.

Nanoproduct register

We reject a "nanoproduct register" in general, both nationally and in Europe.

The necessary transparency and information about substances are provided under the REACH and CLP Regulations: Irrespective of a nano-property, substances are assessed with respect to to their hazards as a matter of principle.

Transparency at product level should be created by means of various product-specific pieces of regulation – with all of them having a uniform definition that would prevent the same substance being deemed "nano" under one set of rules and "not nano" under another. This would also enhance consumer safety and transparency.

[7] *Migration von Nanopartikeln*, Johannes Bott, Horst-Christian Langowski und Maria Wagenstaller, *FORUM WISSENSCHAFT TWB.*
[8] *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.
[9] *Migration potential of nanomaterials in food contact plastics*, Angela Störmer, Johannes Bott & Roland Franz, *1st Joint Symposium on Nanotechnology,* Fraunhofer – BfR, Berlin, **5.-6. March 2015**.
[10] *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)**.
[11] *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**.
[12] http://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:52012DC0572&from=EN .
[13] Numbers given by ECHA, status 8 April 2022.
[14] Result of an internal survey on the number of nanoform registration among VdMi members.
[15] Evaluation of the Draft Guidance on the Registration of Nanoforms with regard to the REACH Annexes, Eurocolour e. V., status 08.04.2019.

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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).