Verband der Mineralfarben-industrie e. V.

# 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 regulation – even though these pigments and fillers have been in use for a very long time.

On 3rd Decembre 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 from 2011 (see below). Therefore, all nanoforms of a substance must be characterized accordingly by the companies treated separately in the registration starting on 1st January 2020. This leads to a significant additionaly effort for the pigments and fillers industry as the characterization requirements on produkts 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 centuries, 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 Definition[2] 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. The inclusion of aggregates and agglomerates 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 Definition in the year 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. Building on long-standing expertise in the pigment and filler industry, we demonstrated in a project together with the Joint Research Centre (JRC) in Ispra that no universally accepted method exists for making this decision.[3]

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[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] A nanoform is defined based on the recommended Commission's definition of a nanomaterial from 2011 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".*

[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.

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## Hazard profile of pigments and fillers

### Toxicity

Like for all powder form substances, 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 their breaking up, e.g. in the lung fluid.[4]

In comprehensive testing regarding toxicity of nanomaterials[5] so far there has been no indication of nano-specific toxicity. 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 need to be deemed nanomaterials.

## Studies on the release of nanomaterials

### Release 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.
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]

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[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.*

[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**.

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 concur 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.

Besides the substance identity, a nanoforms is characterized by its partice 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.[13] 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.

## 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 the nano-property, substances are examined as 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.

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

[13] Evaluation oft he Draft Guidance on the Registration of Nanoforms with regard to the REACH Annexes, Eurocolour e. V., status 08.04.2019.