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**Joint Eurocolour and VdMi position on German BfC Report
“Assessment of the enforceability of the rules for nanomaterials in REACH – review
five years after entry into force”**

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 them.

Pigments and fillers were not invented as part of nanotechnology but have existed for centuries or are the result of industrial research work over the last hundred years. With the introduction of the EU recommendation from 2022¹ many pigments and fillers became nanomaterials by definition.

The report “Assessment of the enforceability of the rules for nanomaterials in REACH – review five years after entry into force” provided by the German BMUV and other German authorities, from here on called the BfC-Report, goes into detail on why the European approach on nanomaterials has failed and what needs to improve.

Our key messages:

- **The dossiers are complete and prove that substances in nanoform are safe**
 - There are no data gaps
 - Downstream user applications are already covered within the dossiers
- **Current concept of set of similar nanoforms should be redefined and simplified**
 - It was intended to simplify the process, but it has proven to be overcomplicated
 - A new, simple and workable concept is needed
 - Deletion of the System would lead to thousands of animals dying only to account for different grades by name instead of different materials
- **No additional information requirements necessary**
 - Enough data is available to assess the material
 - Already available data is relevant for substances in nanoform

VdMi and Eurocolour as associations with members being the lead registrants for many nanoforms available to the market do not agree with large parts of the assessment in the BfC-Report.

¹ Commission Recommendation of 10 June 2022 on the definition of nanomaterials 2022/C 229/01

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There are no data gaps; Proposed Article 38a is not required

In the BfC-Report, the discrepancy between the registered nanoforms and the predicted number of nanoforms by ECHA is at least partially contributed to downstream users unknowingly producing nanomaterials while working with bulk materials. It should be noted that the size and the number of the constituent particles drives the identification as nanomaterials for most substances. Extremely high energy, beyond what is used in the manufacture of articles and mixtures, would be required to create a nanoform from a bulk form, as a breakdown of the constituent particles to smaller sizes is needed. We respectfully submit that the BfC-Report errs in its conclusion that nanoforms can be generated from the bulk form of materials. Already the splitting of agglomerates and aggregates requires a lot of energy. Further processing is not expected to result in any significant changes to the nanoform within the meaning of the REACH Regulation. In fact, commercially relevant nanoforms usually are produced by bottom-up processes, i.e. the nanoform is generated during the chemical synthesis of the product. In many cases for pigments and fillers the formation of nanoforms and nanostructures during the chemical synthesis is almost unavoidable, i.e. the nanoform/nanostructure is the “normal” form of the product, existing in this form since centuries. Thus, complete data sets for the evaluation of these nanoforms are already available.

The proposed changes to the REACH Regulation as documented in Appendix 1 of the BfC-Report, especially Article 38a would lead to an estimated millions of articles/finished goods which need to be checked for “new” nanoforms². It is difficult enough to characterize nanomaterials as is, uniformly across the industry. Once nanomaterials have been incorporated in articles/finished goods, it becomes, to the best of our knowledge, impossible to verify changes in the particle size distribution of the constituent particles.

Re(de)fine the concept of set of nanoforms; SIMPLICITY IS KEY!

The intention of the concept of set of nanoforms was to group nanoforms to simplify their evaluation. We agree with the conclusion that the current concept is burdensome and needs to be redefined to bring real simplification for the authorities and the industry. The concept was reasonable as such that it foresees the grouping of (nano)forms having similar (eco)toxicological profiles. Removing the concept completely would lead to many additional studies being necessary, which will go against the goal of reducing animal testing. As an example, many fillers and pigments, which need to be considered as nanoforms according to the EU definition, have been on the market for decades if not centuries. Over time many different commercial grades of each substance have been developed, with slightly different application driven characteristics but comparable toxicological profiles. Removing the concept of ‘set of nanoforms’ ultimately would lead to the necessity for repeating animal studies on each commercial grade with neglectable gain in knowledge, especially concerning the safety of the consumer. We support a practical revision of the concept developed jointly with industry.

² Final study report DG5/MR/JP/12026, ([Download](#)), 2013

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Such revision, however, must bring about real simplicity and a reduction of animal testing as the Commission promised in their Guidelines³.

Do not increase information requirements for Nano dossiers

We contend that the dossiers with nanoforms do meet the requirements set out by the REACH Regulation. Compared to other substances, we expect that the compliance of nano dossiers is higher as nanomaterials have been the focus of regulatory attention for a couple of years. An increase of information requirements for nanomaterials would lead to more animal studies being done contradicting the wish of the Commission to reduce animal testing. Furthermore, it would hinder the competitiveness of companies producing nanoforms compared to companies just tagging along as in some cases they are not willing to share the cost or are searching other ways to circumvent the fees associated with new studies. It is true that missing guidance documents are a problem when evaluating nanomaterials but often industry is tangentially involved in the preparation of these documents.

Old “bulk” data should be applicable to nanomaterials

Most substances called nanomaterials today have been manufactured as such for decades. Their rebranding as nanomaterials does not change their intrinsic properties. In most cases, product specifications have remained the same throughout the decades. Therefore, studies performed in the past were performed with samples that bear now all the characteristics of nanomaterials. A change in terminology from bulk to nano does not categorically disqualify all past studies. A case-by-case assessment is required. If a registrant can demonstrate continuity of substance specifications across decades, then studies performed in the past should be given the same weight as studies carried out today.

When these substances were registered, they met the requirements for registration and passed compliance checks done by ECHA. It is wrong to assume that nanomaterials have drastically different hazards compared to bulk materials.

³ Political Guidelines 2024-2029 | European Commission

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About Eurocolour:

Eurocolour e. V. is the umbrella association for manufacturers of pigments, dyes, fillers, frits, ceramic and glass colours, and ceramic glazes in Europe.

About VdMi:

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).

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