

Statement regarding Amendments to the REACH Annexes to address nanoforms of substances and impacts on the pigment and filler industry

Introduction

Position papers related to the EU Commissions' proposed amendments to the REACH Annexes to address nanoforms of substances are already available from Cefic and VCI. Eurocolour supports the position of these chemical associations. Nevertheless, Eurocolour would like to point out some specific issues regarding pigments and fillers in this paper.

In the adopted amendments, a definition of nanoforms is newly introduced that is based on the Commission Recommendation 2011/696/EU on the definition of a nanomaterial. If one applies the EU Commission Recommendation and the definition of nanoforms of a substance in the amended REACH Annexes to pigments and fillers, a large number of these traditional materials could be called nanomaterials, resp. nanoforms or at least may be seen as borderline cases. In this regard, the outcome of the NanoDefine Project shows that for most fillers and pigments and other comparable particulate substances, the assessment and conclusive determination of their nanostatus is hardly feasible, even with the most labour and cost intensive methods like electron microscopy. The identification of constituent particles within agglomerates and aggregates still represents a major challenge for evaluation, not least because of the irregular shape of the particles. This may also lead to the same substance being evaluated differently by different registrants.

Unnecessary duplication of studies

The European chemicals legislation REACH (EC 1907/2006) requires registrants to share available data, to search public databases for relevant information and to review the data for adequacy and reliability. Filling of data gaps necessitates GLP and OECD testing guideline compliant studies, unless criteria laid out in annex XI to the regulation are met. The adopted amendments to the REACH annexes to address nanoforms of substances require for additional studies on substances in nanoform especially in lower volume bands. This increases the costs per registered substance dramatically (according to current estimates more than 150,000 Euro per nanoform even for the lowest volume band 1-10 t). An unavoidable consequence will be a negative impact on the competitiveness of European pigments and fillers industry. In addition, the adopted text gives the opportunity to duplicate animal testing, whenever authorities consider that another route of exposure is more appropriate. This stands in clear contradiction to the animal welfare considerations of article 25 of the REACH regulation, which states that tests on vertebrates shall only be conducted or proposed as a last resort. Unless pragmatic read-across and grouping approaches are implemented in conjunction with the amended annexes, excessive and unnecessary animal testing becomes unavoidable. Furthermore, the financial burden will impact negatively the ability of European industrial stakeholders to compete in the market.

In addition, volume-dependent information requirements under REACH refer to the registered volume of the substance in all forms (nano and bulk) covered by the registration. Where several forms of a substance are covered in one REACH registration dossier, a huge number of new data requirements may follow, even where a nanoform is only manufactured or imported in kg quantities. For reasons of workability, proportionality, animal welfare and cost-efficiency, only the volume band of the nanoform or set of nanoforms should be considered.

Further, we see an increased risk that the amended regulation would also result in the duplication of existing valid animal studies, without substantial benefit of information, in case an authority considers that another route of exposure is more appropriate. This would be in clear contradiction to article 25 of the REACH regulation which states that tests on vertebrates shall only be conducted or proposed as a last resort. With no practical rule for read-across and grouping, Eurocolour expects that at least 60 – 80 vertebrates per nanoform would be sacrificed unnecessarily.

Reasonable and workable approach is needed – categorization as a way forward

For reasons of workability, proportionality, animal welfare and cost-efficiency, pigments and fillers manufacturers ask for a more pragmatic approach either by a reasonable and practical interpretation of the definition of nanomaterial/nanoform which addresses the targeted materials or by combining size with functionality as it is currently practised in other countries like Switzerland and the United States. One potential way could be a categorization of nanoforms of pigments & fillers by size, based on their general properties (e.g. quantum effects vs. surface properties vs. thermodynamic properties). Eurocolour recommends that such an approach should be further investigated. Switzerland and USA have recognized the unnecessary burden for industry and have therefore chosen a much more pragmatic approach in order to avoid that such non-hazardous substances which have been on the market for decades fall under their reporting schemes. After revision of the Swiss chemicals Ordinance (ChemO), only dangerous nanomaterials (synthetic fibrous or tubular) are subject to reporting in Switzerland. In the USA, the Environmental Protection Agency (EPA) has combined size and functionality and published a reporting rule for nanoscale materials, which must have unique and novel properties because of their size.

Pigments and fillers are traditional materials

Pigments and fillers have been on the market for several decades now – and already as what we call nanosized particles today. The experience of Eurocolour and the scientific results over this time have given no indication of any adverse effects that can be attributed solely to the nanoform of these substances.

Pigments and fillers are used for the colouring and surface structuring of nearly all products found in our daily life. They consist of small particles which are mostly insoluble and firmly bound in the application medium (e.g. paints, coatings, inks and plastics). Pigments and fillers have not been “invented” just recently under nanotechnology promotion programs; they have been used for centuries and are the result of industrial research from the past one hundred years.

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About Eurocolour:
EUROCOLOUR is the umbrella organization for manufacturers of pigments, dyes and fillers in Europe.
Eurocolour is a sector group of CEFIC.