

Eurocolour comments on the JRC Guidance on the implementation of the Commission Recommendation 2002/C229/01 on the definition of nanomaterial¹

Introduction

The new Commission's Recommendation on the definition of nanomaterial (2022/C 229/01) was published in June 2022, replacing the former Recommendation 2011/696/EU.

According to the revised definition, the particle size (1-100 nm) remains the decisive criterion to identify a nanomaterial. Accordingly, a substance is defined as a nanomaterial if ≥ 50 % of its particles have a diameter in the range of 1-100 nm. This turns many pigments and fillers into nanomaterials per definition. Because the differences between the new and the old Recommendation are minor, the "nanomaterial status" of pigments and fillers is unchanged.

The guidance published by JRC intends to support the implementation of the Commission's "new" nano-definition. It gives an overview of the key terminology and concepts, provides a decision tree to identify nanomaterials and addresses identification of nanomaterials through measurements for the Recommendation on the definition of nanomaterial (2022/C 229/01).

The Guidance does not introduce any significant new findings

The EU Commission's definition of "nano" is based solely on the particle size of the material.

Firstly, it is important to note that even when a substance fulfils the criterion for a nanomaterial, this does not infer intrinsic hazardous properties. Hence, identification as nanomaterials does in itself not imply any hazard or risk for humans or the environment.

Since the publication of the first definition in 2011, public authorities and stakeholder industries have been searching intensively for workable measurement methods to enable a straightforward and clear decision on whether a substance meets, or does not meet the criterion for a nanomaterial.

Building on long-standing expertise in the pigment and filler industry, Eurocolour, in a project together with the Joint Research Centre (JRC), demonstrated that there is no universally accepted method for making this decision². This determination is still true for pigments and

¹ JRC Publications Repository - Guidance on the implementation of the Commission Recommendation 2022/C 229/01 on the definition of nanomaterial (europa.eu)

<https://publications.jrc.ec.europa.eu/repository/handle/JRC132102>

² 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>

fillers as it relates to their nanomaterial identification in connection with the revised Commission Recommendation.

The new guidance document provides a decision tree to identify nanomaterials and it addresses the identification of nanomaterials through measurements for the implementation of the Recommendation on the definition of nanomaterial.

With regard to the measurement methods to verify whether a substance / material is nano or non-nano according to the new definition, there are no significant new findings.

- Most of the pigments and fillers still require TEM/SEM to identify clearly whether the criterion for nanomaterial is fulfilled or not.
- The criterion $VSSA < 6 \text{ m}^2/\text{cm}^2$ cannot be applied to most of the pigments and fillers.
- Sample preparation (especially dispersion) is critical for performing a valid and representative particle size distribution determination and has therefore the decisive influence on the results of a TEM/SEM analysis.
- The reproducibility of the results of TEM is highly critical, as the evaluation is often done manually. Even an automatic approach does not resolve this problem being inherently dependent on the input variables.

One of the original intentions of the new nano definition of the Commission was the harmonization of the nano definition in downstream legislation.

It is worthwhile to mention that this guidance does not prejudice how to incorporate a definition of nanomaterial in legislation, nor what the criteria for such a definition could be.

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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.

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