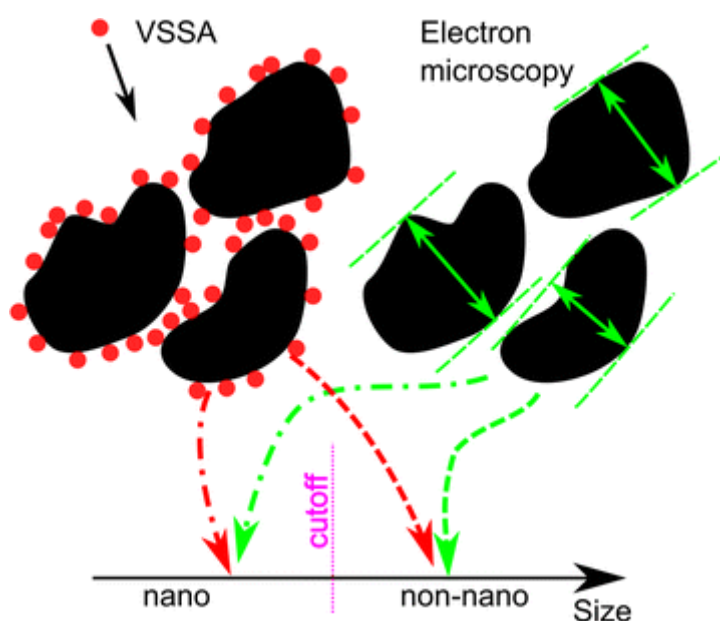


## Abstract

The volume-specific surface area (VSSA) of a particulate material is one of two apparently very different metrics recommended by the European Commission for a definition of “nanomaterial” for regulatory purposes: specifically, the VSSA metric may classify nanomaterials and non-nanomaterials differently than the median size in number metrics, depending on the chemical composition, size, polydispersity, shape, porosity, and aggregation of the particles in the powder. Here we evaluate the extent of agreement between classification by electron microscopy (EM) and classification by VSSA on a large set of diverse particulate substances that represent all the anticipated challenges except mixtures of different substances. EM and VSSA are determined in multiple labs to assess also the level of reproducibility. Based on the results obtained on highly characterized benchmark materials from the NanoDefine EU FP7 project, we derive a tiered screening strategy for the purpose of implementing the definition of nanomaterials. We finally apply the screening strategy to further industrial materials, which were classified correctly and left only borderline cases for EM. On platelet-shaped nanomaterials, VSSA is essential to prevent false-negative classification by EM. On porous materials, approaches involving extended adsorption isotherms prevent false positive classification by VSSA. We find no false negatives by VSSA, neither in Tier 1 nor in Tier 2, despite real-world industrial polydispersity and diverse composition, shape, and coatings. The VSSA screening strategy is recommended for inclusion in a technical guidance for the implementation of the definition.



### Graphical abstract

We evaluate the extent of agreement between classification by electron microscopy (EM) and classification by Volume-Specific Surface Area (VSSA) on a large set of diverse particulate substances. These represent the challenges anticipated for identification of nanomaterials by the European Commission recommendation for a definition of nanomaterials for regulatory purposes.

### Keywords

Nanomaterial Classification Regulation VSSA Size measurement Particle size

Wendel Wohlleben and Johannes Mielke contributed equally to this article.

## Electronic supplementary material

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