

# **NanoDefine: Development of an integrated approach based on validated and standardized methods to support the implementation of the EC definition of nanomaterial**

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The fact that engineered nanomaterials (ENM) already exist in a large variety of industrial and consumer intermediate and end products challenges the development of methods to reliably identify, characterize and quantify their occurrence both as substance and embedded in various matrices. The proposed European Commission definition for nanomaterial [1] requires a quantitative size determination of the primary particles in a sample down to sizes of 1 nm. According to [1] a material is defined as nano if 50% of the primary particles are observed to comprise a smallest dimension <100 nm.

The NanoDefine project [2] has been set up to develop and validate a robust, readily implementable and cost-effective measurement approach to obtain a quantitative particle size distribution and to distinguish between nano and non-nano materials, to help to implement the EU recommendation on the definition of a nanomaterial. Based on a comprehensive evaluation of existing methodologies, intra- and inter-lab comparisons have been launched with the final aim to develop validated measurement methods and instruments that are capable to reliably measure the size of particles in the range of 1 - 100 nm, with different shapes, coatings and for the widest possible range of chemical composition, in both industrial materials and consumer products. Practical case studies will prove and support their applicability for various sectors, including food, cosmetics etc.

One major outcome of the project is the establishment of an integrated tiered approach including validated rapid screening methods (tier 1) and validated confirmatory methods (tier 2) with a user manual to guide end-users, such as manufacturers, regulators and contract laboratories, to implement the developed methodology. Another main product will be the NanoDefiner eTool, a standardised semi-automated procedure for the selection of appropriate methods and material classification (nano/non-nano) according to the definition. NanoDefine will also contribute to ongoing standardization efforts, such as CEN TC 352 or ISO TC 229, by developing one or more work item proposal(s) for method standardization.

An overview of results achieved so far will be given on material selection, comparative techniques evaluation, method and instrument development as well as technique selection, decision support and classification.

[1] COMMISSION RECOMMENDATION of 18 October 2011 on the definition of nanomaterial 2011/696/EU)

[2] [www.nanodefinede.eu](http://www.nanodefinede.eu)