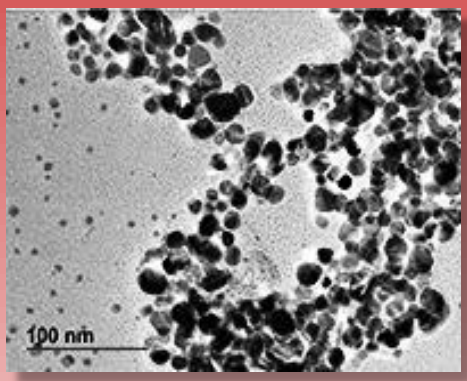
Development of an integrated approach based on validated and standardized methods to support the implementation of the EC recommendation for a definition of nanomaterial

Why the NanoDefine Project?



Electron microscopic picture of metal nanoparticles

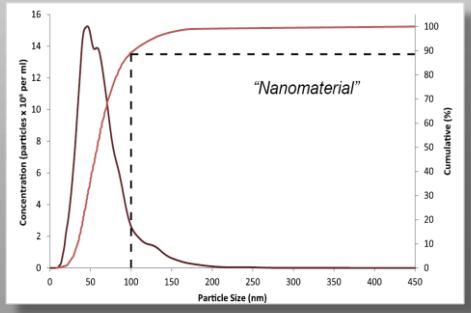
In 2011, the European Commission published a recommendation on the definition of nanomaterial.

Widely accepted analytical methods are required to implement the definition in various regulatory contexts. These methods must be capable of determining reliably i.a. particle size and number based size distribution.

NanoDefine will provide tools to answer the question: When should an unknown material be considered a “nanomaterial”?

How will NanoDefine achieve this?

Nanomaterials are included in a number of products such as cosmetics



Number based particle size distribution indicating 89% of sample below 100 nm

NanoDefine will conduct a comprehensive evaluation of existing and emerging methodologies against relevant performance criteria.

Selected techniques in combination with tailored analytical instruments and software will be used to develop a tiered set of screening and confirmatory methods for detection both in raw materials and in various products and complex matrices.

The provided approach will be robust, readily implementable, cost-effective and capable of reliably measuring the size of particles in the range of 1-100 nm, with different shapes, coatings and for the widest possible range of materials.

The methods will be rigorously validated in intra- and interlaboratory studies, using the NanoDefine reference materials. Case studies will assess their applicability for various selected sectors.

NanoDefine will closely collaborate with standardisation bodies, metrology initiatives and the NanoSafety Cluster.

This project has received funding from the European Union’s Seventh Programme for research, technological development and demonstration under grant agreement No 604347.

Expected Products and Outcomes

- **The NanoDefiner e-tool**
  Decision framework including a standardised semi-automated procedure for the selection of appropriate methods and material classification (nano/non-nano) according to the definition
- **The NanoDefine Method Manual**
  Technical guidance on the use of available methodologies
- **Standard operation procedures (SOPs)**
  Protocols for the analysis of materials and products
- **CEN/ISO work items**
  NanoDefine methods to become international standards
- **Reference materials**
  To be used for instrument calibration and method validation
- **Instrument prototypes and software**
  Tailored to the requirements of the definition
- **Technology transfer**
  Transfer of developed methods to end users

NanoDefine at a Glance

Title: NanoDefine - Development of an integrated approach based on validated and standardized methods to support the implementation of the EC recommendation for a definition of nanomaterial

Programme: FP7 Cooperation

Total Budget : 9.3 million € with an EC Contribution of 7 million €

Duration: 1st November 2013 – 31st October 2017

Coordinator: RIKILT Wageningen UR

Consortium: 29 partners from 11 countries, including top European RTD performers, metrology institutes, (nano)materials industry and instruments manufacturers

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