**European Partnership on Metrology**
**Call 2023 –Fundamental Metrology, Industry, Normative and Research Potential**

Selected Research Topic number: **SRT-i22**
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# Title: Nanometrology for consumer products

## Abstract

Nanotechnology is increasingly used in the production of a wide range of consumer products such as cosmetics and novel food. The EU Cosmetic Products Regulation (1223/2009) and guidance SCCS/1501/12 stipulate that characterisation data must be provided for nanomaterials used in cosmetic products. The novel food regulation EC 2015/2283 states that foods consisting of 'engineered nanomaterials' are considered novel foods and, therefore, subjected to pre-market authorisation. Due to the lack of a systematic metrology platform able to support industry, this project will develop methods for the physico-chemical characterisation of nanomaterials to support product innovation and efficacy and industry compliance with existing regulation.

## Keywords

Nanomaterials, cosmetic industry products, novel nanoscale food, consumer products, measurement uncertainty, sampling strategies for nanomaterials, reference test matrix materials, A4F (asymmetric flow field-flow fractionation).

## Background to the Metrological Challenges

The cosmetics and personal care industry generates more than 29 billion of € in added value to the European economy annually. Innovative technologies such as nanotechnology have been introduced in the production of a wide range of cosmetic products to improve their performance. The EU Cosmetic Products Regulation No 1223/2009 and the SCCS/1501/12 specify that detailed characterisation data must be provided on the identity and composition of nanomaterials in their original form (raw material) and in the final cosmetic product. Inclusion of physical and chemical properties are required for approved nanomaterials such as purity (mainly for raw materials), maximum concentration in ready-for-use preparation, particle number size distribution, shape, crystal structure and coating chemical composition (surface chemistry). In addition, stability data during production, storage and packaging is needed. Three EU funded projects developed methodology for the identification and characterisation of engineered nanomaterials (ENPs) in a range of samples including sunscreen products (only intended as sun protection), INSTANT (Innovative sensor for the fast analysis of nanoparticles in selected target products), SMART-NANO (Sensitive MeAsuRemenT, detection, and identification of engineered nanoparticles in complex matrices) and NanoDefine (Development of an integrated approach based on validated and standardized methods for a definition of nanomaterial). In these projects, the feasibility of the methods developed was not investigated for the characterisation of nano UV-screens in real cosmetics (intended both as makeup and sun protection) as required by regulation 1223/2009. Moreover, no metrological characterisation of the methods developed in terms of uncertainty estimation was achieved and no systematic monitoring of the functional properties of nanomaterials during the different stages for the industrial process was undertaken.

The Europe food and grocery retail market size was 1790 billion of € in 2021. The novel food regulation EC 2015/2283 states that foods consisting of 'engineered nanomaterials' are considered novel foods and, therefore, subjected to pre-market authorisation. A novel food will only be approved for use in the EU if they do not present a risk to public health, are not nutritionally disadvantageous when replacing a similar food, and are not misleading to the consumer. There are several food additives containing nanoparticles including titanium dioxide (TiO2, E171), silver (Ag, E174), gold (Au, E175), silicon dioxide ($SiO_2$, E551), iron oxide ($Fe_2O_3$, E172), zinc oxide (ZnO), and copper (Cu). Projects such as Nanofood@ - EFSAnano, NanoLyse, etc have developed expertise for the characterisation of nanomaterials in food matrices. In particular the NanoLyse project (ended in 2013) attempted to produce matrix reference materials which were never released due to stability issues. Despite the many analytical advances for nanomaterials in food, a metrology platform with well characterised methods for measurement uncertainty is not available. Moreover, reference test or quality control nanomaterials in food matrix do not exist.

Most nanomaterials, approved as additives, in cosmetics and novel food do not have a spherical shape (EU 2016/1143, EU 2016/1120, and EU 2016/621). Past and current metrology projects including EMRP NEW03 NanoChop, and EMPIR 14IND12 INNANOPART and 17NRM04 nPSize, mostly focused on particles which are monodisperse and spherical or non-spherical but in simple suspensions. Deviations from sphericity have been found to pose challenges to some techniques (e. g. novel single particle ICPMS and SAXS for size distribution measurements) requiring combining microscopic techniques, determining particle geometry, with data correction algorithms to minimise the effects of deviation from sphericity and describing the residual uncertainty.

The presence of complex matrix and/or sample preparation processes often cause nanomaterials to dissolve and/or agglomerate or aggregate. It is required to review existing sample preparation strategies and, on that basis, develop and validate sample preparation/fractionation methods that minimise nanomaterial transformation (e. g. based on field-flow-fractionation, enzymatic hydrolysis, solvent extraction) in combination with appropriate controls (e. g. spiking experiments with well characterised/isotopically-enriched behaving-like materials). These represent an improvement above and beyond the "state of the art" of existing capabilities since no measurement uncertainty evaluation has been reported so far for the few methods dealing with nanomaterials in complex samples.

No existing metrological infrastructure is available for nanometrology of consumer products such as food additives or cosmetics, requiring the participation of leading industrial groups and SMEs for proper technological progress, smooth transfer of innovation to production and their rapid introduction into the broader European and International market.

## Objectives

Proposers should address the objectives stated below, which are based on the PRT submissions. Proposers may identify amendments to the objectives or choose to address a subset of them in order to maximise the overall impact, or address budgetary or scientific / technical constraints, but the reasons for this should be clearly stated in the protocol.

The JRP shall focus on the traceable measurement and characterisation of nanomaterials in consumer products for the cosmetic and food industry.

The specific objectives are:

1. To develop and validate traceable methods for determining the physical and chemical properties (e.g. purity, surface chemistry, dissolution rate, number-based size distribution, UV absorption, crystal structure, surface area, aggregation/agglomeration and shape) of nanomaterials used as approved additives in cosmetic (e. g. $TiO_2$, ZnO, $Al_2O_3$) and novel food products/dietary supplements (e. g. $SiO_2$, $TiO_2$, FeO, ZnO, liposome based products). The target relative expanded uncertainty is better than 10 % following the EU Cosmetics Regulation (EC) No 1223/2009.
2. To develop sampling strategies and implement developed measurement methods for monitoring stability and functional properties of target nanomaterials i) at different stages of the production process, ii) in the final product, and iii) after storage and packaging.
3. To develop sample preparation/fractionation techniques (e. g. enzymatic or alkaline hydrolysis, $AF_4$ fractionation) that enable quantitative separation of nanomaterials from the complex matrix without changing their properties by using model matrices spiked with corresponding nanomaterials. An interlaboratory comparison for a target combination of nanomaterial and matrix will be conducted to compare measurement capabilities for selected measurand(s) and resulting in reference test matrix nanomaterials.
4. To facilitate the take up of the technology and measurement infrastructure developed in the project by the measurement supply chain (e. g. manufacturers of nanomaterials), standards developing organisations (e. g. CEN TC 352, ISOTC229, ISO TC24), end users (e. g. cosmetic and novel food industries), and via the EMN on Safe and Sustainable Food.

These objectives will require large-scale approaches that are beyond the capabilities of single National Metrology Institutes and Designated Institutes. Proposers shall give priority to work that meets documented industrial needs and include measures to support transfer into industry by cooperation and by standardisation. An active involvement of industrial stakeholders is expected in order to align the project with their needs – both through project steering boards and participation in the research activities.

Proposers should establish the current state of the art and explain how their proposed project goes beyond this. In particular, proposers should outline the achievements of the EMRP project NEW03 NanoChop, and EMPIR projects 14IND12 INNANOPART and 17NRM04 nPSize, and how their proposal will build on those.

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 1.9 M€ and has defined an upper limit of 2.3 M€ for this project.

EURAMET also expects the EU Contribution to the external funded beneficiaries to not exceed 35 % of the total EU Contribution across all selected projects in this TP.

Any industrial beneficiaries that will receive significant benefit from the results of the proposed project are expected to be beneficiaries without receiving funding or associated partners.

## Potential Impact

Proposals must demonstrate adequate and appropriate participation/links to the ’end user’ community, describing how the project partners will engage with relevant communities during the project to facilitate knowledge transfer and accelerate the uptake of project outputs. Evidence of support from the “end user” community (e.g. letters of support) is also encouraged.

You should detail how your JRP results are going to:

- Address the SRT objectives and deliver solutions to the documented needs,
- Feed into the development of urgent documentary standards through appropriate standards bodies,
- Facilitate improved industrial capability or improved quality of life for European citizens in terms of personal health, protection of the environment and the climate, or energy security,
- Transfer knowledge to the cosmetic and novel food industries sector.

You should detail other impacts of your proposed JRP as specified in the document “Guide 4: Writing Joint Research Projects (JRPs)”

You should also detail how your approach to realising the objectives will further the aim of the Partnership to develop a coherent approach at the European level in the field of metrology and include the best available contributions from across the metrology community. Specifically, the opportunities for:

- improvement of the efficiency of use of available resources to better meet metrological needs and to assure the traceability of national standards
- the metrology capacity of EURAMET Member States whose metrology programmes are at an early stage of development to be increased
- organisations other than NMIs and DIs to be involved in the work.

## Time-scale

The project should be of up to 3 years duration.