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Publisher: Taylor & Francis

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Food Additives & Contaminants: Part A

Publication details, including instructions for authors and subscription information:
<http://www.tandfonline.com/loi/tfac20>

Detection of nanomaterials in food and consumer products: bridging the gap from legislation to enforcement

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Accepted author version posted online: 28 May 2012. Version of record first published: 22 Jun 2012

To cite this article: H. Stamm, N. Gibson & E. Anklam (2012): Detection of nanomaterials in food and consumer products: bridging the gap from legislation to enforcement, Food Additives & Contaminants: Part A, 29:8, 1175-1182

To link to this article: <http://dx.doi.org/10.1080/19440049.2012.689778>

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Detection of nanomaterials in food and consumer products: bridging the gap from legislation to enforcement

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(Received 15 February 2012; final version received 26 April 2012)

This paper describes the requirements and resulting challenges for the implementation of current and upcoming European Union legislation referring to the use of nanomaterials in food, cosmetics and other consumer products. The European Commission has recently adopted a recommendation for the definition of nanomaterials. There is now an urgent need for appropriate and fit-for-purpose analytical methods in order to identify nanomaterials properly according to this definition and to assess whether or not a product contains nanomaterials. Considering the lack of such methods to date, this paper elaborates on the challenges of the legislative framework and the type of methods needed, not only to facilitate implementation of labelling requirements, but also to ensure the safety of products coming to the market. Considering the many challenges in the analytical process itself, such as interaction of nanoparticles with matrix constituents, potential agglomeration and aggregation due to matrix environment, broad variety of matrices, etc., there is a need for integrated analytical approaches, not only for sample preparation (e.g. separation from matrix), but also for the actual characterisation. Furthermore, there is an urgent need for quality assurance tools such as validated methods and (certified) reference materials, including materials containing nanoparticles in a realistic matrix (food products, cosmetics, etc.).

Keywords: regulations; method validation; metals

Introduction

Nanotechnology and more particularly nanotechnology-based products and materials have a huge potential for providing novel solutions to many of the current challenges facing society such as energy supply and resources efficiency, a clean environment, information and communication, mobility and security, and the efficiency of health-related products. The tapping of this potential is likely to contribute to the realisation of the collective targets of the European Union's Europe 2020 Strategy (European Commission 2012) and the associated research and innovation goals.

Already to date, many food and consumer products containing nanomaterials may be found on the market, e.g. cosmetics or sunscreen lotion containing titanium dioxide in nanoform or food packaging containing nanosilver. Examples of consumer products that may contain nanomaterials are listed in Table 1. This list includes materials used as food additives, and it can be expected that novel foods and food packaging materials incorporating nanomaterials will be developed in the future. Such developments may be aimed at, for example, improving the taste or nutritional value of

food, or at extending the useful shelf-life of fresh products (Chaudhry et al. 2010).

In order to understand how many products containing nanomaterials are already available to consumers, a comprehensive inventory on types and uses of nanomaterials on the market, ideally on a European Union or a global level, would be desirable, as requested by a growing number of European Union member states and by the European Parliament. Since 2006 there is a voluntary database – the Woodrow Wilson Inventory – accessible to consumers (Woodrow Wilson International Center for Scholars 2012). In 2006, the inventory contained about 200 different products which has increased to more than 1000 to date. This inventory is indeed a valuable source of information on commercially available products that contain nanomaterials or involve a production process using nanotechnology, however inclusion of products in the database is made on the producer's claim that the product is of this type. Other product databases have been established by European consumers' organisations such as ANEC-BEUC (ANEC = European Association for the Coordination of Consumer Representation in Standardization; BEUC = Bureau

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Table 1. Examples of consumer products that contain or may contain nanomaterials and of nanomaterials already used.

Consumer products potentially containing nanomaterials	Frequently used nanomaterials in general
Consumer electronics	Aluminium, aluminium oxide and aluminium hydroxide
Cosmetics and personal care products	Antimony oxide and antimony pentoxide
Flavours/aromas	Barium carbonate
Food products	Bismuth oxide
Food packaging material and kitchenware	Boron oxide
Household products, e.g. for cleaning	Calcium oxide
Neutraceuticals	Carbon black
Paints and coatings	Cerium oxide
Pesticides	Cobalt and cobalt oxide
Sports products	Copper oxide
Textiles	Fullerenes
	Germanium oxide
	Gold
	Indium oxide
	Iron and iron oxides
	Lanthanum oxide
	Lithium titanate
	Magnesium oxide
	Molybdenum oxide
	Nickel
	Palladium
	Platinum
	Polyethylene and polystyrene
	Rhodium
	Silicon dioxide
	Silver
	Titanium dioxide
	Tungsten
	Zinc oxide
	Zirconium oxide

Européen des Unions de Consommateurs) (ANEC/BEUC 2010) and the German Environmental NGO Bund für Umwelt und Naturschutz Deutschland (BUND) (2011), which both include products claiming to contain nanomaterials. In view of the Cosmetics Directive entering into force in 2013, a database with information on nanomaterials in cosmetic products is under development.

In general, notwithstanding the benefits of products derived from nanotechnology or the fact that engineered nanomaterials are already in use in a variety of applications, including some food additives, their associated health and environmental effects are not yet clearly understood (Chaudhry et al. 2008; Aebi et al. 2011). To avoid the situation in which the technological advantages may be counterbalanced by longer-term drawbacks, it is important to have the means for evaluating any possible associated risks. The timely approval of products containing nanomaterials

should, however, be subject to the same regulatory principles and sector-specific practices that exist for products in general to ensure that goods placed on the market are safe. This should be based on the principle of safety by design together with effective communication about hazards, risks and uncertainties in order to gain consumer confidence.

It is broadly accepted (Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) 2007; Morris et al. 2011) that the general risk assessment paradigm based on hazard identification and characterisation and on exposure assessment can be equally applied to the current generation of nanomaterials which are used in food and consumer products. According to this paradigm any nanomaterial needs to be assessed with respect to potential hazards and exposure to humans or the environment. In particular for products containing nanomaterials with a not well-known hazard, and with possible direct contact to consumers, realistic exposure scenarios and subsequent exposure assessment are crucial prerequisites for risk management. In case there is no or insignificant exposure, there are generally low safety concerns.

This holds true for any chemical or biological agent that may cause harm to consumers. Regarding exposure to nanomaterials the lack of reliable data prevents realistic assessments in most cases. Here it is an important aspect to distinguish between nanomaterials embedded in a solid matrix and nanomaterials which are free or contained in a matrix where they are mobile in their immediate environment (e.g. cosmetics or food). It must be emphasised that the status of a material may vary during its lifecycle. This is particularly important for nanomaterials as they have special properties at the nanoscale which may influence their distribution and fate in the environment once they are released after use. The increasing use of nanomaterials in industry and directly in consumer products may, over time, lead to increasing concentrations in the environment of the more stable types (Tiede, Hassellöv, et al. 2009; Tiede, Tear, et al. 2009; Samontha et al. 2011; Weir et al. 2012) with possible subsequent uptake into the food chain. In the case of these, and more importantly of nanomaterials incorporated directly into food products, it is of high importance to establish their bio-persistence and biokinetic characteristics, and whether long-term accumulation might occur in any organs. In the case of food packaging, where the nanomaterials are initially embedded in a solid matrix, it is necessary to determine whether nanomaterial release and migration into food products might occur over a range of different scenarios.

In the context of safety assessment of products containing nanomaterials, it is of the utmost importance to understand which consumer products – particularly

those coming into direct contact with the human body such as cosmetics, and especially food products – actually contain nanomaterials. Some recent papers and reports give an overview of the use of nanomaterials in food including food additives and food packaging materials (Chaudhry et al. 2008, 2010; Blasco and Picó 2011), and cosmetic products (Ansell and Ito 2011; Mihranyan et al. 2012). Although embedded in a matrix, nanomaterials in such products are mobile and their use leads to direct and often intentional exposure to the human body. For a sound risk assessment of such products it is therefore important to know whether a material is a nanomaterial and to understand its properties (size, shape, chemical composition, etc.). This calls both for a definition of the meaning of ‘nanomaterial’ and a clear definition of the nanoscale limits.

In this respect, the European Commission (2011) has recently adopted a recommendation for the definition of nanomaterials, based on scientific advice from the SCENIHR (2010) and the Joint Research Centre (JRC) (Lövestam et al. 2010) giving European Union legislators a legal reference for nanomaterials, when adopting new or implementing existing legislation. The definition refers specifically to particulate nanomaterials and uses size (and the related size distribution by number) as the defining property (see the second section). In this context it is important to note that the definition does not anticipate specific risks, since nanomaterials are not hazardous per se but a specific approach in their risk assessment may be required.

For some consumer products such as cosmetics containing nanomaterials, labelling will be mandatory from 2013 onwards (European Parliament and European Council 2009). Other legislation, e.g. for food, is adopting a similar approach in this respect (European Parliament and European Council 2011). With the European Commission recommendation for the definition of nanomaterial at hand, there is now an urgent need for appropriate and fit-for-purpose analytical methods to assess whether a product or ingredient contains nanomaterials in order to apply and enforce labelling requirements.

Considering the lack of such methods to date, this paper will elaborate on the challenges of the legislative framework regarding analytical methods for the detection, quantification and characterisation of nanomaterials in products. Such methods are needed not only to ensure correct labelling. They are equally important in the safety testing of nanomaterials for hazard assessment.

The regulatory framework

In general, nanomaterials and related products are dealt with under existing broader regulatory

schemes and worldwide there are very few examples where nanospecific regulation has been put in place.

In order to define actions for the implementation of a safe, integrated, and responsible approach for nanosciences and nanotechnologies, the European Commission made recommendations in an Action Plan for Europe 2005–2009 (European Commission 2005). Subsequently, in line with the commitments made in the Action Plan, the Commission reviewed the relevant European Union legislation to determine the applicability of the existing regulations to the potential risks of nanomaterials (European Commission 2008). It was concluded that existing European legislation in principle would cover the potential health, safety and environmental risks although the term ‘nanomaterials’ was not mentioned specifically in the legislation at that time. It was acknowledged by the European Commission that regulatory changes may be needed in light of new information becoming available concerning potential risks in relation to nanomaterials. The European Food Safety Authority (EFSA) also considered the suitability of current regulations relating to food and published an opinion on potential risks deriving from nanomaterials and use of nanotechnology in the food and feed area (EFSA Scientific Committee 2009). In a subsequent document EFSA published guidance on risk assessment of nanomaterials in the food and feed chain (EFSA Scientific Committee 2011).

An urgent need for appropriate legislation to manage potential safety concerns related to nanomaterials was communicated in a non-binding resolution adopted in April 2009 by the European Parliament (2009). This resolution questioned whether current European Union legislation would be adequate to deal with the potential hazards of nanomaterials and the European Commission was requested to review all relevant legislation by 2011. Furthermore, the European Parliament considered it particularly important to address nanomaterials explicitly, at least within the scope of legislation on chemicals, food, waste, air and water, and worker protection. At present, the regulations governing these areas are being scrutinised to assess whether nanospecific provisions are necessary. The European Parliament resolution also included requests for the adoption of a ‘comprehensive science-based’ definition of the term ‘nanomaterial’, the labelling of products containing nanomaterials, and the establishment of an inventory on types and uses of nanomaterials on the European Union market.

In response to the European Parliament requests, the European Commission has recently adopted a recommendation on a definition of nanomaterials (European Commission 2011). This definition marks an important step towards better protection of European consumers by clearly defining which materials will need special treatment in specific legislation.

The definition addresses particulate materials only, is intended for broad application in European Union legislation and uses particle size as the defining property. It covers natural, incidental or manufactured (engineered) materials, and having a rather broad scope is likely to cover many existing and future products. The purpose of the definition is to have clear and unambiguous criteria at hand to obtain the same classification of a material for the various sectors and to identify those materials that require labelling or specific considerations for their safety assessment.

Nanomaterials are defined as materials:

containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm – 100 nm.

It is further specified that:

in specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%.

The definition should be used as a reference for determining whether a material should be considered as a nanomaterial for legislative and policy purpose in the European Union. It must be stressed, as acknowledged in the Commission Recommendation, that there is no unequivocal scientific basis to suggest a specific value for the threshold level in the size distribution below which materials containing particles in the size range 1–100 nm are not expected to exhibit properties specific to nanomaterials.

The definition only covers nanoparticles and not other nanostructured (nanoporous, nanocomposite) materials. This decision was made deliberately as there is to date no sufficient evidence for a clear guideline on what needs to be included. The European Commission is aware of the challenges for implementation of this definition despite the fact that technological development and scientific progress indicate an urgent need for assessing whether materials fall under the definition. Therefore a review of the current definition is foreseen for the end of 2014.

It needs to be stressed that the Commission Recommendation for a definition implies no direct obligations for European member states or the industry at the present time.

The European Cosmetic Products Regulation of 2009 (European Parliament and European Council 2009) had already introduced a definition which also uses the 1–100 nm size range. It is currently under discussion whether this definition will be replaced by the one given in the recent Commission Recommendation. The regulation requires that labelling of cosmetic products specifies which ingredients are in the nano-form, and will come into force in

July 2013. In the list of ingredients the names of such substances shall be followed by the word ‘nano’ in brackets. This will facilitate consumer choice and must not be considered as ‘hazard labelling’.

It can be expected that more specific legislation will follow the recommendation including also the requirement for labelling of other products containing nanomaterials. The recent European Regulation on ‘Food Information to Consumers’ (European Parliament and European Council 2011) also requires specific labelling of nanomaterial ingredients.

Analytical methods for nanomaterials – requirements and challenges

The regulatory requirements already envisaged for food products and cosmetics necessitate the availability of fit-for-purpose analytical methods to detect, quantify and characterise nanomaterials. This not only applies to individual ingredients or additives, but also may be necessary for enforcement/compliance purposes in final products. In such products nanomaterials are likely to form part of complex mixtures which may naturally contain particles at the nanoscale (e.g. liposomes, micelles, colloids, etc.), thus making it much more difficult to discriminate intentionally added nanoparticles from natural nanoscale structures (which may also include large organic molecules). Therefore the development of analytical methods, which can be applied routinely by enforcement bodies, is particularly challenging. The European Commission definition of nanomaterials requires the determination of the number fraction of primary particles which have at least one dimension in the range 1–100 nm. At the present time, to the best of our knowledge, there are no validated methods that can perform such a measurement with the required precision, especially in a sample with a wide range of primary particle sizes and shapes. The problem is even more challenging if one wishes to detect and measure nanoparticles embedded in complex and quite variable matrices such as food and consumer products, e.g. if controls on the correct labelling of products that could contain nanoparticles must be performed.

When dealing with nanomaterials in food and consumer products like cosmetics, the analysis will in most cases comprise the following steps:

- Detection, i.e. are there any nanomaterials present in the matrix.
- Identification, i.e. what type of particulate material(s) (substance identification) is present and in what approximate form and range of sizes.
- Separation of the material(s) of analytical interest from the rest of the matrix.

- Quantification, in terms of the fraction of primary particles present in different size ranges (size distribution), if necessary taking shape into account.

In each of these steps considerable experimental challenges must be faced. The last step presents additional difficulties if an average particle diameter (and various definitions exist for this, some linked to specific measuring techniques) cannot be used as the size metric.

Some very recent reviews have analysed the different techniques that can be used for the detection of nanomaterials, both in general terms or focusing on specific techniques such as electron microscopy (Dudkiewicz et al. 2011) or field flow fractionation (von der Kammer et al. 2011), or specific matrices such as food (Tiede et al. 2008) including the detection of organic nanoparticles (Peters et al. 2011).

From the analysis of the existing literature it is clear that the vast majority of the experimental work up to now has been concerned with simple detection and characterisation of nanomaterials and not with the determination of the particle size distribution. There are only a few examples that have tackled the problem of measuring the particle size distribution. Sophisticated techniques, such as field flow fractionation (FFF) (e.g. von der Kammer et al. 2011), especially combined with other techniques such as inductively coupled plasma mass spectrometry (ICPMS) (Samontha et al. 2011; Schmidt et al. 2011), are, after appropriate sample preparation, capable of determining particle size distributions in complex matrices, though quantitative accuracy requires detailed knowledge of the types of NPs present. However, even such methods may not be applicable to all types of nanoparticles or matrices, and may not be accurate or reproducible enough for legal conformity measurements. In any case, they cannot directly distinguish between primary particles and aggregates/agglomerates, and because they determine an effective (spherical) particle diameter they are incapable of taking shape into account in the way the European Commission definition requires.

In our own laboratories using an approach combining FFF with dynamic light scattering (DLS), Calzolari et al. (2011) were able to separate and measure the size distribution (in terms of the hydrodynamic diameter of the particles) of a mixture of gold nanoparticles. Figure 1 shows that DLS analysis of a mixture (1:1:1 by volume) of AuNP of 5, 20 and 50 nm, but it fails to show the presence of the small and intermediate gold nanoparticles. This again confirms (Calzolari et al. 2011; Kato et al. 2012) that DLS is not a generally useful method for determining the size distributions of polydisperse nanoparticles, despite its widespread use. The mixture of AuNP can be

separated into the individual components by FFF and their hydrodynamic diameters then measured with DLS (the separation procedure was verified by electron microscopy). In addition, the relative ratio of nanoparticle numbers could be estimated by UV-Vis spectroscopy. It must be noted that this successful reconstruction of the particle size distribution has been performed in a quite simple system composed of gold nanoparticles of different sizes in water.

It should be noted at this point that the conversion of scattered light intensity, used in techniques like DLS, to nanoparticle numbers must be employed with extreme caution, especially in the case of polydisperse samples, due to the strong dependence of scattered intensity on nanoparticle size. Likewise, conversion of optical absorption data to mass may be unreliable for certain nanoparticle types, and size calibration of FFF systems is critical in any subsequent conversion of mass to numbers. Various other factors (assumed particle density, stoichiometry, refractive index, shape, etc.) may strongly influence or distort particle number size distributions as determined by different techniques, not to mention inherent measurement uncertainties in the low size range and uncertainty introduced by sample preparation procedures. Thus, with regard to the numbers-based European Commission definition, nearly all measurement techniques probably fall short of the required accuracy and inter-laboratory comparability at the present time. This is especially true when one considers that it is primary particle size that must be determined, and that primary particle shape has to be taken into account.

Need for harmonisation and standardisation of test methods

The implementation of legislation regarding the use of substances and materials in industrial and consumer products placed on the market requires a set of internationally accepted and standardised test methods. These are needed in order to enforce legal requirements for domestic and imported products, to ensure free trade and fair competition, and also to provide industry with experimental and analytical tools to ensure compliance with the legal requirements.

Regulation specific to nanomaterials therefore requires standardised and harmonised analytical test methods allowing the clear identification of nanomaterials according to the definition. This is important to make sure that the nanomaterials are then subject to appropriate safety testing, which again has to be based on a set of harmonised and standardised methods. Standardisation of analytical test methods via international bodies is however a time-consuming process, and therefore in this rapidly developing field the

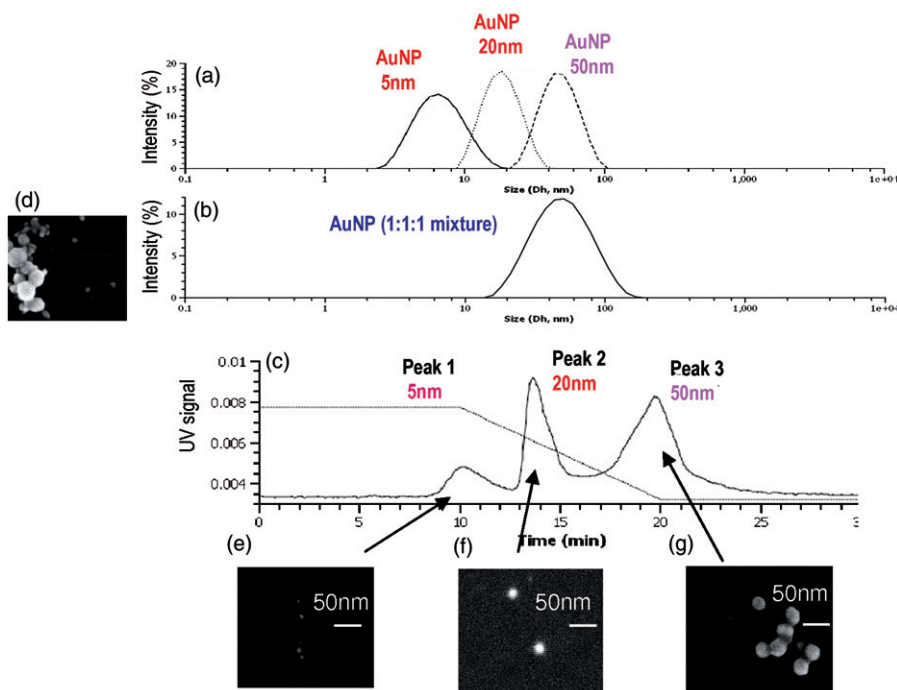


Figure 1. Separation and size measurement of gold nanoparticles mixture of 5, 20 and 50 nm: (a) DLS of the three AuNP samples; (b) DLS data of the AuNP mixture; (c) flow field flow fractogram of the AuNP mixture; (d) scanning electron microscopy image of the AuNP mixture; and (e–g) scanning electron microscopy images of the three flow field fractionation peaks of (c).

development of validated analytical methods and reference materials should also be undertaken.

If there are labelling requirements for nanomaterial ingredients as in the case of food or cosmetics, analytical methods must ensure that the ingredients are classified according to binding rules in any authorised official control laboratory. Regulatory labelling moreover requires control measures in order to check if products are labelled correctly following the established requirements. To this end, analytical methods for detecting, quantifying and characterising nanomaterials in complex matrices such as food and cosmetics are urgently needed.

The OECD and standardisation bodies such as ISO and CEN have already established working groups (CEN 2005; ISO 2005; OECD WPMN 2006) and technical committees that play an important role in the development of measurement standards and formally recognised test methods and guidelines for nanomaterials. Table 2 lists the activities of the various bodies in this respect.

All organisations aim to work on test methodologies; however, the focus to date is very much on the safety assessment of nanomaterials and on their characterisation rather than on analytical procedures for detection and quantification in complex matrices such as food and consumer products.

There is already progress being made regarding method development for specific particles, matrices,

sample preparation and detection (von der Kammer et al. 2011). It must however be stressed that only a limited number of methods are described in the scientific literature to date. None of these has proven to be fully fit for purpose, nor have they been validated so far according to harmonised and internationally accepted standards.

There is a need for integrated analytical approaches, not only for sample preparation (in the sense of separation from the matrix), but also for the actual characterisation. Furthermore, there is an urgent need for appropriate materials for instrument calibration and for (certified) reference materials representing food or other consumer products, e.g. produced by spiking a reference matrix with well-characterised nanomaterials.

It is only by having these quality assurance tools at hand that the analysis of nanomaterials in complex matrices will lead to reliable and comparable results.

Conclusions and outlook

The problem of the detection and analysis of nanomaterials in complex matrices is only starting to be addressed. The analysis is challenging not only due to possible matrix interference, but also because appropriate and fit-for-purpose methods are not yet available.

Table 2. Harmonisation and standardisation bodies and their activities on nanotechnology.

OECD Working Party on Manufactured Nanomaterials (WPMN)	ISO Technical Committee Nanotechnologies TC 229	CEN Technical Committee Nanotechnologies TC 352
SG1/2 OECD Database on manufactured nanomaterials to inform and analyse EHS research activities	JWG1: Terminology and nomenclature	WG 01: Measurement, characterisation and performance evaluation
SG3 Safety testing of a representative set of manufactured nanomaterials	JWG2: Measurement and characterisation	WG 02: Commercial and other stakeholder aspects
SG4 Manufactured nanomaterials and test guidelines	WG 3: Health, safety and environmental aspects of nanotechnologies	WG 03: Health, Safety and Environmental Aspects
SG5 Co-operation on voluntary schemes and regulatory programmes	WG4: Material specifications	
SG6 Co-operation on risk assessment	Consumer and societal dimensions Task Group	
SG7 The role of alternative methods in nano toxicology	Nanotechnologies and sustainability Task Group	
SG8 Exposure measurement and exposure mitigation		
SG9 Co-operation on environmentally sustainable use of nanotechnology		

Note: JWG, Joint Working Group; SG, Steering Group; WG, Working Group.

Safety testing requires characterisation of nanomaterials in appropriate test matrices in order to assess their potential toxicity properly. Moreover, the detection and quantification of nanomaterials in biological matrices is also essential to determine their bio-distribution in tissues and organs. Similar arguments apply for nanomaterials in environmental media.

To implement legislation making specific reference to nanomaterials, for example in the areas of cosmetics and food, requires urgent integrated efforts to develop appropriate methodologies and to assess their suitability. The authors' laboratory, hosted by the European Commission's Joint Research Centre (JRC), in close collaboration with European Union member states' laboratories, will aim to provide fit-for-purpose and internationally validated methods not only for safety assessment, but also more especially for the detection and analysis in food and consumer products. The JRC has already made available a certified reference material for size determination (SiO₂) and hosts a Repository of Representative Nanomaterials as tools to improve the quality of testing.

In general, methods to be developed and validated (in-house or collaboratively) need to be fit for purpose, i.e. suitable, robust, standardised and of reasonable cost, in order to be applied highly specialised laboratories and official control bodies and importers.

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