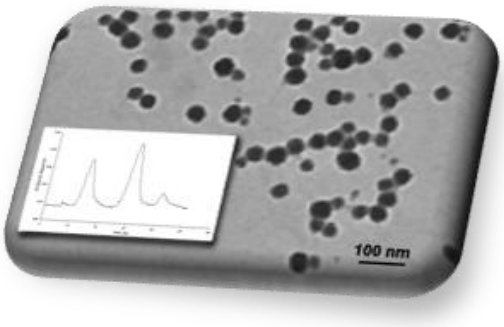
Nanomateriali nel Settore Alimentare: Nuovi Approcci per la Valutazione di Sicurezza

Nanomaterials in the Food Sector: New Approaches for Safety Assessment

Abstract Book

ISTITUTO SUPERIORE DI SANITÀ
Dipartimento di Sanità Pubblica Veterinaria e Sicurezza Alimentare



con il patrocinio del Ministero della Salute

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Premessa

Le nanotecnologie rappresentano una vasta area di ricerca e applicativa con importanti ricadute in tutti gli ambiti produttivi, con il settore alimentare in prima fila. Lo sviluppo delle nanotecnologie offre delle opportunità e contemporaneamente configura rischi potenziali associati ad aspetti specifici, la cui valutazione presenta grande complessità e richiede approcci innovativi. Da diversi anni il Dipartimento di Sanità Pubblica Veterinaria e Sicurezza Alimentare è impegnato nella valutazione delle ricadute dell'impiego di nanomateriali sulla sicurezza degli alimenti e la salute dei consumatori, dalla partecipazione all'attività di sviluppo di metodi analitici promossa dalla Commissione Europea, alla valutazione del rischio in sede EFSA (NanoNetwork), ai progetti europei di nanotossicologia appena conclusi (NANOGENOTOX) e in corso di svolgimento (NANoREG). Sulla base dell'esperienza maturata, in questo primo convegno nazionale dedicato ai nanomateriali nel settore alimentare gli esperti del Dipartimento intendono offrire una panoramica il più possibile ampia di questo ambito di intervento e fornire solidi riferimenti tecnico-scientifici per un quadro aggiornato degli sviluppi della valutazione di sicurezza dei nanomateriali negli alimenti. Con il contributo portato dal Ministero della Salute, il convegno rappresenta un momento importante di riflessione, approfondimento e discussione fra gli 'addetti ai lavori' e i soggetti interessati a diverso titolo al tema del *nano* in relazione alla produzione agroalimentare e alla qualità e sicurezza degli alimenti.

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Introduzione

Il convegno 'Nanomateriali nel Settore Alimentare: Nuovi Approcci per la Valutazione di Sicurezza' si propone di fare il punto della situazione in un settore rapidamente emergente e soggetto a imminente regolamentazione per effetto del regolamento UE 1169/2011, il quale dispone l'etichettatura dei nano-ingredienti nei prodotti alimentari dal dicembre 2014. Lo scopo del convegno è portare a conoscenza dei soggetti istituzionalmente interessati − a cominciare dal SSN e dal sistema della sicurezza alimentare − e degli stakeholders (industria e consumatori *in primis*), una tematica di crescente rilevanza, inquadrandola nel contesto internazionale ed evidenziando le prospettive a breve e medio termine e i problemi da affrontare per l'analisi del rischio. Particolare attenzione viene posta sulle iniziative intraprese nell'ambito dell'applicazione delle nanotecnologie al settore alimentare dall'EFSA e dalla Commissione Europea, con interventi di relatori dell'Autority e del JRC di Ispra.

Il convegno rappresenta un'occasione per un primo bilancio dell'attività svolta dal *team* del Dipartimento di Sanità Pubblica Veterinaria e Sicurezza Alimentare che si occupa della valutazione di sicurezza dei nanomateriali nel settore alimentare, attività che va dalla determinazione analitica di nanomateriali negli alimenti agli studi di nanotossicologia alimentare e che viene esaustivamente illustrata da alcune delle relazioni in programma. Nel complesso, gli *abstract* che seguono danno l'idea della varietà di argomenti affrontati dai relatori che hanno contribuito al convegno, dal contesto regolatorio agli aspetti chimico-analitici, dalla nanotossicologia alla valutazione del rischio.

Questo convegno si svolge sotto il patrocinio del Ministero della Salute e con l'attiva collaborazione della Direzione Generale per l'Igiene e la Sicurezza degli Alimenti e la Nutrizione, per la quale si ringrazia il Direttore Silvio Borrello. Un particolare ringraziamento va rivolto alla Segreteria Tecnica della Direzione Generale nella persona di Sarah Guizzardi. A nome della Segreteria Scientifica del convegno si ringrazia inoltre la Segreteria Tecnica, nelle persone di Maria Cristina Barea Toscan e Andrea Raggi, per il prezioso contributo nell'organizzazione dell'evento.

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Responsabile scientifico del convegno

Abstracts

Applications and prospects of nanotechnologies in the food sector

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The exciting properties exhibited at the nano-scale have led to the development of vast numbers of different types of engineered nanomaterials (ENMs) also for the food industry. Food packaging is a key area, with nanotechnology-derived polymers offering new solutions to keep food secure during transportation, increase the shelf life of products and protect them from pathogens [1]. Other nanotechnology applications in the food sector range from altering the texture of food, to encapsulating food components or additives, to increasing the bioavailability of nutritional components, and to developing nano-sensors for traceability and monitoring the condition of food during the value chain [1]. Whilst such developments potentially offer enormous benefits, they have also raised a number of issues in relation to consumer safety and environmental impacts, involving ethical, policy and regulatory issues. Indeed, the unusual properties of nanomaterials make it difficult to predict their biological reactivity; therefore, it is essential to be able to assess the risk associated with their use. This is why food nanotoxicology is an important and emergent field.

A number of nano-sized additives and supplements for food and healthfood products, and nanotechnology derived food packaging materials, are already available in some countries, and their number is expected to increase in the coming years. In terms of market volume the main categories on the global market (*i.e.* not limited to food applications) include inorganic non-metallic ENMs (*e.g.* synthetic amorphous silica, aluminium oxide, titanium dioxide), carbon based ENMs (*e.g.* carbon black, carbon nanotubes), metal nanoparticles (e.g. nanosilver) and organic, macromolecular or polymeric particulate materials (e.g. dendrimers). In terms of industrial impact and public exposure the above-mentioned ENMs are of immediate regulatory relevance [2]. In particular, carbon black and amorphous silica represent by far the largest volume of ENMs currently on the market. Together with a few other ENMs, they have been on the market for decades and are used in a wide variety of applications. The group of materials currently attracting most attention are nano-titanium dioxide, nanozinc oxide, fullerenes, carbon nanotubes and nanosilver. Those materials are marketed in clearly smaller quantities than the traditional ENMs, but the use of some of these materials is increasing fast [2]. So far, in the EU three ENMs are authorized as additives for plastic materials and articles intended to come into contact with food, *i.e.* carbon black, silicon dioxide and titanium nitride [3].

Since several years, the team dealing with food nanomaterials in the Department of Food Safety and Veterinary Public Health of the ISS has been carrying out studies in the following three main areas [4-8]:

– Analytical determination of ENMs in food and biological tissues

– *In vitro* studies to assess ENM modification/dissolution/degradation after ingestion (simulated GI digestion models)

– *In vivo* oral toxicity studies (ADME/biodistribution, repeated dose toxicity, effects on endocrine/development/reproductive system, etc.).

The objective of these activities is, on the one hand, the development of analytical methods for the determination of inorganic ENMs in food and, on the other hand, the generation of new data to support risk assessment of food ENMs by the National Authority and the EFSA.

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Engineered nanomaterials: authorization under novel food regulation 258/97/EC

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In order to guarantee the public safety, the market of foods that have not been consumed to a significant degree in the European Union earlier has to undergo a premarketing authorization procedure to assess the safety for human consumption according to Regulation 258/97/EC (hereafter named 'the regulation') [1].

According to the regulation, novel food and novel food ingredient, that do not have a significant history of consumption before may 1997, can be divided into the following categories:

1. (letter c in the regulation) foods and food ingredients with a new or intentionally modified primary molecular structure (letter c in the regulation);
2. (letter d in the regulation) foods and food ingredients consisting of or isolated from microorganisms, fungi or algae;
3. (letter e in the regulation) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;
4. (letter f in the regulation) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

The Regulation does not cover foods and ingredients for which an approval procedure is already in place, such as Food additives, Flavourings, Extraction solvents and GMOs. If foods and/or food ingredients were used exclusively in food supplements, new uses in other foods require authorisation under the Novel Food Regulation e.g. food fortification require authorisation.

To market a novel food or ingredient, companies must apply to the competent authority of one of the member states for authorisation, presenting a dossier, containing all the scientific information to support the safety of the product. When the competent authority decides that no additional assessment is necessary and if the Commission and EU member states do not object the product can be marketed in the EU. Otherwise, an additional assessment is necessary and the approval or refusal of marketing of the product is stated in a Commission decision, approved after receiving the opinion of the Standing Committee on Food Chain and Animal Health.

A novel food or ingredient included in the categories (2) and/or (3) may be marketed through a simplified procedure called "notification". The company notifies the Commission about the marketing of a novel food or ingredient based on the opinion of a food assessment body of one of the member states that has established "substantial equivalence".

Food or food ingredients that can be classified as *engineered nanomaterials*, different from additives, flavourings or enzymes, are considered novel in the meaning of category (4). The authorization procedure must be followed prior to their marketing.

1. European Parliament and Council, 1997. Regulation (EC) No 258/97 of 27 January 1997 concerning novel foods and novel food ingredients. Official J. Eur. Communities No L 43, p. 1.

Labelling of Nanomaterials in food: The Regulation 1169/2011

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On 25 October 2011, the European Parliament and the Council adopted the Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC Regulation) [1].

The FIC Regulation modifies existing food labelling provisions in the European Union to allow consumers to make informed choices and to make safe use of food, while at the same time ensure the free movement of legally produced and marketed food. It entered into force on 12 December 2011. It shall apply from 13 December 2014, with the exception of the provisions concerning the nutrition declaration which shall apply from 13 December 2016.

In order to inform consumers of the presence of engineered nanomaterials in food, Article 18(3) of Regulation (EU) No 1169/2011 provides that all ingredients present in the form of engineered nanomaterials must be clearly indicated in the list of ingredients and the names of such ingredients must be followed by the word 'nano' in brackets. In addition, it provides a definition of engineered nanomaterials, which may be adjusted and adapted to technical and scientific progress or to definitions agreed at international level, by means of delegated acts, for the purposes of achieving the objectives of the Regulation.

On 18 October 2011, the Commission adopted Recommendation 2011/696/EU on the definition of nanomaterial [2]. According to the Commission Communication to the European Parliament, the Council and the European Economic and Social Committee on the Second Regulatory Review on Nanomaterials, the Commission intends to use the definition of 'nanomaterial' set out in the Commission Recommendation 2011/696/EU in EU legislation and instruments of implementation, where appropriate. Where other definitions are used in EU legislation, provisions will be adapted in order to ensure a consistent approach, although sector specific solutions may remain necessary.

On the basis of Article 18(5) of Regulation (EU) No 1169/2011, for the purposes of achieving the objectives of the Regulation, the Commission shall, by means of delegated acts, adjust and adapt the definition of engineered nanomaterials to technical and scientific progress or to definitions agreed at international level. The Commission thus decided to adapt the definition of 'engineered nanomaterials' laid down in Article 2(2)(t) of Regulation (EU) No 1169/2011 to the Commission Recommendation 2011/696/EU, taking into account the necessary sector specific considerations, by a Delegated Regulation.

The new definition has been discussed within the Working Group with experts from Member States set up by the Commission’s Health and Consumer Directorate General and the draft delegated act has now been notified to WTO under the Technical to Barriers Agreement (TBT notification).

1. European Parliament and Council, 2011. Regulation (EC) No 1169/2011 of 25 October 2011 on the provision of food information to consumers. Official J. EU No L 304, p. 18.
2. European Commission, 2011. Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU). Official J. EU No L 275, p. 38.

Analytical determination of nanomaterials in food

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Analytical methods normally need to answer two questions: (1) whether a certain substance is in the sample (identity); (2) how much of the substance is in the sample (for a nanomaterial – hereafter NM – mass or number of particles). Both identity and quantity define the traceability of the analytical result.

Determination of nanoparticles presents analytical challenges for definition of identity as well as quantification [1]. The term ‘‘identity’’ consists of two parts, namely size and chemical composition. For known single chemical substances, mass fractions (*e.g.*, mg/kg) can easily be converted to amount of substance fractions (mol/kg) using the molar mass of the substance. No such simple conversion from mass fractions to number of particles exists for nanoparticles, as particles of the same chemical composition can differ in size, mass and density. As far as size is concerned, additional challenges are that (1) every non-spherical particle can be characterised by multiple ‘‘sizes’’ and (2) sizes may differ between the dried or dispersed state of a particle and measured sizes are always method-defined. Different particle size analysis techniques measure fundamentally different parameters, nonetheless all output is called ‘‘size’’. Examples of the output of size measurements with different techniques are:

- Transmission electron microscopy: lateral dimensions of a 2D projection of the particle, usually in dry state (average diameters are either average, median, or modal values obtained from the number-based size distribution)
- Dynamic light scattering: hydrodynamic diameter of particles (expressesd as diameter of a spherical particle that has the same Brownian motion behaviour in suspension)
- Centrifugal liquid sedimentation: sedimentation behaviour of a particle and expresses size as diameter of a sphere of equal sedimentation properties.

As far as quantity is concerned, it has to be highlighted that unless the particles are near-spherical and of uniform and known density, mass based, number based, and intensity based results, which are by definition not comparable, may also be virtually non-convertible [1].

Based on the nanodefinition of the EC [2], validation of methods for detecting and quantifying nanoparticles in food must answer three questions, i.e. (1) Are there nanoparticles in the sample? (size identity); (2) If yes, what kind of particles? (chemical identity) and (3) How much NM is in the sample? (mass or number fraction). Both size identity and quantity of nanoparticles are intrinsically method-defined. Direct comparison of results from different methods is therefore only possible if several assumptions on the shape and density of the particles are made. This limits the concept of the screening/confirmatory method.

Overall, all the metrological and conceptual problems highlighted above can be solved by a clear definition of the measurand. However, there are also practical challenges related to

detecting and quantifying nanoparticles in food. The particulate nature of the analyte may cause problems in the final quantification step, *e.g.* in imaging by electron microscopy only a small fraction of the analytical portion is studied whereas it must be ensured that a sufficiently large number of particles are counted. Another problem is that particles may undergo changes during sample preparation and final quantification (*e.g.* agglomeration, disagglomeration, or even dissolution). Finally, the different sensitivity to different particles of the same kind should be kept in mind as a potential problem (properties of nanoparticles may vary from producer to producer and even from batch to batch due to differences in morphologies, stabilising agents, etc.).

The most important techniques for measuring nanoparticles size distribution are centrifugation-based techniques (*e.g.* centrifugal particle sedimentation/CPS and analytical ultracentrifugation/AUC), laser light-scattering techniques (*e.g.* dynamic light scattering/DLS), electron microscopy (*e.g.* scanning electron microscopy/SEM and transmission electron microscopy/TEM), hyphenated ICP-MS-based methods (e.g. hydrodynamic chromatography ICP-MS/HDC-ICP-MS and Field Flow Fractionation ICP-MS/FFF-ICP-MS), and single particle ICP-MS [3]. However, only ICP-MS-based techniques are able to also determine the chemical identity and this, along with their speed allowing for a reasonable sample throughput, makes them the most promising for the detection and characterisation of inorganic NMs in food.

Irrespective of the analytical technique used, a proper measurement of nanoparticles requires a simplification of the matrix into which they are embedded, which call for extensive, carefully executed and documented sample preparation. In general, extracting the nanoparticles from the embedding matrix is required and it must be ensured that the sample preparation treatment does not modify the original particle size distribution.

So far, three interlaboratory studies have been carried out by the EC on the determination of Ag particles in food simulants/matrices, two of them by single particle-ICP-MS and one by FFF-ICP-MS. The team dealing with food NMs of this Departement is one of the few laboratories worldwide that participated in all of these exercises. Besides nano-Ag, the team has focused on the determination of nano-SiO_2 and TiO_2 [4, 5]. The determination of these NMs presents great challenges when an ICP-MS-based analytical platform is used. The way these challenges were addressed is discussed, with focus on chemical resolution of polyatomic interferences on Si and Ti masses by gas phase reactions in the quadrupole.

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Dietary exposure to nanomaterials

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The principles of exposure assessment of engineered nanomaterials (ENMs) *via* food and feed are basically the same as in exposure assessment of non-nanoform materials [1]. The starting point for determining the amount of ENM for the exposure assessment currently has to rely on information on the material added to food/feed or that is in contact with food/feed [1]. The initial characteristics of the added ENM can be used as an assumption in the exposure assessment, but it is preferable to determine the amount of the ENM present in the food/feed matrix. In fact, the structure of the ENM in food/feed may be changed in the food/feed production chain during processing or storage because of their interactions with proteins, lipids and other substances present in the food/feed matrices. Hence, effects of processing and storage and the stability of the ENM should be accounted for. For ENM added to feed, the potential carry over to food should be considered for human exposure, which could be determined by measurement of the ENM in relevant animal tissue or products.

Use scenarios where it can be anticipated that consumer exposure does not arise include food contact materials with no nanomaterial migration and ENMs that are soluble or biodegradable, included delivery systems for bulk substances in nanoscale (e.g. micelles, nanoemulsions or other encapsulation). On the other hand, there are cases where dietary exposure to nanomaterials is likely to occur and inorganic, insoluble and potentially bio-persistent nanoparticles are of particular concern in this respect. In general, the following are indicators of a potential for high exposure:

- High production volume for the field of application
- High mobility of the nanoform in organisms, *i.e.* probability of internal exposure (e.g. transport via macrophages; transport through cell membranes, blood-brain barrier and/or placenta) and mobilization potential (e.g. infiltration, sorption, complex formation)
- Targeted or controlled release
- Persistence/stability (e.g. in water, fat, and body fluids, lack of solubility/degradation)
- Bioaccumulation.

For thorough exposure assessment, the determination of the amount and characterisation of the ENM present in the food as consumed, i.e. prepared as ready-to-eat (including cooking, etc.), is needed. However, it should be kept in mind that the ENM can undergo major alterations during the transit in the human gastrointestinal (GI) tract. GI digestion may degrade/dissolve the ENM turning it into the corresponding non-nanoform and such transformation may be complete or partial. On the other, nanoparticles with new properties may be formed and the amount of particles in the nano range can increase as compared to the original food. In general, substantial modifications are to be expected (e.g. in terms of agglomeration, surface charge), even due to the effects of degradation of the matrix on ENM

characteristics, with unpredictable effects on absorption and potential toxicity. This highlights the importance of evaluating the effect of GI digestion.

In vitro digestion methods can be used to assess the stability of the ENM in the GI tract. With an *in vitro* digestion model, the conditions of the human gastrointestinal tract can be simulated, i.e. temperature, mixing, transit time, composition of salt, enzymes and other constituents such as bile. When evidence is provided convincingly demonstrating, by appropriate analytical methods, that that an ENM completely dissolves/degrades in the gastro-intestinal tract, the hazard identification and hazard characterisation can rely on data for the non-nanoform substance as long as the possibility of ENM absorption before the dissolution/degradation stage can be excluded.

In the absence of such detailed exposure data and where it is not possible to determine the nanoform in the food/feed matrix, it should be assumed that all added ENM is present, ingested and absorbed in the nanoform.

Nano-SiO_2 and TiO_2 are appropriate examples of nanoparticles to which consumers are already exposed. In bulk form they are authorised food additives (E551, E171) but contain a nano-sized fraction [2, 3]. Nano-SiO_2 and TiO_2 are produced in high tonnage volumes with present and/or prospective uses in the food sector and are potentially bio-persistent nanoparticles. A recent study addressed the effect of GI digestion on nanosilica and found that upon consumption of foods containing E551, the gut epithelium is most likely exposed to nano-sized silica [4]. Overall, it appears that further studies on this critical aspect are definitely needed.

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Food nanotoxicology and risk assessment

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The traditional risk assessment paradigm (hazard identification, hazard characterization, exposure assessment and risk characterisation) is considered appropriate for evaluating nanomaterials (NMs) from a food safety point of view [1]. Similarly to other substances potentially present in food, NMs are a heterogeneous group with respect to their chemical, biological, physiological, pharmacological and toxicological behavior. The risk of an ENM depends on its chemical composition, physico-chemical properties, its interactions with tissues, and potential exposure levels [1]. The European Food Safety Authority has highlighted the need for generating new data and approaches able to cope with NM characteristics affecting their biological activity (higher reactivity and bioavailability as compared to the non-nanoform) and modulating their toxicological properties with mechanisms and effects still to be elucidated.

Among the NMs of greater relevance in the food sector titanium dioxide and silicon dioxide rank high. TiO_2 in bulk form is a food additive approved by the European Union (E171) and often present in sweets. A recent study has shown that in food grade TiO_2 ca. 36% of the particles may be <100 nm in at least one dimension, indicating potentially significant dietary exposure to nano-TiO_2 especially for children [2].

In this respect, the possible effects on reproductive, endocrine and immune system after repeated oral administration of nano-TiO_2 to rat at dose levels (0, 1, 2 mg/kg body weight per day) compatible with potential human intake have been studied [3]. Nanoparticles were characterised by scanning electron microscopy and transmission electron microscopy, and their presence in spleen, a target organ for bioaccumulation, was investigated by single-particle inductively coupled plasma mass spectrometry and SEM/EDX. Results show that TiO_2 nanoparticles administered i) orally for five days (short-term exposure), ii) to adult animals, iii) at the lowest dose levels so far investigated, elicited sex-related effects in endocrine-active tissues such as thyroid, adrenal cortex, adrenal medulla and ovarian *granulosa* with changes in the serum levels of testosterone and T3 concurrently present, in the absence of general toxicity and with limited tissue deposition. A sex-related susceptibility was observed, with female reproductive, endocrine immune systems more affected [3].

Synthetic amorphous silica or SAS (SiO_2) is extensively used in food production as additive (E551). Nano-sized primary particles are formed in the production of E551 and then agglomerate later in the production process to larger structures [4]. Until now, nanosilica for food applications (Aerosil) has been produced but there is no information on the use, presence and concentration of nanosilica in food products also due to the insufficient regulatory frame at present.

Within the Joint Action NANOGENOTOX (http://www.nanogenotox.eu/) short-term oral exposure to SiO_2 nanoparticles (primary size ca. 20 nm) resulted in a limited absorption and

deposition in liver and spleen of female rats. However, after IV administration, SiO_2 was still present in the organs at day 90 after the last treatment indicating biopersistence. The FP7 project NANoREG (http://nanoreg.eu/index.php) pursues a common European approach to the regulatory testing of manufactured NMs in order to provide tools for the definition of a credible and thorough nano-regulation. Within this project, Nanogenotox SAS study will be followed-up by performing a repeated-dose 90-day oral toxicity study in rat.

In conclusion, from this outline it is clear that further studies are required on oral exposure to TiO_2, SiO_2 and other NMs of relevance for present or future food applications. Risk assessment of NMs in food requires more data from long-term studies, at doses comparable with human intake *via* the diet and possibly focusing on susceptible populations and life-stages.

1. EFSA Scientific Committee; Scientific Opinion on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. EFSA Journal 2011;9(5):2140.
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Risk assessment of Nanomaterials by the European Food Safety Authority (EFSA)

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Nanomaterials have many potential applications in food/feed products. In Europe, various food/feed products require prior authorisation before being placed on the market, and EFSA is responsible for delivering scientific risk assessment opinions for this decision making process. A number of opinions have been delivered or are in the pipeline. In 2011 EFSA published detailed guidance on how nanomaterials in food/feed products should be assessed for human health risks [1]. This resulted not only in clearer and more transparent risk assessments by the concerned EFSA panels, but also in harmonisation when the same material was concerned for multiple food/feed purposes. European Member States and other countries have welcomed this guidance and EFSA will provide updates as appropriate. New EU legislation for a definition and labelling of nanomaterial is expected and will feed into updating this guidance document. Also data of recent toxicological studies and test developments relevant for the oral route of exposure are useful for fine-tuning the risk assessment guidance.

To ensure good information exchange regarding data, expertise and risk assessment experiences, EFSA convenes on a yearly basis its Network for Risk Assessment of Nanomaterials in food/feed [2]. This network consists of delegates from the European Member States and pre-accession countries, delegates from the European Commission (e.g. DG Research&Innovation, JRC) as well as EFSA staff, Panel Members and Scientific Committee Members. The network has identified priorities and concentrated in its meetings on (1) the recommended definition for nanomaterial [3], (2) methods for detecting nanomaterial in complex matrices such as food/feed, e.g. those developed by the NanoLyse consortium [4], (3) inventory lists of nanomaterial used in food/feed and (4) on toxicological data (with relevance for food/feed) from national and European research projects.

EFSA awarded in March 2013 a contract for making inventory lists of nanomaterials being used in food/feed products. This information is collected from literature reviews and direct contact with applicants. Additional information on decisions for market authorisation, risk assessments or safety studies will be included in the database. These inventory lists are expected by March 2014 and will help to update the above mentioned EFSA risk assessment guidance. This database will also allow the EFSA Panels to anticipate the potential presence of nanoforms in their assessments and to check available information on the material of interest.

The activities of EFSA for nanomaterials help to ensure the safety of the European consumers. For the environment, risk assessments are carried out as well under the foreseen legal provisions.

1. EFSA Scientific Committee; Scientific Opinion on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. EFSA Journal 2011;9(5):2140
2. http://www.efsa.europa.eu/en/scnetworks.htm?wtrl=01
3. EC Recommendation of 18 October 2011 on the definition of nanomaterial http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF
4. http://www.nanolyse.eu/default.aspx

The activities of the JRC of the European Commission on nanotechnologies related to the food sector

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Nanoparticles are already used in several consumer products including food, food packaging and cosmetics and their detection and measurement in food represent a particularly difficult challenge [1].

The European Commission has published in October 2011 its recommendation on the definition of nanomaterial [2]. This definition calls for the measurement of the number based particle size distribution in the 1-100 nm size range of all the primary particles present in the sample independently of whether they are in a free, unbound state or as part of an aggregate/agglomerate. This definition does present great technical challenges for developing measuring methods [3].

In this presentation we will give an overview on the current activities of the Joint Research Center of the European Commission in supporting existing and planned legislation (at the European Union level) in the field.

In particular we will illustrate the development of techniques for the size measurement of nanoparticles when addressing this new definition of nanomaterials. These new methods are based on the combination of size separation techniques, such as flow field flow fractionation [4], with identification and quantification techniques, such as ICP-MS.

The problems to be overcome in measuring nanoparticles in food and consumer products will be illustrated with some practical examples, including the interlaboratory performance study “detection/quantification of silver nanoparticles in an aqueous matrix” organized by JRC which is currently in progress.

1. Calzolai L., Gilliland D., Rossi F. 2012. Food Additives and Contaminants 29, 1183.
2. Recommendation on the Definition of nanomaterials (2011/696/EU).
3. Linsinger T.P.J., Roebben G., Gilliland D., Calzolai L., Rossi F., Gibson P., Klein C. JRC Reference Reports. EUR 25404 EN (2012).
4. Calzolai L., Gilliland D., Garcia C.P., Rossi F. 2011. Journal of Chromatography A 1218, 4234.