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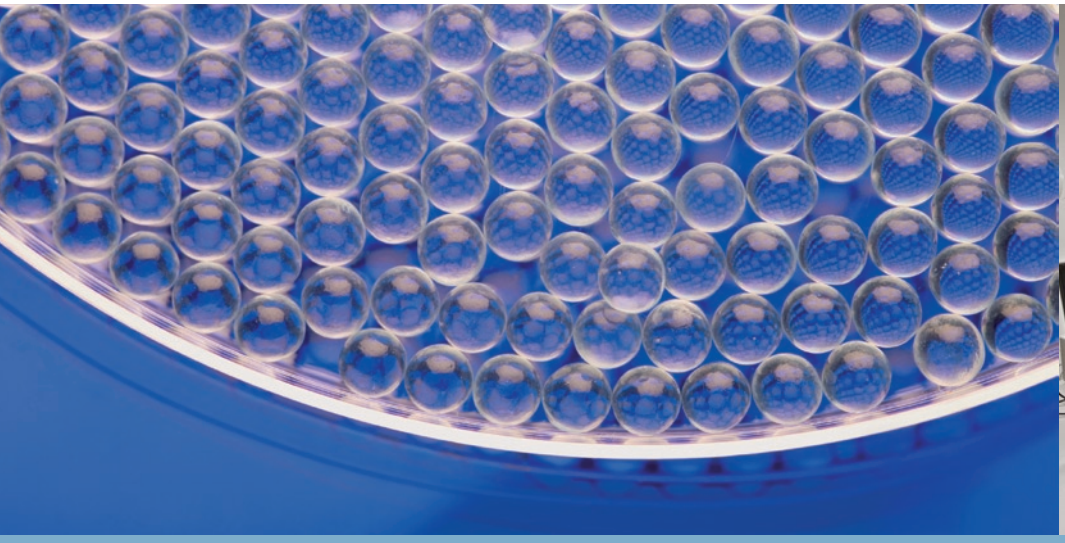

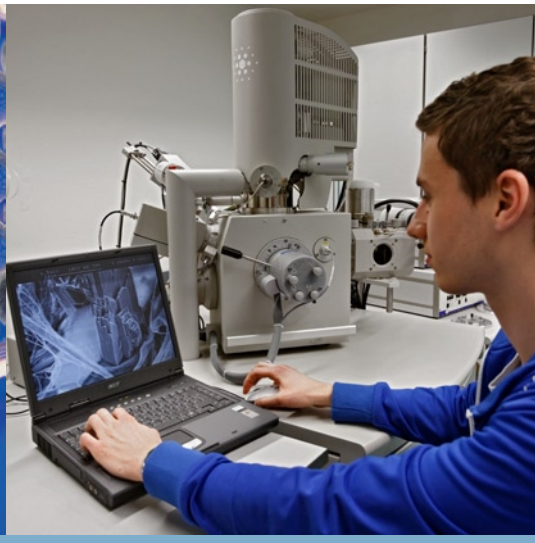

Max Rubner Conference 2010

Nanotechnology in the Food Sector

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Abstracts

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Application of Nanotechnologies in the Food Sector

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Many of the world's largest food companies are reported to support specific research programmes to explore the potential of nanotechnology for use in the food sector. It has been suggested that the number of companies currently applying nanotechnologies to food could be as high as 400 and that this number is expected to increase dramatically in the near future. The market for nanotechnology-derived products for the food sector is predicted to grow rapidly in the coming years. Research activities on applications of nanotechnology in the food sector already include development of improved taste, colour, flavour, texture and consistency of food products, increased absorption and bioavailability of nutrients and bioactive compounds, improved quality, shelf-life and safety of food products due to new food packaging materials with improved mechanical, barrier and antimicrobial properties, and nanosensors for traceability and monitoring the condition of food during transport and storage. Broadly, the following categories of nanotechnology applications in the food sector have been identified:

- The use of nanotechnology processes or materials to develop food contact materials. This category includes nanofilters, material for food packaging and coatings for kitchen utensils, processing equipment, and food containers.
- Nano-sized, nano-encapsulated or engineered nanoparticle ingredients including bioactive compounds, nutrients, additives and processing aids.
- Food ingredients that have been processed or formulated to form nanostructures and nanotextures for example to alter taste, texture, and consistency of food products.
- Biosensors for monitoring conditions of food during storage and transportation including packaging with integrated indicators.

Currently many nanotechnology applications in the food sector are at R&D or near-market stages. Only nanotechnology-derived materials for food packaging to improve mechanical and barrier properties and some delivery systems for biologically active compounds are available in some countries. However, data on the benefits, improvements and risks of nanotechnology applications in the food sector as well as their economical competitiveness are still almost lacking.

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Nanostructures: Key to Deciphering Chinese Herbal Medicine

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Micelles have long been known to exist in Chinese herbal decoctions. Their potential pharmacological implications, however, have never been explored. Our recent studies on nanosized micelles in antidiabetic bitter melon extract (BME) and antiviral radix isatidis extract (RIE) have shed first light on this overlooked part of herbal decoction, and demonstrated that they are not only a bioactive unit, but also may render a key to the elucidation of the mechanism behind Chinese herbal medicine's essential characteristics such as channel tropism, organized action by various compositions, and the herb's dramatic change in pharmacological properties due to processing.

Micelles formation was investigated by monitoring light scattering of BME and RIE in the course of decoction, respectively. It was found that micelles formed concurrently with the generation of maillard reaction products resulted from the interaction of free amino groups of protein, peptides and amino acids with reducing sugar, as was indicated by the appearance of brown color. Basic amino acid contents in BME and RIE dropped from 4.41% and 13.6% of total dried matter in fresh bitter melon and radix isatidis to 0.10% and 0.83%, respectively, in the decoctions. Meanwhile, cytotoxicity was dramatically reduced after decoction as is indicated by the change of LC50 from 39.0 to 113.5mg dried matter/ml for radix isatidis and from 36.9µg protein/ml to non-toxic for bitter melon.

Micelles were observed with a phasecontrast microscope and scanning electronic microscope. A number of micelles with size range from 30 to 250 nm were identified in both BME and RIE. Micelles were separated by gel chromatography on an Sephacryl S-1000 column and ion exchange chromatography on a Toyopearl DEAE 650 M column. Isolated micelles fractions were further subject to characterizations.

Interaction of isolated micelle fractions with cells was investigated by capillary electrophoresis of selected cell lines with and without incubation with the fractions. One BME micelle fraction(BMEm) and one RIE fraction(RIEm) were found to change migration time of HIT-T15 cell and MCDK cells, respectively, in a cell-specific manner, suggesting an interaction between the micelle fraction and cells with specificity. The assembly of micelles in BMEm and RIEm was demonstrated to be pH-driven, and the assembly started at pH7 and completed at pH8. Both BMEm and RIEm were shown to possess the ability to encapsulate small molecules.

Remarkable bioactivities were shown of BMEm and RIEm both in vitro and in vivo. BMEm was demonstrated to increase insulin secretion of HIT-T15 cell damaged by alloxan as much as 160% of the control. Feeding GK/Crj type II diabetic rat with BMEm for a month dramatically reduced the numbers of deformed and unhealthy pancreatic islets of Langerhans as was displayed by the histological observation. Meanwhile, RIEm was shown to interact with MDCK cells and prevent the infection by influenza virus A. The oral administration RIEm at a dosage of 400mg/kg reduced the death rate from 80% to 50% in the challenge assays on mice by influenza A virus.

All those results suggest that micelles in BMEm and RIEm are pharmacologically active unit, and may constitute the major forms of pharmacological actions of BME's antidiabetic effect and RIE's antiviral effect. Possessing versatile characteristics of nanomedicines, herbal medicine micelles can provide an unprecedentedly plausible model for unique properties of Chinese herbal medicines and a promising key to deciphering their mystery.

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Improved plastics packaging via nanocomposites and nanoparticles

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The most crucial technical functions that are required today from plastics packaging are barrier properties against the permeation of substances through the wall of the package. This is because most polymers that are used in packaging show substantial permeation rates for many substances. Permeation processes may occur from the environment to the inside or vice versa. In this context, the most relevant substances are the following:

- oxygen and water vapour, as examples for substances permeating from the environment to the product
- flavours and carbon dioxide, as example for permeation in the reverse direction.

In addition, the migration of contaminants from the package to the packed product has to be kept as low as possible, at minimum to the standards given in several EU directives.

Now, nanocomposites and nanoparticles allow for a substantial improvement of the barrier properties of common plastics. The following examples show areas where different technologies are used for this purpose:

- Laminates from films that have been coated by thin inorganic layers, mostly from Aluminium (Al), but also from some oxides, in a thickness range between 10 and 100 nm. Related film laminates are used in many applications, such as pouches and lidding films, where they are used since decades to replace thicker and more expensive materials like Al foil. The most prominent examples are polyethylene terephthalate (PET) film, coated with Al and laminated to polyethylene (PE) or polypropylene (PP), also coated with Al and laminated to PP or PE.
- Plastic films and containers either from polyamide 6 (PA 6) or PET which incorporate nanoparticles from layered silicates.
- Plastic containers, mostly from PET, coated on their inner surface with thin barrier layers, made by plasma coating techniques in a thickness range between 20 and 80 nm.

In most cases, especially in the first group, the barrier improvement is just used to reduce the amount of material, thus leading to cost reduction.

In some cases, new types of products may be generated by the improved barrier properties. This happened in the case of high barrier plastic containers which, although not cheaper than glass bottles, give other advantages to the consumer, especially light weight.

In most of these examples, structures are created in form of layers, meaning that the nanometer scale only extends over one geometrical dimension, whereas the structures are macroscopic in the other two. Moreover, with exception of containers coated on their inner side, there will be no direct contact between nanoscale structures and packed product because an additional polymeric layer will always be used to as an additional cover.

Other functions may be created as well by using nanoscale layers or nanoparticles:

In the case of plastic containers with an interior coating, additional functions that will be used in the future are a reduction of migrating contaminants from the container wall or an improvement of the emptying properties.

Nanoparticles may also be used to increase the absorption of PET for infrared radiation, thus allowing for reduction of energy input and cycle time in the stretch blow moulding process of PET bottles. Here, e.g. Titanium nitride (TiN) or Carbon nanotubes have been tested. Recently, the application of TiN in PET bottles has been classified by a panel of the European Food Safety as not giving rise to toxicological concern.

As a conclusion, nanotechnology may help to achieve substantial functional improvements in packaging materials. However, the innovation created is more incremental than radical and it is mainly used for a reduction of material input and of the related cost.

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Intelligent packaging as potential field for nanotechnology

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The main function of food packaging is to maintain safety and quality of food and beverage products during storage and transportation, and to extend shelf-life by controlling the permeation of moisture, gases, especially oxygen, and volatile components (e.g. flavours). Additionally, food packaging is nowadays associated with other features that relate to the active improvement and/or maintenance of the product quality, and to the measurement, storage and distribution of information about the product. These features are enabled by new emerging technologies in the form of active and intelligent packaging.

The food and beverage industry has always been seeking new technologies including new, efficient gas barrier materials to improve quality, shelf-life, safety and traceability of their products. In addition, packaging concepts and materials with other functionalities like oxygen scavenging capacity, antimicrobial activity, light barrier properties, indication of food quality and indication of product authenticity etc. offer new possibilities for the maintenance of quality and safety of food products.

Nanotechnology is opening up a way for innovations in food packaging field. It has been approximated that food packaging forms approximately half of the whole value of the current applications of nanotechnologies for the food sector. It has also been estimated that over 200 companies worldwide are conducting R&D into the use of nanotechnology in engineering, processing, packaging or delivering food and nutritional supplements .

In this presentation the prospects of nanotechnology in packaging will be discussed. The possibilities including the improvement of properties (flexibility, durability, temperature/moisture stability, barrier properties against oxygen and light) of both conventional packaging materials and biodegradable polymers will be discussed. In particular, the focus will be in the possibilities of nanotechnology in intelligent food packaging, incorporating sensors, indicators and power sources for packaging applications and tools for authentication of the packaged product.

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Nanosafety and Risk Assessment: Nanomaterials and their biological impact

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Nanoparticles are being considered for use in a wide variety of applications ranging from biomedical use, e.g. as drug delivery systems, technical devices and in the food sector, e.g. for food packaging. However, biocompatibility must be addressed in order to promote the safe use of nanomaterials in these fields. Consequently, nanotoxicology was established as a new discipline focusing on the biological effects of nanoparticles and nanomaterials.
The question is, what makes nanoobjects thus special in biological systems? Three principles have been identified which characterise the mode of action of nanoparticles most likely. Firstly, the ‚transport principle' which explains the ease of cell entry for most of the nanoobjects, secondly, the ‚surface principle' comparing the huge enlargement of the specific surface area of small nanoparticles against their bulk counterparts and last, the ‚material principle', regarding the differences of biological effects even at the same particle size and concentration depending only on the different material composition.
The ease of movement of these tiny little particles may give rise for some important reservations. Thus, as an example, silver nanoparticles coming from food packages and other products such as textiles are under suspicion to become health related if penetrating into biological systems like cells or tissues. Additionally, other nanomaterials are in discussion as well as many studies exist which demonstrate biological effects in cells, tissues or animals. However, many of such studies showing adverse effects are themselves under discussion because of severe deficits within the experimental set-ups. It has been demonstrated by several groups that a huge number of publications show no valid results as the methods used are not reliable for nanotoxicological approaches [1-7]. Several examples from published studies will demonstrate the pitfalls which are most obvious and may be avoided in the future. Important flaws concern the suspensions of nanoparticles which may contain small amounts of solvents or do not consider the density of the material. Moreover, many experimental designs use the wrong test systems for the specific endpoints and most often, the concentrations used are ultimately high. Thus, many publications lead to wrong conclusions and may guide the discussion about nanomaterials and their possible risks into an unsuitable direction.

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Protein corona associated with nanoparticles

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For nanomedicine and nanosafety, there is a growing desire for a rational basis within which to understand nanoparticle-cell and organ level interactions. Nanoparticles in biological fluids (blood, or otherwise) generically associate with a range of biopolymers, especially proteins, organized into the 'protein corona' which is continuously exchanging with the proteins in the environment. In some cases the residence times of proteins in the corona are sufficiently long that they confer an effective biological identity onto the nanoparticle. The transport and fate of nanoparticles (from intracellular trafficking to clearance pathways) likely reflects the corona, rather than the nanomaterial itself.
We have characterized the protein composition of the corona formed around polystyrene, gold and silica nanoparticles and have shown that for particles of the same material, differences in size and surface charge alter the composition of the corona significantly. This implies that extreme care must be taken in the development of nanomedicine and nanotherapeutics in terms of controlling the manufacturing process of nanoparticles and control of the surface properties of the final product. We have applied several different methodologies, in a time resolved manner, to follow the lifetime of such biomolecular 'coronas'. For several nanomaterial types we find that blood plasma-derived coronas are sufficiently long lived that they, rather than the nanomaterial surface, are likely to be what the cell sees. Such particle-corona complexes can be physically isolated from the surrounding medium, and studied in some detail. From fundamental science to regulatory safety, current efforts to classify the biological impacts of nanomaterials (currently according to bare material type and bare surface properties) may be assisted by the methodology and understanding reported here.
By studying these systems, the goal is to predict how nanoparticles are "seen" by cells, and from this it may be possible to design nanoparticles to selectively deliver nanoparticles to specific targets inside living organisms.

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Nano and microparticles of the gastrointestinal tract

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Typically, the gastrointestinal tract is exposed to a myriad of particles arising from two distinct origins: man-made and naturally-occurring. Man-made particles, which are now of common use in the modern Westernised diet, occur, for example, as non-biological inorganic microparticulate food additives and comprise titanium dioxide, silicates and aluminosilicates.
Indeed, titanium dioxide (100-200 nm diameter, designated E171 in Europe) is used for whitening and brightening of foods while particulate silicates and aluminosilicates (100-700nm in length, designated E554, E556 and E559 in Europe) are used in pharmaceuticals, neutraceuticals and in the food industry as anti-caking agents.
Naturally-occurring particles, unlike their exogenous counterparts, are naturally present in food (e.g. ferritin) or are formed de novo in the gut lumen (e.g. calcium phosphate). Ferritin is a naturally-occurring nanoparticulate structure found in meat and plant-based foods (circa 12 nm diameter protein shell containing an iron oxide core of 6-8 nm diameter), while calcium phosphate nanoparticles (20-200 nm diameter) are formed de novo in the mid-distal aspect of the small intestine due to 'homeostatic' re-secretion and co-precipitation of calcium and phosphate ions.
Both man-made and naturally occurring particles are able to translocate the gastrointestinal mucosa tract by a number of pathways and have been observed in underlying mucosal cells, both apically and basally in the Peyer' s patch. Thus the gut is exposed to particles of all sizes, sometimes 'purposefully' and sometimes 'inadvertently', and for which 'purposeful' or 'inadvertent' pathways of uptake exist. In the talk, some of the above phenomena will be described and associated beneficial or detrimental cellular outcomes discussed.

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A 3D intestinal tissue equivalent promises a good correlation with the human organism and enables the testing of nanoparticular formulations

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INTRODUCTION

The small intestine is the organ where the vast majority of the absorption of oral administered drugs takes place [1]. Active ingredients are transported over the intestinal epithelia due to several transport mechanism and released at the adjacent circulation. Many potential drug candidates fail in phase II and III of the clinical trials because of their low solubility, low permeability and/or a high first-pass-metabolism in the gut and liver [2]. Therefore a wide knowledge is needed regarding the absorption and oral bioavailability of new drug candidates in the early stage of preclinical trials to minimize costs and valuable recourses. The testing of new candidates predominantly takes place in preclinical trials by the use of cellular and animal experiments.
Due to their oversimplified construction, reflect monolayer cultures the physiology of the small intestine insufficiently. Due to species-specific differences data from animal experiments have only limited relevance [3]. Furthermore, not only because of ethical aspects, animal testing should be reduced in terms of the 3R-Principle by the use of alternative test methods to a minimal necessary degree [4].

EXPERIMENTAL METHODS

A 3D dynamic intestinal tissue equivalent has been developed at the Fraunhofer Institute IGB (Stuttgart, Germany), which reflects the micro environment of the small intestine. By the use of an acellularised collagen scaffold and a dynamic bioreactor system the structure of the villi and the morphology of the high prismatic epithelial cells could be recreated.
Due to the remaining crypt region, the three-dimensional structure of the collagen scaffold represents a protective mechanism for the reseeded cells against high shear stresses and could therefore enable the regeneration of the epithelial layer and multiple testing in future.
The 2-chamber-bioreactor module enables the accomplishment of resorption studies under dynamic conditions due to the designed apical and basolateral sides. This causes the continuous evacuation of the test substances and metabolites and maintains the physiological sink conditions.

RESULTS & DISCUSSION

Preliminary studies with co-cultivated Caco-2 cells and human microvascular endothelial cells showed an increasing paracellular permeability of the epithelial cells under dynamic culture conditions. Therefore an improved correlation of the generated transport data with the human organism could be proven by the use of low permeable substances (Fluorescein & Desmopressin). In addition the accomplishment of directed transport studies for the investigation of the carrier protein p-gp by the use of Rhodamine 123 was possible and correlated with the data of the conventional Caco-2 assay [5].
Furthermore we performed experiments with new solid particle formulations.
Due to the increasing shear stress the Caco-2 cells on the top were sheared off. But the former crypt region protects the lower cell barrier. Thus the transport study could be transferred to the human organism.
A standardized and easy handling was focussed as well and could be realised by the miniaturization of the bioreactor module with a theoretical seeding area of 1 square cm.
The enhancement of the intestinal tissue equivalent with primary porcine epithelial cells has been accomplished only partially yet. The isolated cells could be cultivated under dynamic conditions for a short period of 5 days. Beside absorptive enterocytes, mucus producing goblet cells were shown with histological staining methods (PAS & Alcian blue).
With the long-term establishment of the primary cell culture a model system could be developed in future, which reflects the entire barrier function of the small intestine under simulation of the physiological micro environment.

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Detection and characterisation of nanoparticles in food

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A number of recent reports and reviews have identified the current and short-term projected applications of nanoparticles for food and beverages. These include nano-sized or nanoencapsulated ingredients and additives for food, beverages, and health-food applications as well as the use of engineered nanoparticles for the improvement of food contact materials with view to mechanical properties, gas permeability or antimicrobial activity. Although potential beneficial effects of nanotechnologies are generally well described, their potential (eco)toxicological effects and impacts have so far received little attention. A prerequisite for toxicological, toxicokinetic, migration and exposure assessment is the development of analytical tools for the detection and characterisation of nanoparticles in complex matrices such as food. Given the huge diversity of engineered nanoparticles for potential use in the food and feed sector in terms of chemical composition, size, size distribution, surface activity/modifications etc. and possible interactions with food matrix components (e.g. proteins) this is a challenging task requiring tailored solutions.
The presentation highlights some current analytical approaches suitable to address food safety related issues of nanotechnology. This includes sample preparation aspects, imaging techniques such as electron microscopy, separation methods (e.g. flow field fractionation, hydrodynamic chromatography) and detection/characterisation techniques (e.g. light scattering, mass spectrometry). First applications are shown for the analysis of inorganic nanoparticles in food matrices.

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Nanoparticles in Food and Life Science Products - How does Process Engineering contribute?

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Nanoscaled structures have been found in nature for decades. Well-known natural products are full of particular structures ion the nanometer scale. However, most often these are composed of organic material and structured on a molecular level. These structures are responsible for the specific functions of these “particles”. With increasing technical possibilities, also inorganic materials can be produced in a nanometer scale. These have been used in foods and life sciences products for many years without being discussed intensively.

When nanotechnology emerged it enabled scientists to design particles for target product characteristics. These particles are found more and more in daily life’s products and increase consumers’ awareness. Ongoing are discussions on the specific advantages of these particles going hand in hand with the assessment of their risks.

In the talk nano-scaled particles and particular structures will be presented with regards to their today’s and possibly future application in foods and life science products. The specific scale of these particles does not only influence product properties but also poses specific problems in their production and application. These will be discussed. We will also take a look into ongoing research in the nanotechnology field focusing on nanostructured particle systems.

New technologies are strongly connected to responsibility. Exemplarily, some results on the bioactivity and bio-impact of nanoparticular structures within the gastrointestinal tract will be finally presented.

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Nanomaterials in food – risk perception of experts versus laymen

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Nanotechnology is deemed to be one of the key technologies of the 21st century. The hopes and expectations placed in it as a driver of innovation are enormous. At the same time knowledge about the impact of nanotechnology on human health has been largely speculative up to now. The fact that new materials produced on the basis of nanotechnology are increasingly being used in the production process and in consumer products means there is a growing need for an urgent examination of the safety and risk issues of nanotechnology. Regarding risk perception of experts versus laymen in terms of nanotechnology the BfR conducted so far five studies:
1.) A Delphi survey on the risks of nanotechnological applications in the fields of foods, cosmetics and consumer products was performed. The goal of this project, involving a multi-phase expert survey, was to pre-structure the technology field nanotechnology on the basis of potential risks. In the project current or potential uses of nanomaterials were identified and assigned to concrete applications. Based on the knowledge available on exposure and hazard potential, the applications were classified according to the level of probable risk. When comparing the oral, dermal and inhalation intake of nanoparticles, experts were of the opinion that the inhalation route is probably the most problematic route from the health angle. 2.) As risk communication extends far beyond pure information on the current level of scientific research and knowledge about health risks, the BfR Consumer Conference Nanotechnology was launched as a pilot project. The basis of risk communication activities within BfR is a participatory dialogue. The staging of a consumer conference constituted the practical execution of this task as it directly involved consumers in the discussions of opportunities and risks prior to the broad application of nanotechnology in society. The consumers also drew up a vote. This was the first time in Germany that a public institution had made use of this risk communication tool. The central demands of the consumers were for comprehensive labelling and accompanying risk research on ‚nano' products. 3.) In order to determine how the public at large currently sees nanotechnology in Germany, BfR conducted a research project on public perceptions about nanotechnology. A representative population survey, combined with a basic qualitative-psychological study, sought to provide insight into the factors that influence people's perception, the social dynamics that may be of importance in conjunction with nanotechnology and the direction in which public opinion on nanotechnology could move. Risks or risk areas were identified which are present in a manifest, latent or potential manner in public perception and the impact factors for risk communication in this new risk area were described. The majority of the 1,000 respondents were of the opinion that the benefits of nanotechnology outweigh the risks (66%). They, therefore, had a good or very good feeling about this technology (77%). Whereas the use of nanotechnology in the food sector is described as a sensitive area, support in the area of textiles, paints and varnishes was high (86%). 4.) In another BfR project on the Analysis of Media Reporting, attention focused on how the subject nano¬technology is taken up in the mass media discourse, which stakeholders adopt which positions in the debate and which argumentation patterns and language images put their stamp on that debate. For this, 1.696 articles from nine newspapers (Financial Times Deutschland, FAZ, Frankfurter Rundschau, Süddeutsche Zeitung, taz, Welt, Zeit, Focus, Spiegel) have been analysed for the years 2000 up to 2007. With an average of two articles about nanotechnology per newspaper per month nanotechnology is not a subject of great controversy in the media in Germany at the present time. Hence, it has a more positive image. The media tend to focus on the beneficial aspects in daily products like cleaning products or medical applications. 5.) In an internet analysis of the years 2001 up to 2008 alltogether 501 contributions from online fora and weblogs have been analysed. This special group of consumers who are active in internet fora judge nanoproducts mainly from the angle of their potential benefits. Here, nanoproducts in the field of medicine, textiles and automobiles are highly accepted, whereas products which are not yet ready for the market, e. g. in the area of foods, are seen rather doubtfully.
In conclusion, risk perception regarding nanotechnology of experts differs from that of laymen, especially in terms of foods. It is a great challenge for all involved stakeholders from science, trade and industry, political circles, the media, consumer associations and non-governmental organisations to intelligibly communicate the risks and benefits of nanotechnology to the public.

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Nanomaterials in food - an industry perspective

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Nanotechnology is an area of emerging interest and opens new possibilities for the food industry, including uses in food products, processing and packaging.
Application of nanotechnologies in the food industry is at an early stage.
As an innovative and progressive industry, the food sector is interested in science-based research and developments, including the application of nanotechnologies. CIAA members, together with other stakeholders and academia, are therefore actively supporting and carrying out research in this area.
There is a need to distinguish between the natural occurrence of nanoparticles (such as in protein, fat or sugar molecules), their presence through conventional processing techniques (such as milling, homogenising and emulsifying) and where particle size has been deliberately engineered to behave differently to its conventional counterpart.
Safety is paramount. Therefore, there is a need for adequate safety assessment on a case-by-case basis where the use of nanotechnology gives rise to changes in existing products or processes.
Openness and transparency are key. Both are necessary in raising awareness about the potential of the technology. Industry therefore pursues and participates in all relevant stakeholder dialogues at national and European level.
A common working definition for nanomaterials is crucial. Such a definition must consider several important factors such as size, engineered vs naturally existing and nanoscale specific properties. Without a common working definition, it is impossible for industry to implement regulations.

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EFSA's approach for the safety evaluation of nanotechnology products in the food and feed area

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Nanotechnologies have been claimed to offer a variety of possibilities for application in the food and feed area, especially in production/processing technology, to improve food contact materials, to monitor food quality and freshness, improved traceability and product security, modification of taste, texture, sensation, consistency and fat content, and for enhanced nutrient absorption.

On the other hand, little is know about possible effects such products might have on the health of consumers. Therefore the European Food Safety Authority (EFSA) provided at the beginning of 2009 a scientific opinion on potential risks arising from nanoscience and nanotechnologies on food and feed safety. This opinion addresses engineered nanomaterials but is generic in nature and is in itself not a risk assessment of nanotechnologies as such. One observation in the opinion is that current guidance documents for the preparation of applications in the food and feed area do not address engineered nanomaterials.

As a follow up EFSA is currently preparing a guidance document on the risk assessment concerning potential risks arising from applications of nanoscience and nanotechnologies to food, feed and pesticides.

The current presentation will discuss the various data requirement for the safety assessment of e.g. food additives, enzymes, flavourings, food contact materials, in the context of the new guidance document.

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Practical guidance for the safety assessment of engineered nanomaterials (ENM) in food; an ILSI Europe Working Group opinion

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Recent technological developments and a greater understanding of food structures have led to much discussion over the potential to add new, purposefully engineered nanomaterials (ENMs) into foods and any implications for safety. Such ENMs could be finely divided forms of existing ingredients, or completely novel chemical structures. To keep things in perspective it is important to acknowledge that food processing nanotechnology and nanomaterials are respectively a natural part of food processing and conventional foods, because the characteristic properties of many foods rely on nanometre sized components (such as nanoemulsions and foams).
Safety assessment procedures and requirements for novel foods are already available, and are implemented via the EU Novel Food regulation (EC) 258/97. Requirements for specialised safety assessments of ENM have been discussed over the last decade by intergovernmental organisations including the Organisation for Economic Cooperation and Development (OECD)[1] as well as the United Nations' World Health Organisation (WHO) and Food and Agriculture Organisation (FAO)[2]. The European Commission (EC)[3]. Moreover, EU Member States have held international fora as well as funded research into the topic. Nevertheless, despite these considerable efforts, and continued research programmes, there is still debate as to what might constitute a rigorous science-based risk assessment process for ENM in food use. Concerns for unexpected effects have arisen partly from nebulous descriptions of "properties that are characteristic to the nanoscale"[4] and emphasis on toxicological uncertainties[5] due to the lack of a historical database on toxicology studies on ENMs.
This paper summarises the interim conclusions and recommendations of the International Life Sciences Institute – European Branch (ILSI Europe) Expert Group on „The Safety Assessment of Nanomaterials in Food", which was formed to provide a clear guidance to industry on how to assess the safety of foods that may contain ENM. The guidance provides a framework which exploits accepted risk assessment procedures and existing toxicological and toxicokinetic databases of reference materials (traditional counterparts) to ensure that any ENM is identified and tested appropriately. A key safety criterion is to establish any change in functionality (i.e. in how a substance interacts with the body) of the ENM in comparison with the bulk reference material. A stepwise approach is taken that first characterises and compares the identity (ID), purity and physico-chemical characteristics, including aqueous solubility, of both the ENM and the reference material (if available). Key properties and differences are then evaluated which allow prioritisation for safety assessment using a „Decision Tree". A 2 Tier testing approach is then proposed where screening is initially conducted using in vitro and in vivo methodologies to determine the comparative toxicity and comparative absorption characteristics of the ENM in relation to the bulk material. Depending on the outcome, more detailed testing may be required using a 90-day repeat dose sentinel rat study: the findings may dictate the investigation of further further toxicological or toxicokinetic endpoints. Because the behaviour of the ENM may alter when incorporated into a food matrix, an initial non-experimental assessment should be undertaken to consider the need for any further testing of the ENM "as consumed". If indicated, experimental assessment could include inter alia the determination of solubility, dilution factor and likely intake. For completely novel ENM structures assessment will focus on the individual components in relation to any available bulk comparator(s).
It is concluded that this stepwise and integrated approach involving detailed physico-chemical characterisation together with standardised general and targeted test methods for the risk assessment of the ENM "as manufactured" and "as consumed" provides a robust and structured strategy for assuring the safety of a particular ENM in food.

[1] OECD http://www.oecd.org/document/35/0,3343,en_21571361_41212117_42378531_1_1_1_1,00.html
[2] FAO http://www.fao.org/ag/agn/agns/files/FAO_WHO_Nano_Expert_Meeting_Report_Final.pdf
[3] EU Commission http://cordis.europa.eu/nanotechnology/
[4] House of Lords Committee Report on Nanotechnologies and Food Posted on January 14, 2010 http://www.publications.parliament.uk/pa/ld/ldsctech.htm
[5] EMERGNANO http://www.safenano.org/Uploads/EMERGNANO_CB0409_Full.pdf

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