NanoDialogue
of the German Government

Use of nanomaterials in food and food packaging

Report by the German Federal Environment Ministry

29.10.2015

Authors: Antonia Reihlen & Dirk Jepsen

Imprint:

ÖKOPOL GmbH
Institut für Ökologie und Politik

Nernstweg 32–34
D – 22765 Hamburg

www.oekopol.de
info@oekopol.de

Tel.: ++ 49-40-39 100 2 0
Fax: ++ 49-40-39 100 2 33

Content

1 Introduction

The use of engineered nanomaterials in the food sector is expected to generate several benefits, among others an improvement of the food's taste and texture or an increased bioavailability of its nutrients. Engineered nanomaterials may also be used in food to prolong its shelf-life.

Human exposure from nanomaterials could occur from ingestion of nanomaterial-containing food and via the environment because of releases from nanomaterial-containing food and food packaging. This constitutes a general concern on potential risks for human health and the environment.

The use of engineered nanomaterials in the food sector was discussed in the NanoCommission's working group on the regulation of nanomaterials in 2010[1] and at a two-day expert dialogue in June 2015. In both occasions it was, among others concluded that easily understandable information on the potential benefits and risks of the application of engineered nanomaterials in the food sector are missing.

This report summarises how the use of engineered nanomaterials in the food sector is regulated, describes the state of knowledge on their actual use in foodstuffs and food packaging on the European market, discusses issues regarding potential environmental and health risks of these applications and provides a summary of the discussions at the expert dialogue.

It should be noted that nanomaterials could also occur naturally in food, for example as nanostructures of proteins. In addition, nanomaterials can be generated using traditional techniques of food production, such as milling of powders. This report only relates to the intended use of engineered nanomaterials in food, food supplements and food packaging.

2 Regulatory requirements

The use of engineered nanomaterials is differentiated in this report according to:

- food and food additives,
- food supplements and
- food packaging.

[1] At this time a revision of the Novel-Food Regulation was controversially discussed. The revision was therefore stopped and started anew. The various opinions voiced by the EU-actors were reflected in the NanoCommission's working group and are documented in its report.

2.1 Definition of nanomaterials

At present there is no unique and harmonized definition of the term 'nanomaterial' in the EU. In the area of (novel) food, food additives and food ingredients the current definition of the regulation on the provision of food information to consumers applies[2]. Article 2t contains the following definition of an engineered nanomaterial:

> *'engineered nanomaterial' means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale*
>
> *Properties that are characteristic of the nanoscale include:*
>
> *(i) those related to the large specific surface area of the materials considered; and/or*
>
> *(ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material*

The use of this definition has proven difficult, among others because some of the terms are ambiguous (e.g. properties that are characteristic of the nanoscale) und because there are no analytical standards to identify and quantitatively determine the content of nanomaterials in food (see also the discussions at the expert dialogue).

In addition, it is possible that a substance is not an engineered nanomaterial according to the definition of the regulation on the provision of food information but fulfils the criteria of a nanomaterial according to the EU Commission's recommendation on a definition of nanomaterials. This is due to the different criteria in the two definitions. One example is nanosilica[3], which is used as anticaking agent.

As the EU regulations in the food sector are being revised (c.f. Chapter 2.4) it is expected that a new and modified definition of nanomaterials will be developed for application in food legislation. If and in how far this will reduce or eliminate the existing inconsistencies in relation to definitions applied in other regulatory areas is unclear, as is the question if the analytical problems will be solved.

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[2] REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011 on the provision of food information to consumers

[3] For more information compare e.g. the opinion of the EU Commission's Scientific Committee on the Safety of Consumers regarding the various nanoforms of silica and the statement of the Association of Silica Producers (ASASP) "Statement for Synthetic Amorphous Silica regarding the definition of 'engineered nanomaterials' for use in food in the European Union".

2.2 Regulation on the safety of food

The EU-regulation on the safety of food[4] defines general requirements and principles for food safety. The aims of the regulation are, among others, the protection of consumer health and consumer interests.[5] In this regard the following requirements are defined for food products:

- only safe food may be placed on the EU market. Food is considered not safe, if it a) poses a health hazard or b) is not appropriate for human consumption[6];
- it is to be ensured that the production chain of food can be fully traced back (Article 18) and consumers are neither misled nor deceived and that no adulteration of food takes place (Article 8);
- the Member States are responsible for the enforcement of the requirements.

The general requirements are specified in further food-related legislation.

2.3 Food additives

Food additives are substances, which are added to food during its production or processing because of technological reasons and which thereby become part of it.[7] These substances have to be authorized for use according to the regulation on food additives.[8] This means that the European Agency for Food Safety (EFSA) evaluates if a food additive causes harm to human health and for which purpose it is used. Only substances without health concerns and which are beneficial can be authorized. Positive lists applicable in all EU Member States exist for all authorized substances.[9]

[4] REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

[5] http://ec.europa.eu/food/safety/general_food_law/principles/index_en.htm and http://ec.europa.eu/food/safety/general_food_law/general_requirements/index_en.htm

[6] Regulation on food safety, Article 14(2)

[7] Article 3(2)a of the regulation on food additives: "'food additive' shall mean any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods;"

[8] REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives

[9] Annex of the Commission Regulation (EC) No.. 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients

The requirements on food additives apply regardless of the substance' size and therefore also include nanomaterials.

2.4 Regulation on novel foods and novel food ingredients

The so called novel food regulation[10] concerns food and food ingredients, which have not been used for human consumption in the EU to a significant extent before the 15th of May 1997 and which can be assigned to certain groups. The types of food and food ingredients relevant for nanomaterials are those which have a new or intentionally changed molecular structure or which are produced using new technologies, which largely determine their structure. Examples of novel foods and novel food ingredients, which may be nanoscale are agricultural products from other countries (e.g. Chia-seeds), extracts of traditional food (e.g. proteins from rape seed) or synthetic nutrients.

Similarly to food additives, novel foods and novel food ingredients have to be authorized. [11] In the authorisation application the producer has to demonstrate that the novel food or food ingredient is not harmful to human health. In unambiguous cases the Member State authority to which the producer applies grants the authorisation. In other cases the EU commission is responsible. In the Novel-Food Catalogue food and food ingredients are listed which either are or could be novel.

The novel food regulation is currently being revised. In this context, the introduction of specifying rules for engineered nanomaterials are being discussed.

2.5 Regulation on food information

The regulation on food information[12] defines EU-wide applicable rules on what information is to be made available for a food product. Among others, a food's ingredients are to be listed in the ingredients list. Since 13 December 2014 engineered nanomaterials contained in a food are to be labelled in this ingredient list followed by the term '(nano)'.

[10] REGULATION (EC) No 258/97 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 1991 concerning novel foods and novel food ingredients

[11] Food and food ingredients from plants, animals and microorganisms may be used after notification to the EU Commission and not have to be authorized.
http://www.bvl.bund.de/DE/01_Lebensmittel/04_AntragstellerUnternehmen/05_NovelFood/lm_novelFood_node.html

[12] REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004

2.6 Regulation on products intended to come into contact with food

The use of certain substances in certain materials, which are intended to come into contact with food is regulated at EU-level, e.g. for packaging materials. Currently such regulations exist for plastics, cellulose foils and so-called 'active and intelligent' materials[13]. The regulations and the directive define, among others that substances used to produce these materials are to be authorized by EFSA.

3 Use of nanomaterials in the food sector

3.1 Opportunities

There are several opportunities to improve the quality and durability of food products by the use of engineered nanomaterials. In several publications it is described that nanoscale additives may change consistency, taste and colour of foodstuff or that undesired aromas can be masked. Furthermore, the use of encapsulation techniques based on nanomaterials in food may increase the bioavailability of nutrients.[14]

Another potential use area of engineered nanomaterials are food supplements. Food supplements are defined as food stuffs, which complement the normal diet with concentrates of substances, frequently vitamins or minerals, which are favourable to human health. Food supplements are offered in different forms (tablets, powders etc.). Nanomaterials may either be the constitutional substance to be provided or could be used to encapsulate one, to make it more bioavailable to the body.

A third application area of engineered nanomaterials is the optimization of food packaging. Whereas consumers could benefit from the resulting increased shelf-life of food, the benefits for food packaging producers could be savings of materials and resources.

[13] COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food; COMMISSION DIRECTIVE 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs; COMMISSION REGULATION (EC) No 450/2009 of 29 May 2009on active and intelligent materials and articles intended to come into contact with food

[14] See for example Oehlke, K.; Greiner, R.: Nanomaterialien in Lebensmitteln und Lebensmittelverpackungen. Ernährung im Fokus 13.03.2004 or Bayrisches Landesamt für Gesundheit und Lebensmittelsicherheit: Nanomaterialien in Lebensmitteln und Verbraucherprodukten. 2012.

3.2 Products on the market

It is not known, which nanomaterial-containing food or food packaging materials are currently available on the European market. In the following, statements from different sources on the availability of respective products are compiled.

3.2.1 Report by the European Food Safety Agency (EFSA)

The EFSA has identified in their study[15] that the most frequent application of engineered nanomaterials in the food sector are uses in food packaging materials. Two examples are nano silver and nano zinkoxide, which are both used because of their antibacterial properties. In addition, nanomaterials are frequently used in food supplements (selenium, magnesium and calcium in their nanoforms).

Since no unified definition of the term nanomaterial was used in the EFSA's study, it is not clear which of the applications would be regarded as a use of engineered nanomaterials pursuant to the definition of a nanomaterial according to either the Commission recommendation or the regulation on food information. The authors of the study observed a trend towards an increased use of organic nanomaterials as encapsulation and carrier systems.

3.2.2 Study by TA Swiss

The TA Swiss carried out a market survey in 2009[16] and concluded the following: In Switzerland amorphous silica (E551) is used as an anticaking agent and carotinoids are used as colorants and health-promoting ingredients of food (food additives). The use of nanomaterials to encapsulate nutrients for improved bioavailability was also identified as relevant to the Swiss market. The study authors also identified several nanomaterial-containing types of food packaging, among others PET-bottles and composite films with improved gas permeation properties. The predominantly used nanomaterials in packaging were silica, aluminum and aluminum oxides as well as carbon and clays.

3.2.3 Databases

The Woodrow Wilson Centers database[17], which mainly covers the United States' market includes 117 nanomaterial-containing products in the section 'Food and Beverages'. Among the listed products are:

[15] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/621e.pdf

[16] Möller et.al.: Nanotechnologie im Bereich der Lebensmittel TA-SWISS (hrsg.) – Zentrum für Technologiefolgen-Abschätzung, 2009; verfügbar unter https://www.ta-swiss.ch/nanofood/

[17] Project on Emerging Nanotechnologies (2013). Consumer Products Inventory. Abgerufen am 15.08.2015 auf: http://www.nanotechproject.org/cpi. In dieser Datenbank w erden Produkte aufgenommen, für die der Gehalt an

- 15 kitchen products (anti-stick pans, antibacterial cutting boards etc.);
- 7 foodstuffs;
- 20 materials intended to come into contact with food, mainly packaging and refrigerators;
- 69 food supplements.

The database[18] by Friends of the Earth Germany (BUND) contains 26 entries on food supplements and 5 entries on packaging and food containers.

3.2.4 Statements of individual actors

The Federal Institute for Risk Assessment (BfR) states on its website[19]:

> *"It is being reported that nanomaterials are used as auxiliaries and additives in foods. For instance, silicic acid and other silicon-containing compounds are said to be used as anticaking agents or thickeners to prevent table salt crystals and powder-form foods from sticking together and to make ketchup pour more easily. Silicic acid is also used as a flocculant in wine and fruit juice production. It is not yet clear whether silicic acid is actually used as a nanomaterial.*
>
> *Nanomaterials are also allegedly used specifically as food supplements. There are reports of the use of inorganic materials such as silicon dioxide, colloidal silver, calcium and magnesium in nanoparticle form. It is not clear whether these materials are present in foods as nanoparticles or in aggregate form. The food industry is currently developing functional foods in which vitamins, omega 3 fatty acids, phytosterols and aromas are enclosed in nanocapsules made of organic materials such as liposomes and then released at a specific spot in the body."*

The Bund für Lebensmittelkunde und Lebensmittelrecht e.V. states in its report and position paper "Nanotechnologies in the food sector"[20]:

Nanomaterialien durch den Hersteller explizit ausgelobt w ird und dies als plausibel erscheint. Ob tatsächlich Nanomaterialien enthalten sind, w ird nicht geprüft.

[18] http://www.bund.net/nc/themen_und_projekte/nanotechnologie/nanoprodukt datenbank/produktsuche/; in this database products are identified as 'nano products' based on their producers' information.

[19] http://www.bfr.bund.de/de/fragen_und_antworten_zur_nanotechnologie-8552.html#topic_131548

[20] BLL: Sachstands- und Positionspapier "Nanotechnologien im Lebensmittelbereich". Dezember 2009; available at www.bll.de/download/sachstand-nanotechnologie.pdf

> *"It is possible to use nanotechnologies in the food sector and in materials intended to come into contact with food and to create benefits for consumers and producers. At present, no such food is available on the EU market."*

In his presentation at the expert dialogue on nanotechnologies in the food sector[21], Prof. Dr. Greiner of the Max Rubner Institute stated that only few of the products, for which a nanomaterial content was claimed by their producers actually did contain nanomaterials. In addition, only few authorisation applications for engineered nanomaterials in packaging materials would exist in the EU. At a conference of the Fresenius-Akademie[22] he mentioned that appropriately 1000 enterprises are assumed to currently be working on the development of nanomaterials for the food sector. However, most of these would be located outside the EU.

None of the actors at the expert dialogue was aware of any food product containing an ingredient labelled as '(nano)' on the ingredient list.

3.2.5 Conclusions on the market situation

It is not possible to conclude on the overall nanomaterials market in the food industries due to the various, partly contradictory, information on the types of nanomaterial and their use in different product types.

It is common and confirmed knowledge that several food additives are used in food for a long time, for example the anticaking agent amorphous silica. Amorphous silica was a prominent example of the use of nanomaterials in food in stakeholder discussions the past. However, at present there are different opinions on whether or not it is a nanomaterial in accordance with the definition of a nanomaterial in the regulation on food information. Since the food producers feel that amorphous silica does not fulfil the criteria of a nanomaterial according to the legal definition, its content in food is not labelled. This irritates consumers and was identified as one of the reasons for lacking transparency on the presence of nanomaterial in food products at the expert dialogue.

Some producers explicitly mention the presence of nanomaterials in food supplements[23]. In these cases, consumers are well informed and can make an informed choice on whether or not to buy the product. However, a comprehensive overview of the uses of nanomaterials in food supplements in general is missing.

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[21] Prof. Dr. Ralf Greiner: Nanomaterialien in Lebensmittelverpackungen: Anwendungsbereiche und Chancen; Vortrag beim FachDialog 4 zur Anwendung von Nanomaterialien im Lebensmittelbereich; available at:http://www.oekopol.de/wp-content/uploads/12_Greiner_Anwendung-in-Verpackungen.pdf

[22] http://www.akademie-fresenius.de/presse/info.php?page=930

[23] This can be concluded from the fact that these products are identified in the databases.

Several possible applications of nanomaterials in food packaging are described in literature. An analysis of packaging stated to contain nanomaterials carried out by an authority showed that only a small share of these actually contains nanomaterials. Furthermore, few authorisations exist for the use of nanomaterials in food packaging.

An improved transparency of the market would be useful from the perspective of a better informed public, as well as improved conditions for market surveillance and regulation.

4 Possible environmental risks

Environmental risks from nanomaterials contained (as additives) in food stuffs, present in food supplements or included in food packaging could in principle occur if the nanomaterials:

- have properties which render them hazardous for the environment, for example low biodegradability (persistence) or tendency to accumulate in organisms (bioaccumulation) or toxicity for water ecosystems (aquatic toxicity) AND
- are released from these products into the environment and are present in the environmental compartments in relevant concentrations (exposure).

The assessment of environmental risks entails modelling or measuring the environmental concentration(s) of a nanomaterial, e.g. in water (lakes, rivers) and comparison to its effect threshold identified from toxicity testing. The effect threshold is the concentration or dose of a substance above which effects can be observed on the well-being of an organism. If the environmental concentration of a nanomaterial exceeds its effect threshold, a risk to the environment is identified.

4.1 Environmental hazards

A nanomaterial's environmentally hazardous properties have to be identified separately for each substance. It may, however be possible to conclude on its environmentally hazardous properties from respective information on the bulk material or structurally similar nanomaterials.

Nanomaterials have to be registered in accordance with the European chemical legislation REACH, which includes the identification of its hazardous properties. Therefore, for all registered substances basic information on the hazardous properties should be available. However, the number and type of properties to be

identified increases with increasing registration volumes of the substance / nanomaterial[24].

If nanomaterials are intended for use only in food products, they do not have to be registered under REACH (exemption). Furthermore, substances manufactured or imported in amounts below 1 tonne per year and registrant do not have to be registered either. Consequently, in both cases no information on hazardous properties is generated under REACH.

According to food legislation, the use of nanomaterials in the food sector has to be authorized, if the nanomaterial:

a) is used as food additive;

b) fulfils the criteria of a 'novel food' or

c) is used in plastics, celluloid foils or 'intelligent packaging' used as food packaging materials.

For the use of nanomaterials in food supplements notifying the national relevant authority is sufficient.

The assessment for an authorisation of a nanomaterials' use(s) in food or food packaging focuses on its innoxiousness for human health and the purpose of use. For uses in food packaging, limits for the migration from the packaging to the food have to be complied with.

The nanomaterials' environmental hazardousness is not assessed in the frame of the authorisation procedures and therefore, no respective data are generated. Consequently, no legal requirements exist to identify a nanomaterials environmental hazards if it is only used in food or if it needs not be registered under REACH due to low market volumes.

According to EFSA's study[15] on the use of nanomaterials in the food sector, information on the environmental hazards of many nanomaterials are missing, in particular for the long term effects.

4.2 Environmental exposure

Environmental releases of nanomaterials from food and food packaging could occur:

- from preparing nanomaterial-containing food (e.g. cooking water being discharged, evaporation during cooking);

[24] Hence, for substances registered in small volumes only basic information is available on hazardous properties, i.e. mainly on the acute toxicity.

- due to the excretion of nanomaterials ingested with the food and discharge with household wastewater;
- during disposal of food waste and packaging waste.

Respective exposure information, e.g. if and to which extent nanomaterials are released from food and food packaging, if they are metabolised in the human body or if they lose their nanoform are currently not available. However, there are studies and analyses on some of these aspects, e.g. the behaviour of specific substances in the stomach and digestive system.

The release of nanomaterials from wastes has been researched in a number of studies, which are summarised among others in the report on the 'Expert Dialogue on Nanomaterials and Waste'[25]. The most relevant information on the possible environmental release of nanomaterials from wastes are introduced in the following with regard to food waste and food packaging waste.

Food waste and food packaging waste is normally not landfilled due to its high organic content. Therefore, no release is to be expected from landfills.

The behaviour of nanomaterials in biological waste treatment plants (composting) is not researched according to current knowledge. There are also no specific models to predict emissions from this type of waste treatment. Therefore, it is not possible to conclude on possible emissions of nanomaterials from food and food packaging waste in composting installations.

In thermal treatment plants nanomaterials contained in food and food packaging waste is likely to be retained in filters, ashes and slags according to different studies, hence resulting in low environmental emissions. However, nanomaterials could influence the formation and destruction of other substances in the thermal treatment plants.

Nanomaterials could be released to wastewater from food either directly or from human excretions and could reach sewage treatment plants. According to the current state of knowledge, sewage treatment plants retain a large share of nanomaterials contained in the incoming wastewater. A release could occur if sewage sludge is used in agriculture and from nanomaterials not being held back in the sewage treatment plants and being discharges with its effluents.

In summary, based on the available information it cannot be judged if releases of nanomaterials from the waste stage of food or food packaging is a relevant source of environmental emissions and risks.

[25] http://www.bmub.bund.de/fileadmin/Daten_BMU/Download_PDF/Nanotechnologie/nanodialog_4_fd3_bericht_bf.pdf

4.3 Conclusions on environmental risks

Environmental risks from nanomaterials only used in food are not identified under REACH or in food-related authorisations. Environmental hazards of nanomaterials intended for use in packaging materials are assessed under REACH and their risks are assessed, if a chemical safety assessment is required.

It is currently not possible to make a general statement on whether or not environmental risks could occur from the use of nanomaterials in food and food packaging materials due to a lack of basic information. In general, data is missing on environmental hazards, the use in products, environmental releases as well as the behaviour of nanomaterials in food production, the human body, the environment and during waste treatment.

5 Results of the expert dialogue on nanotechnologies in the food sector

At the expert dialogue on nanomaterials in the food sector approximately 40 actors from different interest groups discussed opportunities and possible risks of the use of engineered nanomaterials in food and food packaging.

There was a broad consensus that the current regulatory situation regarding the definition(s) of engineered nanomaterials is dissatisfying. The use of undetermined legal terms, the different interpretations of the definition(s) and the challenges to operationalise the definition in terms of analytics lead to difficulties and inconsistencies with regard to:

- the implementation of the legal requirements by the market actors;
- the enforcement of the requirements by the authorities;
- the labelling of products and
- the communication with the public.

It could not be clarified at the expert dialogue if and to which extent engineered nanomaterials are placed on the market as ingredient in food and food supplements or as component in food packaging. It was concluded that there is different information on the market relevance of engineered nanomaterials and that no labelled products exist on the market. The lack of transparency was viewed as one of the reasons for the public's loss of confidence in the food sector by some of the participants.

Most actors agreed that the labelling '(nano)' is frequently misunderstood as a warning. Some participants, among others the environmental and consumer organisations as well as representatives from academia, encouraged the food industry to more openly and actively communicate about the benefits of the use of engineered nanomaterials, to prove their safety and to provide easily understandable information. This would enable the general public to better interpret the labelling '(nano)'. In addition, the interpretation of the labelling rules should be aligned with the authorities' understanding and explained to the general public.

The participants at the expert dialogue also concluded that standardised and practically applicable analytical methods for the enforcement of the legal requirements are missing. These methods should be developed to make regulations enforceable. In addition, they prompted the legislators to clarify how the food regulation's definition of a 'nanomaterial' is to be interpreted.

It also became evident at the expert dialogue that the understanding of risks and opportunities of engineered nanomaterials (in the food sector) is still rather undifferentiated among consumers and the food retail sector. This was perceived as noticeable in particular because of the very differentiated and long-lasting stakeholder dialogue on nanotechnologies.

The intense and partly controversial discussion at the expert dialogue on the different aspects of the use of engineered nanomaterials in the food sector, such as the definition, analytics, labelling, general and specific communication on benefits and risks as well as environmental and health issues proved to be important for all actors and should be continued, if possible.

6 Conclusions and recommendations

The use of engineered nanomaterials in the food sector may have different benefits for human health and the environment, for example through saving resources or prolonging the products' shelf-life. Further benefits could be generated from efficiency gains in the production processes of food and food packaging.

Inconsistencies in the wording of various definitions of nanomaterials at the EU level are among the reasons for different opinions on whether or not some substances in food should be regarded as nanomaterials and hence be labelled. Uncertainties in the interpretation of the definition as well as the lack of analytical methods also contribute to difficulties in the enforcement of the labelling of nanomaterials.

There is no confirmed information on the presence of nanomaterials in food and food packaging on the market and respective stakeholder statements are contradictory.

At the expert dialog on nanotechnologies in the food sector it was concluded, among others, that communication on the presence of and the potential benefits and potential risks from nanomaterials in food and food packaging should be improved. The partly contradicting information from stakeholders and the lack of information on benefits from the use of nanomaterials in food and food packaging would weaken consumer confidence.

As for other topics discussed in the NanoDiaologue, it was stated that (environmental) risk assessments are hardly possible due to a lack of information on the nanomaterials' concrete applications, use amounts and releases. Regulations in the food sector do not require environmental risk assessments and substances (including nanomaterials) do not have to be registered under REACH for the use in food. However, human health risks should not result from nanomaterials in food and food packaging due to the general obligation of food producers to only place safe products on the market.

The following recommendations can be derived from the expert dialogue:

- An unambiguous definition of the term 'nanomaterial' is necessary for the implementation and enforcement of the legal requirements in the food sector. The EU Commission should present a respective clarification.
- Harmonised procedures and guidelines should be developed to support the enforcement of legal requirements, in particular of the labelling obligation. These procedures and guidelines should be developed in cooperation with the actors of the food sector.
- Standardised analytical methods as well as procedures for sample preparation are not available, making the control of legal obligations in the food sector impossible. They should be researched and developed taking into account the EU definition as well as the specific matrix 'food'.
- The Federal States and the enforcement authorities should provide the necessary resources for the enforcement of legislation. This includes the capacities and equipment of laboratories.
- The market actors should strive for more transparency on the applications of nanomaterials in the food sector to maintain or regain consumer trust. This includes the communication on potential benefits and risks of the use of nanomaterials in food and food packaging.
- Information, in particular on the use of nanomaterials and their releases are missing and therefore, potential environmental risks from nanomaterials in food and food packaging cannot be estimated. Pilot projects on specific,

environmentally hazardous nanomaterials could give a preliminary evaluation on the need to conduct more comprehensive specific or general risk assessments. Such pilot projects could be launched, for example in the frame of the environmental research programme of the German Government.

- The discussions of stakeholders on the use of nanomaterials in food and food packaging should be continued.