NanoDialog
der Bundesregierung

Expert Dialogue 4: Use of nanomaterials in products - opportunities and potential risks: for the food sector

Summary of the expert dialogue 4

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Content

1 Introduction

The use of engineered nanomaterials in food has not been discussed in much detail at the NanoDialogue of the German government so far[1], although this application is of particular interest to the public due to the potential exposure of humans and the environment.

Since December 2014, in accordance with the EU Food Information Regulation (LMIV)[2], engineered nanomaterials are to be labelled as such in the list of ingredients with ‘nano’ in parenthesis if they are an ingredient in foods. Since the labelling requirement is publicly known, but there are currently no foods labelled ‘(nano)’ on the market, it raises the question from the consumer’s point of view if nano products are really on the market or whether the labelling requirements have not yet been fully implemented.

There is a variety of potential applications of engineered nanomaterials of in foods:

- Nano-encapsulations could be used to better dissolve substances in food (e.g. fat-soluble dyes in an aqueous environment), to distribute or to stabilize them. Micelles as well as liposomes and vesicles or complexes could be suitable candidates. Polymeric particles are also currently being discussed as ‘nano-transporters’.
- Engineered nanomaterials could be used as food additives by means of their food characteristics, e.g. consistency, taste, shelf life, the colour or the pourability change.
- In the food sector with increased health benefits ("nutraceuticals") engineered nanomaterials are considered as an opportunity to increase the bioavailability of health-promoting substances.

Nanomaterials are used in food packaging, among others in hopes of saving material, extend the shelf life of the product, decrease the interchange of gas or to increase the mechanical stability.

At the expert dialogue ‘Application of nanomaterials in products - opportunities and potential risks: for the food sector’ 40 representatives from business, government, civil society organizations and the scientific community discussed the potential opportunities and risks of using engineered nanomaterials in the food sector. The

[1] The subject was addressed in a working group of the NanoCommission on regulations. Since the discussions about revising the regulations on novel food were ongoing at this time and there were different perceptions of the regulatory situation within the working group, the status of the debates and consensuses, and disagreements were documented in the report.

[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

contents of the lectures and the main discussion points of the event are summarized in this report.

2 Content from the lectures

In the following chapters the main lecture contents are presented as well as some of the discussion sessions subsequent to each talk. These summaries reflect solely the speaker's opinions. They do not reflect any consensus of the participants for each of the topics presented. The participants' discussions and views at the expert dialogue will be described in Chapter 3. Most of the speeches are available on the internet.

2.1 Definition of nanomaterials in the food sector

2.1.1 Implementation of the definition recommendation of the EU Commission[3]

The EU Commission's recommendation on the definition of a nanomaterial was published with the document 2011/696/EU. The European Commission has made further comments in Appendix 1 of the Staff Working Document SWD (2012) 288th. It was explained in the lecture that the toxicological aspects in the development of the definition of a nanomaterial were not taken into consideration. The definition only classifies according to particle size and is not based on hazards or risk assessment – as pointed out by the EU Commission.

The criteria of the definition are:

- the size of a material,
- the particle size distribution and
- aggregates und agglomerates.

Based on experience in safety research Dr. Klockner stated that there is an increasing general understanding of what data is required for the risk assessment of a nanomaterial.

In the presentation a hierarchical approach was proposed to clarify what legal consequences arise if a substance falls under the definition of nanomaterial. According to this the status of 'nanomaterial' would be defined under REACH. Legal requirements beyond those coded by REACH could be coded in specific sectoral regulations - where necessary.

[3] Presentaion from Dr. Klockner, VCI

2.1.2 The German Federation of Food Law and Food Science (BLL) information on the labelling of nano ingredients[4]

In its decision-making tool[5] the German Federation of Food Law and Food Science (BLL) depicts the definition of engineered nanomaterials in LMIV[6] for its association members. It also provides a decision tree of the labelling to ensure a uniform interpretation and implementation of food industry's legal provisions.

The BLL sees problems with the metrological implementation of the legal requirements and expects that future adjustments of the nanomaterial definition are made in the LMIV which are intended, among other things to overcome these difficulties.

2.1.3 Nano-analytics in Food – State of the Art, difficulties and perspectives[7]

To identify and quantify nanomaterials, the size and the particle size distribution of the nanomaterial, their shape as well as their chemical composition must be analysed. It was explained that in order to check whether a substance is a nanomaterial, different measurement and evaluation methods must be combined, since none of the methods currently available cover the entire range of sizes of nanomaterials.

Every measurement method has specific limitations which are to be taken into consideration when choosing the procedure. The operating principles of the most important available methods are electron microscopy, light scattering, size-dependent separation of substances and/or mass spectroscopy. Both the measurement method, as well as sample preparation used to extract the substances to be measured from the (food) matrix can affect the particle size distribution.[8]

2.1.4 Food monitoring assessment[9]

The monitoring of the mandatory labelling of engineered nanomaterials in food by the authorities makes it necessary to interpret the legally binding definition of the term

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[4] Lecture: Dr. Stähle, BLL

[5] The decision-making tool is currently not available to the public.

[6] The definition given refers to a later version of the definitions, which is covered in the draft of a delegated regulation 1363/2013 from 12.12.2013.

[7] Lecture: Dr. Winterhalter, Bavarian State Office for Health and Food Safety

[8] For example, the particle radius measured (geometric or hydrodynamic diameter or radius of gyration) depends on the method used. The respective measurement results changes because either more, or less particles are smaller than 100 nm. Regarding the influence of sampling preparation on the measurement results, various methods for sample homogenization were shown in studies, so that the particle size distribution changes.

[9] Lecture: Dr. Preuß, LAVES - Food and Veterinary Institute Oldenburg Oldenburg

'nanomaterial' of the LMIV on concrete applications, respectively products, and to prove compliance with or a breach of the legal requirements. From the speaker's perspective this is not possible, for one due to the unclear nanomaterial definition in LMIV, which for example results from the undefined terms 'magnitude' or 'through the nanoscale-related properties'. On the other hand there are standardized and validated analytical detection methods still missing that provide comparable results. In addition, the 100% reference value for the obligatory labelling of nanomaterials if over 50% fall under the planned definition of the term nanomaterials in the LMIV (SANCO / 11478/2014) has not been defined. Therefore, it is currently not possible to officially monitor the legal requirements.

2.2 Application of nanomaterials

2.2.1 EFSA Report: Inventory of Nanotechnological Applications[10] in Agriculture, and Foods and Feedstuffs

On behalf of the European Agency for Food Safety (EFSA), the Joint Research Centre (JRC) of the European Commission and the Netherlands Institute for Food Safety (RIKILT) carried out a study on the current and planned applications of nanomaterials in the areas of agriculture, food and feedstuff. In the course of the study about 650 literature references (2005 - 2015) were evaluated, company websites were analysed and companies were interviewed. During the survey no uniform definition for nanomaterials was used as the EU Commission's recommendation for the definition of 'nanomaterial' was first published in October 2011.[11]

The analysis shows that nano-encapsulations, nanosilver and nano-titanium dioxide[12] are the most commonly used materials. However, a trend to increase the use of organic nanomaterials can be observed. Most applications of nanomaterials are packaged and labelled as additives to enhance the taste and texture as well as increase the solubility and bioavailability of ingredients. According to the study, data about (environmental) toxicity, particularly for nanomaterials rarely used is often missing, especially about the long term effects.

After the lecture, it was determined that no conclusions could be made from the report about the extent to which the applications described represent engineered nanomaterials in terms of Food Law because no uniform definition was used for nanomaterials.

[10] Lecture: Dr. Rauscher, European Commission – Joint Research Center

[11] When the authors of the bibliographical references identify the substances as nanomaterials and the authors of the EFSA report found these to be creditable, then the materials were regarded as 'nano'.

[12] 'Nano-titanium dioxides' does not comply with 'E 171' and is therefore not approved as a food additive in the EU.

2.2.2 Application of nanomaterials in packaging[13]

The presentation showed that nanomaterials are used in food packaging, among other things, to increase their barrier effect (to reduce the gas exchange with the environment), or to extend the shelf life of the packaged food as well as to save material. Hence, different materials could be used, for example nanoscale titanium dioxide and silicon dioxide or composites with nanoclay. In multi-layer food packaging, the vapour-deposited layers (e.g. aluminium) can be nanoscale due to their low layer thickness. Nanosilver and nanozinkoxide could provide protection against bacterial infestation; however they are not approved for this application. Some information about the release of nanomaterials from polymers is available in the migration studies carried out by the Fraunhofer Institute (s. Chapter 3.3.2).

The Max Rubner Institute noted that few products they investigated contain nanosilver particles as stated by the manufacturer. Additionally, there are only a few applications for approval for synthetic nanomaterials in packaging materials within the EU.

2.2.3 Nanocrystals and lipid nanoparticles in food and nutraceuticals[14]

In the presentation several products were introduced in the area of cosmetics and dietary supplements that contain nanomaterials. The applications in food supplements are in the experimental stage and are not yet available on the market. Basically, materials whose components are greater100 nm[15], biodegradable and at best nature-identical are used in both applications. The benefits of nanomaterials in the products are stabilization and improvement of the bioavailability of health-promoting substances.

The presented materials were nano-encapsulations from nature-identical lipids, nanocrystals from vitamins and nutrients, which should be absorbed with the nutraceuticals and nanoporous structures containing these substances. Future areas of application could be a dietary supplement in pills and capsules, or added to beverages.

In the discussion session after the lecture it was debated if the featured applications, particularly due to the higher bioavailability of the substances in question, could be considered as subject to approval as novel foods or even drugs. This was not completely clarified.

[13] Lecture: Prof. Dr. Herrn Greiner, Max Rubner Institute

[14] Lecture: Prof. Dr. Keck, Fachhochschule Kaiserslautern and Prof. Dr. Rainer Müller, Freie Universität Berlin

[15] Materials that are bigger than 100 nm are also recognized as nanomaterials by the participating research institutes.

2.3 Communication about nanomaterials

2.3.1 Consumer communication and dialogue[16]

One of the main messages of the presentation was that transparent communication about the application of engineered nanomaterials in the food sector creates trust in product safety and can contribute to an innovation promoting market environment. Particularly, the display of possible product benefits is currently missing in the public presentation by the players of the food industry.

From the speaker's point of view, increasing consumer mistrust will become ever more probable, respectively a loss of positive interest and knowledge of the applications of nanotechnologies, without target group geared multi-step communication that clearly goes beyond just a '(nano)' labelling. The companies would thus lose their market potential.

Various studies show that consumer knowledge about nanotechnologies in all application areas is decreasing[17]. Possible approaches for consumer-oriented communication have already been compiled in various dialogue processes[18] and published.

2.3.2 Assessments from the perspective of the food industry [19]

The food trading company 'tegut' has the business philosophy of offering its customers good, health-promoting products and advocate making well-informed buying decisions through transparent communication about the ingredients and the processing procedure. This is ensured, among others by carrying out supplier surveys regularly as well as analyzing the benefits and risks of using nanotechnologies. From the trading company's perspective, the use of nanotechnology in food is questionable because it is still unclear if risks exist, (lack of toxicity studies, mobility, behaviour in the body, effects on the environment, etc.).

[16] Letcure: Dr. Grobe, DIALOG BASIS / Stuttgart Research Center for Interdisciplinary Risk and Innovation Studies, University of Stuttgart (ZIRIUS)

[17] For example the studies 'Nanotechnologien aus der Sicht von Konsumenten' and ‚Nanoview Einflussfaktoren auf die Wahrnehmung der Nanotechnologien und zielgruppenspezifische Risikokommunikationsstrategien'

[18] For example the Nanodialogplattform of the BAG or the Dialogforum Nano of BASF

[19] Lecture: Mr. Würz, tegut

2.4 Risk Assessment

2.4.1 Silica in foods – results from the analytics and research need[20]

Nanoscale silica was used as an example to show the challenges in the evaluation of nanomaterials in the body. In particular, the complexity of the digestive processes and the potential impact on the presence of nanoscale particles were made clear.

Regarding nanoscale silica an uptake in the cells was detected. A toxic or mutagenic potential was not observed. However, there was a growth-promoting effect. Simulation studies indicate that nanosilica ingested with food is still present in the intestine. There are uncertainties about the influence of silica on the intestinal flora, possible interactions with other substances in the intestine as well as the bioavailability, especially in cases where impairments of the digestive tract are present (chronic diseases, celiac disease, etc.).

2.4.2 Consumer exposure to nanomaterials in food contact materials [21]

It was explained that nanomaterials can be released from packaging materials by diffusion, desorption and dissolution or through degradation of the matrix as in the example of polymer composites. Substances can penetrate (gas exchange) the packaging material from the inside and from the outside, drift inward or outward from the packaging material, or accumulate on the packaging from the food. These processes can lead to the spoilage of food or other loss of quality, for example in a change of taste and appearance of the food, among other things.

The release of nanomaterials is measured with ‘migration cells’ at the Federal Institute for Risk Assessment. Methods to determine migration in complex matrices are missing as well as reference materials. According to the speaker, the existing exposure models for the evaluation of food contact materials are, in essence applicable, but not validated and adapted for nanomaterials. Appropriate research and development is required here.

3 Main aspects of the discussions

In the following chapters the main contents of the discussions at the expert dialogue are summarized. The discussion key points are divided into the topics ‘definition of nanomaterials’, ‘knowledge about the use of nanomaterials in the food sector’, ‘risk assessment’ as well as ‘communication’.

[20] Lecture: Prof. Dr. Marko, Universität Wien.

[21] Lecture: Dr. Tentschert, Federal Institute for Risk Assessment (BfR)

3.1 Definitions of nanomaterials

In the following the definition of the term 'nanomaterial' of the LMIV as well as the EU cosmetic regulations, will initially be quoted because versatile discussions emerged from this term at the expert dialogue.

3.1.1 Background

In Article 2 t) of the LMIV the following definition for engineered nanomaterials can be found:

> *'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;"*

As part of the revision of the regulation on novel foods the possibilities of revising this definition will be discussed.

At the Expert dialogue, reference was also made to the definition of nanomaterials in the EU Cosmetics Regulation, because the same substances are partly used in food and in cosmetics. A mandatory labelling requirement exits in both of these regulations. The definition in the EU Cosmetics Regulation in Article 2(1)k is as follows:

> *"Nanomaterial" means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nanometers;"*

Contrary to both of the quoted definitions, the EU Commission's recommendation also includes nanomaterials which are not intentionally technically produced.

The criteria of the definitions also differ further, inter alia, whether a threshold of 50% is given for the particle size distribution, or if certain nano-specific properties must be present.

These differences can be explained, inter alia, because the LMIV and the EU Cosmetics Regulation were adopted before the recommendation of the European Commission. With the revision of the definition of engineered nanomaterials in LMIV within the framework of the revision of the regulation on novel foods, the EU Commission's recommendation can now be considered.

3.1.2 Assessment of the situation

The participants at the expert dialogue agreed that the Commission's recommendation of a definition of the term ‘nanomaterial’ is merely limited to which substances, based on the size or smallness of the components, can be recognized as nanomaterials and therefore be regulated where necessary. It was stressed that classification of whether a material is called a nanomaterial, apart from the size, does not say anything about the characteristics it has – including if the nanomaterial is associated with a risk.

At the expert dialogue it was agreed that not only the differences in the statutory definitions, but also the different interpretations of the actors due to unclear parts of the definition (e.g. ‘intentionally manufactured’, ‘nano-specific characteristics’) as well as the current lack of a metrological examination of the definitions, can lead to different assessments of what is an engineered nanomaterial is. As a result, ambiguities and inconsistencies would occur in the implementation of legal requirements, for example the labelling requirement. During the discussion it also became clear that the various objectives that follow the individual legal areas can require differences in the definitions.

Since the LMIV contains the above mentioned vague legal terms and definition is currently not metrologically verifiable, it was justifiable for most players that there is currently no official monitoring of mandatory labelling. However, the necessity to realize clarifications and to agree on a metrologically workable method, respectively a detailed technical guideline to be developed in order ensures a unified implementation was strongly noted.

In view of the necessary analytics it was critically noted that so far only a few federal states have appropriate laboratory equipment available. Even if the laboratories of the state authorities were specialized, it would be unclear when the capacity for routine checking of products could be created.

3.1.3 Proposal for dealing with the definitions

Various approaches were proposed and discussed on how the situation related to the definition(s) of nanomaterial could be dealt with.

Hierarchical Definition

According to this approach a nanomaterial definition would be determined based on the Commission's recommendation, whether a substance or a substance form is a nanomaterial or not. For nanomaterials under REACH certain data and assessment requirements would take effect. The nanomaterial sub-group(s) for which specific requirements should apply could be completely materialized based on risk-related criteria[22] in food-related (and other) regulations.

The advantages to this approach mentioned are that it is already partially established and the nanomaterials would be limited by a potential risk in regards to the specific regulatory concerns. In this approach the inconsistencies between the definitions of various regulations would remain in the future.

Focus on existing problems

Instead of further work on a generally applicable regulatory definition, concrete regulations for well known, problematic nanomaterials as well as for nanomaterials with specific, problematic properties already identified could be created.

It was pointed out that one advantage of this strategy was that the existing available resources can be concentrated on the defence of existing dangers. The players saw a disadvantage of this approach in that the precautionary principle is not consistently implemented and potential risks could possibly be overlooked. The difficulties with the existing definitions remain.

Change of control

Given the difficulties in the detection of nanomaterials in products, it was proposed not to have controls on the finished product, but rather along the supply chain and exactly among the actors who know whether they deal with a nanomaterial. This requires transparent communication in the supply chain as well as other control strategies of the authorities.

A benefit mentioned to this approach was that the control can ensue with the actors and thus a complex analysis could be omitted. Strong concerns regarding the

[22] Whether the criteria for a nanomaterial from the product-related regulations should then be removed or not w as not discussed. This w ould be logical for this approach.

availability of information of imported products have been expressed. The difficulties of the interpretation of existing definitions also remained.

Some actors expressed fundamental doubts about whether it is even possible to find a definition of the term 'nanomaterial' that is satisfying for all actors and objectives. From the occupational health perspective it was reported, that for example based on available and reliable studies, there is no need for a regulatory definition of nanomaterials, since the associated risks have already been addressed adequately by the existing regulations. The nanomaterials must therefore be evaluated according to their type of hazard and be regulated (e.g. hazard by inhaling).

No concrete information about any further action by the EU Commission in revising its definition recommendation was known.

3.2 Market transparency about the use of nanomaterials in the food sector

3.2.1 State of knowledge

During the discussion it became increasingly clear that although (market) transparency is talked about more and more, appropriate studies and surveys are carried out as well as databases are set up, and mandatory labelling were introduced, it is still unclear if and which engineered nanomaterials were actually used in what products and placed on the market.

In the discussion about the results of the study (see Section 2.2.1) commissioned by EFSA it was determined that no adjustment comparison was made to the information in the approval procedure in the food sector. In addition, since information of the possible use of nanomaterials from the REACH registration was not taken into account important application data is missing in the survey, according to some of the actors.

Since different nanomaterial definitions have been used as a basis in the study and as measurement problems exists in the nanomaterial determination (see, inter alia, Chapter 2.1.3 and 2.1.4), it is ultimately unclear which of the applications in accordance with the definition in LMIV are actually to be considered as engineered nanomaterial.

3.2.2 Market perception

Among others, representatives of consumer and environmental protection associations as well as food trade representatives noted that so far no '(nano)' labelled products on the market are known. The Max Rubner Institute confirmed in

the lecture that only a few of the packaging materials which have been investigated to date contained nanomaterials. This is even the case if the packaging material was labelled as containing nanomaterial.

The manufacturers of plastic packaging reported that nanomaterials were not used to a significant extent. However, at the same time it was noted that the production and stability of various plastics is not possible without adding nanomaterials (such as reinforcing fillers).

Some economic actors added that in the value chain of the food industry, the use of engineered nanomaterials via a delivery contract or quality requirement is often ruled out because a low acceptance by the consumers is expected. Therefore, research activities of the companies on the use of nanomaterials in food, among others were de-prioritized or even stopped.

According to some stakeholders, the biggest opportunities for manufacturers to use engineered nanomaterials in the food sector are in food packaging and in products that have a benefit in health promotion. Part of the civil society organizations categorically doubted the benefits of the latter products. However, all organizations also acknowledged that consumers of this product group generally have a higher acceptance and therefore must be ensured that the content of nanomaterials is safe.

3.2.3 Market transparency assessment

Various actors stated that engineered nanomaterials in the food sector are hardly ever used but this contradicts the benefits and potentials of nanotechnology described in the past, as well as the information that certain nanomaterials are actually contained in products on the market (for example, anticaking agents and nanomaterials in plastic bottles).

The participants at the expert dialogue felt that a reason for the discrepancy between the verifiable nanomaterial-containing products expected on the market and those existing, were the inconsistencies associated with the nanomaterial definitions at different levels, beginning with the EU recommendation up to the application-specific regulations. This refers to, among others the unclear defined terms (e.g. ‘engineered nanomaterial’) as well as the use of substances. Even though they are the size of nanomaterials they have no explicit nanoproperties. Additionally, many materials are used, which are somewhat bigger than 100 nm, or are only nanostructured. These do not fall within the definition of nanomaterial of food applications, but exhibit nanoproperties, are perceived by the consumers as nanomaterials and are advertised accordingly in the supply chain. Some of the materials which are not currently labelled were known to the actors to be examples of nanomaterials (e.g. anti-caking agents in spices) in earlier discussions.

Most stakeholders evaluated the conflicting information on the actual use and marketing of nanomaterials as unsatisfactory. Some stakeholders expressed that a product register to the creation of market transparency and to support communication and monitoring would be helpful.

3.3 Risk assessment

3.3.1 Characterisation of engineered nanomaterials

In particular, the authorities pointed out that an adequate characterization of the material is necessary for a risk assessment of the use of engineered nanomaterials in the food sector[23], including a description of particle sizes. There are hardly any harmonized and validated methods and all players felt there was a need for further research.

The NanoDefine[24] project's goal is to work out analytical methods and standards for the determination of engineered nanomaterials. A database should be set up, for the identification of appropriate measurement methods for certain materials (in certain matrices). Further, concrete procedures and guidelines as well as new devices should be developed, in order to expand the method spectrum.

3.3.2 Migration studies

At the expert dialogue, it was reported that a Fraunhofer Institute migration study of various nanomaterials from polymers, which are used as food-contact materials, was carried out and the results thereof have been partially published. For the nanosilver, carbon black, synthetic amorphous silica, as well as mineral additives integrated into the polymer, the migration was below the detection limit. Model calculations indicate that only nanomaterials, which are smaller than 5 nm could migrate in polymers. Though, particles of this size would not exist in the food sector. However, applications in which nanomaterials are not integrated in the polymer, but rather used only on the surface, could show a higher migration rate.

3.3.3 Risk assessment within the framework of novel food[25]

Currently, a new draft regulation on novel food with the purpose of revising existing rules is making its way through the consultation process in Brussels. The now drafted compromise text clarifies that engineered nanomaterials are novel foods and therefore subject to the evaluation and authorization requirements, provided they are

[23] As in other applications and/or to decide if toxicity studies apply to a material.

[24] http://www.nanodefine.eu/

[25] The developments in the regulation area of novel food were suggested frequently at the FachDialog, although not in detail. The status of the discussion is summarized below.

not already used in other EU legislation's provisions – as for example in the case of food additives – including an authorization requirement.

The compromise text also contains a definition for engineered nanomaterials, which is identical to the corresponding definition of LMIV currently valid. The definition in the LMIV should be deleted and replaced by a reference to the definition in the regulation on novel foods. The Commission is granted the authorization to change this definition by means of a delegated act. It is likely that the Commission will present a corresponding legislative act shortly after approval of the compromise text because the definition in the LMIV is from 2011 and in needs to be revised.

3.4 Communication about nanomaterials in the food sector

3.4.1 Target groups and communication

According to various actors, general reliable and independent information about the opportunities and risks of using engineered nanomaterials should be open to the public and available to all citizens, particularly on consumer products.

It was noted that there are consumers who generally reject the use of engineered nanomaterials in the food sector. They see no need to optimize food or their packaging or just prefer to consume products as naturally as possible. Therefore, this group of people is particularly interested in reliable information about the presence or absence of engineered nanomaterials in food.

In addition, the participants found the group of consumers who are fundamentally interested in specifically modified food products (e.g. dietary products, health-promoting drinks or biodegradable packaging materials) and thus are inherently open to nanotechnology. These consumers are interested in information about the tangible benefits, as well as about the safety of products containing nanomaterials in order to make informed choices. According to the participants, this is exactly where the potential to communicate the possibilities of nanomaterial-containing products openly and actively.

3.4.2 Communication by means of labelling ingredients

Although the labelling requirement for engineered nanomaterials should only indicate the size of the components of an ingredient, many actors expressed concern that the general perception of a ‘(nano)’ label could be misunderstood to be warning. Further, the labelling of foods and cosmetics can be inconsistent due to the various definitions and their interpretations. Hence, according to many of the actors in the field the subject of nanomaterials in the food (and cosmetics) sector should be communicated beyond mere labelling.

In particular, consumer associations considered it an important task of the product manufacturers to explain to the consumers if, and where applicable which engineered nanomaterials for the production of foods and their packaging are used.

It was noted that the interpretation of the nanomaterial definition of the BLL is very slim and most (now and future) nanomaterials used would be exempt from the labelling requirement. In cooperation with other food labelling rules, this would mean that substances which in the past were cited in many discussions as examples of engineered nanomaterials in food (e.g. silicon dioxide[26], calcium carbonate, tricalcium phosphate in spice blends) will not be labelled. Consumers are confused about this since it was hardly explained. The contradictions in the communication are at least one reason that consumer confidence in nanotechnologies has decreased.

3.4.3 Communication and trust

Some actors stressed that the basis for confidence in the safety of products in the food industry, are the legal requirements and their implementation: the food regulatory accreditation process ensures safe products and there is a statutory obligation for the company to exercise diligence. Additionally, they should have an interest in securing market confidence, respectively gaining it.

Some participants at the expert dialogue felt that confidence in the statements concerning the safe use of engineered nanomaterials in the food sector arises, inter alia, when they do not contradict the statements and the main message of the various actors.

It was observed that direct dialogue led to significantly more nuanced communication of the stakeholders, and that compared to 10 years ago there is now a significantly improved level of mutual understanding.

4 Summary and Conclusions

At the expert dialog 4, titled "Use of nanomaterials in products - opportunities and potential risks: for the food sector ", approximately 40 actors from a variety of interest groups discussed the opportunities and the potential risks in using engineered nanomaterials in food – particularly in food additives and nutritional supplements as well as in food packaging.

There was a wide consensus that the current regulatory situation in relation to the definition(s) of engineered nanomaterials is not satisfactory for all actors. The use of

[26] In the “Statement for Synthetic Amorphous Silica regarding the definition of “engineered nanomaterials” for use in food in the European Union by the Association of Synthetic Amorphous Silica Producers (ASASP)“, the production association concluded that silica does not meet the criteria of nanomaterials, hence it is not a nanomaterial.

undefined legal terms, the different interpretations of the definition(s) and the challenges of a metrological operationalization still lead to difficulties and inconsistencies,

- in the implementation of the legal requirements by the market players,
- in the enforcement of the requirements by the responsible authority, as well as
- in product labelling and
- in communication with the public.

There was no uniform opinion of how to best deal with this problem.

At the end of the event it also remained unclear if and to what extent engineered nanomaterials are actually present in products from the food industry on the market because there are different statements regarding market relevance of engineered nanomaterials and there are currently no known products labelled.

Many actors, including environmental and consumer organizations are calling on the food industry to more openly and actively provide information about the presence of engineered nanomaterials in products in the food industry on the market. Some actors also suggested making the benefits of using engineered nanomaterials more transparent to prove the safety of products and to provide the consumers with clear information so that they can associate with the contents of the '(nano)' label.

The actors felt that to legally secure control of the legal requirements, standardized and applicable analytical methods have to be developed and the definition of 'nanomaterial' in the LMIV has to be clarified by the legislator.

During the expert dialogue, it also became clear that the understanding of the opportunities and potential risks of engineered nanomaterials (in the food industry) of the consumers, as well as the food retailer is still rather little differentiated. This was perceived by many participants in the context of long-standing and very different discussions, inter alia in the NanoDialogue, as conspicuous.

The intensive and partly controversial discussion has shown that a dialogue on the various aspects of the use of engineered nanomaterials in the food sector, such as the definition, analytics, labelling obligations, the general and specific communication on the benefits and risks as well as environmental and health aspects is important and useful to all actors and if possible should be continued.