Summary of the Consensus Discussion of the Scientific Experts Working Group Nanotechnology/Micelle Technology on 17th/18th April 2009

Participants:

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The working group welcomes the scientific opinion of the EFSA on "The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety" of February 2009 which was published in the EFSA Journal (2009) 958 1-39.

Based on pharmacological and toxicological aspects, questions arose which have to be considered during the processing of nanoscale particles in the food and feed sectors. Here, the EFSA mentions *engineered Nanomaterials* (ENMs). The conventional methods used in food technology, which have been established over decades, are not addressed in this paper.

The working group is therefore in full agreement with the following *supplementary and, above all, more precisely formulated* opinions from:

- BfR (Bundesamt für Risikobetrachtung [Federal Office for Risk Assessment])
- BLL (Bund für Lebensmittelrecht e.V. [Association for Food Regulation]), Bonn
- Hessisches Landeslabor Standort Kassel (Hessian State Laboratory location Kassel), Dr. P. Riehl
- American Chemistry Council

and assumes that with the term "ENMs" mentioned by the EFSA solid and inorganic particles or substances are involved which cannot be metabolised and which come under the Novel Food Directive 258/97 Art. 1/2. This directive controls the question of the approval of such substances and particles, also independently of the question of geometry.

1. BfR (Bundesamt für Risikobetrachtung [Federal Office for Risk Assessment]:

In its position paper "Selected Questions and Answers about Nanotechnology" of 9th September 2008 on the limitation of ENMs compared to conventional methods in food technology the BfR found:

"What is the link between liposomes, micelles or vesicula and nanotechnology?

Organic compounds like liposomes, micelles or vesicles are used in foods to encapsulate other substances like vitamins or flavourings, to transport them around the body and release them in a targeted manner. As the size of these "transport containers" is frequently in the nanometre range, they are also called nanocapsules. However, in contrast to inorganic, in-soluble nanoparticles, their nanoscalability does not lead to any new properties or, by extension, to any new biological effects. Hence, the use of nanoscale organic compounds is not classified as nanotechnology in the narrower sense by BfR. Organic substances like beta-cyclodextrin or polysorbates are frequently used for the capsule membrane. They are toxico-logically tested and assessed, and are approved as food additives (E 459 and E 432 up to E 436)."

2. Bund für Lebensmittelrecht e.V. (BLL, Association for Food Regulation), Bonn:

The BLL also confirms this in its factual and position paper "Nanotechnology in the Food Sector" of March 2008.

In this respect it says:

"The usual technologies in food processing which are based on the production of extremely small particles must be dealt with separately from the new nanomaterials. There are also ingredients of foodstuffs which are present in nature in the nanoscale form. In such cases however the use of new types of nanoscale materials is ***not*** *involved, but rather known foodstuff ingredients or substrates already known as foodstuffs (e.g. with starch and protein polymers) which are used with modified dimensions as required by the process. In this respect established technologies which have currently been used as safe methods in food production for decades, such as emulsification and homogenisation as well as methods based on colloidal properties with particle sizes in the nanoscale range are correctly* ***not*** *designated under the term nanotechnology."*

3. Hessische Landeslabor (Hessian State Laboratory) location Kassel, Dr. P. Riehl:

Taking the example of coenzyme Q10 (ubiquinone), Dr. P. Riehl of the Hessian State Laboratory in Kassel, Drusentalstrasse, confirms in his letter of 19.07.2007:

"In my opinion the packaging of the coenzyme Q10 in micelles does not lead to any other metabolisation in the intestine. Despite the unusual manufacturing process no novel food according to the Directive 258/57 Art. 1 para. 2f is involved."

4. American Chemistry Council:

The *American Chemistry Council* uses in his statement 'Consideration for a Defination of Engineered Nanomaterials' of 13. March, 2007 although as well the term “engineered nanomaterials” but makes there following exceptions:

“Exclusions:

1. Materials that do not have properties that are novel/unique/new compared to the non-nanoscale form of a material of the same composition.

2. Materials that are soluble in water or in biologically relevant solvents. Solubility occurs when the material is surrounded by solvent at the molecular level. The rate of dissolution is sufficiently fast that size is not a factor in determining a toxicological endpoint.

3. For those particles that have a particle distribution such that exceeds the 1-100 nm range (e.g.50-500 nm) if less than 10% of the distribution falls between 1-100 nm it may be considered as non an Engineered Nanomaterial. The 10% level may be on a mass or surface area basis,whichever is more inclusive.

4. Micelles and single polymer molecules.”

Limitation of engineered nanomaterials / micelle technology:

Micelle definition:

Micelles are associated formations of ampliphilic or surface active agents which spontaneously combine in a dispersion medium (self-aggregation). Thus, micelle technology differs substantially from classical nanotechnology. In this respect primarily technologies are involved which have been known for a long time in the field of food technology and are accordingly used frequently. It follows then that the use of new types of nanoscale materials is not involved, but rather known food ingredients or substances already known as foodstuffs, which are used with

modified dimensions as required by the process. These are established technologies which in part have been applied as safe methods of food manufacture for decades, such as for example in emulsification and homogenisation as well as methods based on the properties of colloids and micelles with particle sizes in the nanoscale range.
In these food processes, which have been well-proven over decades, the following emulsifiers are used:

Bezeichnung	**EG-Nr.**
Lecithine	E 322
Mono- und Diglyceride von Speisefettsäuren	E 471
Natrium-, Kalium- und Calciumsalze von Fettsäuren	E 470
Sorbitan-fettsäureester	E 491 bis E 495
Säureveresterte Monoglyceride	E 472
Polyglycerolester von Fettsäuren	E 475
Saccharosefettsäureester (®Zuckerfettsäureester)	E 473
Sucroglyzeride	E 474
Natriumstearoyllactylat bzw. Calciumstearolylactylat	E 481 bzw. E 482
Polysorbate	E 432 bis E 436
Ammoniumsalze der Phosphatidsäuren	E 442
Saccharoseacetatisobutyrat	E 444

Here, well-proven toxicologically harmless additives are involved, whose marketability as food additives has already been controlled since January 1998 within the scope of the additive approval directive.

Conclusion:

Colloidal systems such as liposomes and micelles, which partly due to purely physical reasons are present through self-formation aided by approved additives (emulsifiers) during food production (technologically unavoidable with CMC = Critical Micelle Concentration), have been constituent parts of food for decades. Colloidal systems such as liposomes and micelles can and should therefore not be regarded nor understood as, and therefore not confused with ENMs from a scientific or a regulatory viewpoint for the purposes of the above mentioned EFSA paper.

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