



FEDERATION OF EUROPEAN SPECIALTY FOOD INGREDIENTS INDUSTRIES

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ELC's updated position on the basis of the recent EU regulatory developments on the definition and labelling of nano-ingredients

Background

This position paper is a supplement to the ELC position "Food additives and nanotechnologies¹". It addresses key views on the recent developments in the definition of nano-ingredients laid down in the Regulation on the provision of food information to consumers and in the Commission Recommendation on the definition of nanomaterial (2011/696/EU). It applies not solely to food additives but also to other specialty food ingredients such as nutrients, enzymes etc.

Definition

➤ **Definition provided in the [Food Information Regulation \(EU\) 1169/2011](#)²**

This definition has the merit to acknowledge, in addition to the criterion on size, the intentional production (i.e. the additive is deliberately created as nano-form) and the properties that are characteristic of the nanoscale (i.e. new properties not known for larger counterpart). It also acknowledges that nanomaterials have still to be present as nanomaterials in the final food application.

However it fails to focus on nanoparticles that are insoluble and biopersistent under physiological conditions: when solubilised, the nanomaterials lose their nano-characteristic properties and a potential hazard is only dependent on the amount of the substance entering the body and the toxicity resulting from its chemical structure, as is clearly established by the EFSA³.

According to the Regulation, nano-structured materials are covered by the specific labelling obligation applying to nano-materials, meaning that substances composed of structures complying with the definition of engineered nano-material, but effectively being far beyond any nano-structure, fall into this definition.

Examples are crystalline or amorphous salts, which could form from saturated solutions building nano-crystals/structures and later on crystals/structures of a visible size. Such salts might be captured by the definition although there is no change in production and no structure below 100 nm present in the foodstuff. The nano-labelling of such substances would provide no useful information to consumers; on the contrary it would be misleading to declare an ingredient that is not present in the final food.

¹ See: http://www.elc-eu.org/PDF/2009-10_Food_additives_and_nanotechnologies_-_ELC_position.pdf

² « Engineered nanomaterial » means any intentionally produced material that has one or more dimensions in 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"

³ EFSA Scientific Committee; Scientific Opinion on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. EFSA Journal 2011; 9(5):2140 [36 pp.]

In addition, there are no common methods for determining the particle size; official methods have to be adopted per chemical substance. Accordingly, the particle size can not be determined, neither by industry nor by control authorities.

➤ **Importance of novelty and cut-off date**

The Food Information Regulation establishes that *“taking into account the fact that food containing or consisting of engineered nanomaterials could be a novel food, the appropriate legislative framework for this definition should be considered in the context of the upcoming review of the Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients”*. This reflects the Council political agreement in first reading, which aimed to include in the definition of “engineered nanomaterials” in the Novel Foods and Novel Food Ingredients Regulation.

Hence it is the original intention of the legislator to consider novelty as an essential parameter for a *pragmatic* implementation of the new legislation; this implies the establishment of a cut-off date similar to the cut-off date that applies to all novel foods/novel food ingredients.

➤ **Commission Recommendation on the definition of nanomaterial (2011/696/EU)**

The definition provided in the Commission Recommendation is a size-based scientific definition:

- Since it indifferently refers to natural, incidental or manufactured nanomaterial, it implicitly acknowledges that *“properties or risks posed by a nano-sized material are not determined by the intention of the manufacturer and do not differ depending on whether the nanomaterial is natural, produced incidentally, or the result of a manufacturing process with or without the explicit intention to produce a nanomaterial”*⁴.
- It focuses on particulate materials, which are to be understood as solid particles, and exclude nanostructured materials.

However it fails to take into account novel properties that are characteristic to the nanoscale, and the biopersistence of the particles (see above).

In addition, the approach to aggregates should be further qualified: *“aggregate”* is defined as *“a particle comprising of strongly bound or fused particles”*. As such the definition is very broad and it specifies neither which types of boundaries are addressed (physical, chemical?) nor what *“fused particles”* mean, leading to capture in principle a wide range of organic and inorganic ingredients. The strength of boundaries is important to the qualification of a material as a nanomaterial. If it is not possible to derive nanomaterials from this material under realistic conditions, it cannot qualify as an aggregate for the purpose of this Recommendation: the absence of disaggregation prevents both any evidence that the material consists of nanomaterials and any exposure of the consumer to nanomaterials.

Let’s detail the example of silicon dioxide that is one of the inorganic materials that are used as food additives, with a long history of safe use:

⁴ [Questions and answers on the Commission Recommendation on the definition of nanomaterial](#) – 18 October 2011

Synthetic amorphous silica (SAS) have been safely used in food applications for decades and are not regarded as novel food according to Regulation (EC) 258/97. They are produced in a traditional process either as fumed or precipitated SAS. Both forms are used under the name silicon dioxide (E 551) as food additive and are qualitatively described in the EU Directive 2008/84/EC. All SAS products are composed of fused primary particles of size < 100 nm which form aggregates and agglomerates during the manufacturing process. In fact, in pure SAS materials, as delivered, isolated primary particles do not exist and cannot derive from such material under normal physical conditions. Thus, the mean diameter of the resulting synthetic amorphous silica agglomerates is typically in the micron range and well above 100 nm⁵.

➤ **Cut-off size (50% of number-sized particles)**

Application of this arbitrary cut-off size is not simple, as per the following example: let's imagine a small rock of salt which is manually milled. If the surface of the rock is slightly scratched, just one single particle may be taken of: should this particle be in the size range 1 nm-100 nm, then the product would qualify as nanomaterial since it would be numerically composed of 50 % of nano-material (i.e. 1 particle out of the 2).

Increased bioavailability is not always an issue

The bioavailability of nutrients depends on various factors (diet factors, food matrix, biochemical and metabolic factors, individual characteristics etc), however as long as the bioavailability of a nutrient from formulated products is essentially equivalent to what can be achieved from foods under optimal conditions, it should not be treated differently.

There is no magic behind the technologies used for the production of specialty food ingredients!

Technologies that are used for the production of food ingredients are the same standard technologies than the ones used for the production of foods: emulsification, homogenisation, drying, grinding, milling etc. They equally might result in small particle sizes of ingredients or small structures in the nanosize comparable to foods. For example a colour emulsion is obtained according to the same emulsification process as used for the production of a home-made mayonnaise: it can be noted that the definition provided in the Commission Recommendation excludes non-particular materials such as proteins or micelles as present for example in mayonnaise⁶.

Application of these food technologies to food additives, enzymes and nutrient preparations is generally required for technological purposes, for example stabilisation. Annex III of Regulation (EC) 1333/2008 on food additives⁷ acknowledges for such technological purposes a list of food additives that are needed for the production of food additives, food enzymes, food flavourings and nutrients⁸, with the implicit understanding that in order to make use of these additives in e.g. vitamins, these technologies are necessary.

⁵ Degussa Schriftenreihe Pigmente No.30, 1977; Degussa Schriftenreihe Pigmente No.31, 5th Version 1992

⁶ [Questions and answers on the Commission Recommendation on the definition of nanomaterial](#)

⁷ The Annex III is currently under EP scrutiny and its publication is expected by mid-November 2011. It establishes the Union list of food additives including carriers approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use.

⁸ i.e. vitamins, minerals and other substances added for nutritional purposes, as well as substances added for physiological purposes as covered by Regulation (EC) 1925/2006, Directive 2002/46/EC, Directive 20009/39/EC and Regulation (EC) 953/2009.

Adequate legislation is already in place to address new specialty food nano-ingredients

Food additives and food enzymes are submitted to pre-market authorisation, which implies a safety assessment. Article 12 of [Regulation \(EC\) 1333/2008 on food additives](#) and Article 14.2 of [Regulation \(EC\) 1332/2008 on food enzymes](#) adequately address the requirements applying to these approved ingredients when they are produced according to a modified production methods or different starting materials. All permitted food additives are currently re-evaluated, and this re-evaluation includes specifically a safety assessment of nanoforms (as defined on a size-basis)⁹. All other novel food ingredients are equally submitted to pre-market authorisation.

Labelling

If a food ingredient falls under the definition of nanomaterial, it will be labelled with a reference to “nano” in pre-packed foods, as required from 13 December 2014 by the Food Information Regulation.

In the current stage of the development of the EU regulatory definition, this additional nano-labelling is requested irrespective of any safety issues, unlike e.g. allergen labelling. It shall be then assumed that the request for additional nano-labelling is only motivated by the willingness to deliver to the consumer more complete information. However delivery of fair and non-misleading information to the consumers should consequently imply the absence of labelling discrimination between:

- naturally (unavoidably) occurring nano-ingredients and engineered nano-ingredients (intention to produce effectual nano-particles),
- food and food ingredients obtained by the use of similar technologies.

Careful consideration should be given to the potential consequences of such labelling on the EU market because:

- It would be perceived by most consumers as a warning labelling, as shown in the conclusions of the German BfR report on consumer perception of nano-labelling (see Annex I: Public Perceptions about Nanotechnology, 2009, p17, fig.5; p18 fig. 6; p20 fig8). According to this survey, consumers have strong doubts about the benefits of nanotechnology (average >80%). The acceptance of nano-materials in foodstuffs among consumers is consequently extremely low, because of risk perception.

Since the definition covers existing materials too, the risk about both well-established and new materials will be equally perceived by the consumer. This might limit his choice, especially since the definition is not risk-orientated but rather arbitrary. Already certain allegedly nano-ingredients are banned from the shelves just for marketing purposes, i.e. “to please the consumers” by playing on scaremongering (please see the example in Annex II and the conclusions). Needless to underline the detrimental consequences for the European specialty food ingredients industry who sells these “old” ingredients for decades!

The nano-labelling for cosmetic products will become effective within 2013. What is currently seen by suppliers of cosmetic ingredients is an intensive de-listing of the ingredients that are considered as nanomaterials. Even if the consumer acceptance of

⁹ See for example the [EFSA opinion on the re-evaluation of calcium carbonate](#)

nanotechnology in cosmetic products is much more pronounced than in food, for major parts of the cosmetic industry nanomaterials, although authorised and safety assessed, are not acceptable because of the mandatory labelling. A similar trend is noted by the suppliers of food contact materials for food packaging.

- It would not necessarily be easy to explain that a food present for years on the market be “nano-labelled” all of a sudden whilst the ingredients and the recipe are exactly the same. Since nothing has changed, a communication about the absence of change in food formulation would become potentially necessary. This would oppose the history of information to consumers - commonly the food industry informs about changes in a recipe. It would be an impossible communications exercise to convey to consumers such “nano-information” about a food ingredient, of which safety is established and which is legally present on the market for years.

Specialty food ingredients present in the EU market are well-established and manufactured by well-known technologies. Depending on the technology used, structures in the nano-size may occur but they do neither exhibit specific nano-properties nor pose a risk to health.

They are generally submitted to pre-market authorisation; the regulatory procedure for their authorisation lays down mechanisms to evaluate or re-evaluate their nano-safety.

There is no scientific reason to differentiate:

- *the regulatory approach to naturally-occurring, incidental and engineered nano-particles, as acknowledged in the definition provided in the Commission Recommendation*
 - *the technologies used to produce food ingredients and final foods.*

Given the high risk that a nano-labelling be perceived by the consumers as a warning labelling, such labelling shall be reserved to new substances that do exhibit nano-characteristics: notably size, insolubility, bio-persistence and specific nano-properties that do not exist in their bulk counterparts.

Therefore it is of paramount importance that the impact of the definition applying to food & food ingredients for regulatory purpose be carefully measured before it is implemented.

- Annex I: BfR report “ Public perception about nanotechnologies”
- Annex II: “Information to consumers” leaflet entitled “Nanotechnology: prohibited at Naturland
November 2011

The ELC represents a united voice for the specialty food ingredients industry on scientific, technical and regulatory issues relating to food products in Europe. It is our aim to ensure that all stakeholders - from manufacturers and retailers to regulatory authorities and consumers - are correctly informed of the use, safety and benefits of specialty food ingredients. In total, more than 200 international and national food ingredients companies are currently involved in the ELC's activities through direct membership or an association. 3-8% of EU specialty food ingredients manufacturers' turnover is dedicated to research and development. More information is available at www.elc-eu.org