Executive summary

A robust and comprehensive EU regulatory framework is already in place for food additives, whether nano- or not. Simple and robust scientific principles have been elaborated, such as the SCENIHR’s exposure assessment decision tree. The use of these principles during the usual risk assessment procedure for food additives is sufficient to enable a robust safety assessment of nano-scale materials.

All food additives of ELC membership are legally marketed and compliant with actual purity criteria as set by the European Commission. They all comply with safety assessments performed during the authorisation procedure. If we take the proposed terms used in the EFSA scientific opinion on the potential risks arising from nanoscience and nanotechnologies of food and feed safety (2009) and in the definition proposed by the European Parliament further to their first reading of the Commission’s proposal for a Regulation on Novel Foods (2009) into account, we conclude that there is no food additive produced by nanotechnology.

In line with the most recent scientific developments in the matter, ELC considers that the criterion on size is insufficient and inadequate to qualify the nano-status of an additive: many other aspects have to be considered, in particular:
- the intentional production (i.e. the additive is deliberately created as nano-form),
- the properties that are characteristic to nanoscale (i.e. new properties not known for larger counterpart),
- a risk-based approach: focus on insoluble or persistent nanomaterials since materials that are water-soluble or biodegradable exhibit no nano-specific risks.

Given the potential interest of nanotechnologies in the development of innovative food additives with enhanced technological properties (e.g. better stability in various food matrices), there may be requests for authorisation of nano-additives in future. ELC is committed, on a continuous basis, to deliver transparent and accurate information on the potential nano-status of the food additives produced throughout our membership. ELC members will inform the European Commission of any new scientific or technical information which might affect the assessment of a food additive with regard to nano-properties.

ELC members do not support a mandatory labelling of the use of nanotechnologies in foodstuffs.

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1ELC would definitely favour further EFSA work to ascertain this approach.
All food technologies were new technologies sometime or other...

New technologies referred to as “nanotechnologies” are currently available for the manufacturing of a range of consumer products, from sunscreens to paints and from cosmetics to pharmaceuticals.

As numerous other technologies that were initially developed for non-food areas but that are now widely used to produce common foods, e.g. extrusion for breakfast cereals, spray-drying for milk powder or lyophilisation for coffee, nanotechnologies can also be used in the food industry to improve for instance the food quality and packaging as well as the sensory properties. Food ingredients can also be produced in principle with enhanced technological properties and thus help to obtain innovative ingredients for healthy, tasty and convenient foods.

However nanotechnologies are currently facing a potential distrust from consumers, who may perceive these new technologies as a source of potential health risks if they are applied to the production of foods; in particular it is feared that their use in the food area is still insufficiently regulated. Such concerns are often directed to food additives. It is therefore important to ensure a proper communication towards consumers with regard to science, uses, risks and regulatory framework surrounding this new technology.

Are nano-food additives regulated in the EU?

A robust and comprehensive EU regulatory framework is already in place for food additives, whether nano- or not. From 20 January 2010 onwards, all food additives permitted in the EU must comply with Regulation (EC) 1333/2008 on food additives, i.e. food additives are only authorised if:

- they do not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed; and
- there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means; and
- their use does not mislead the consumer.

In addition, if relevant, other legitimate factors, including societal, economic, traditional, ethical and environmental factors are considered before any authorisation is granted.

Food additives must comply with approved specifications, which shall include information to adequately identify the food additive, including origin, and to describe the acceptable criteria of purity.

It is specifically stated in the Regulation that if a nanoform of an already permitted food additive were to be developed, it would be considered as a different additive, because the change in particle size, for example through nanotechnology, is considered as a significant change in the production method of the additive. Hence, a new entry in the Community lists of permitted additives or change in the specifications will be required before it can be placed on the market, i.e. the nanoform will go through a new safety assessment.

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3 Article 6 - §1 of Regulation (EC) 1333/2008 on food additives
4 Article 14 of Regulation (EC) 1333/2008 on food additives
5 Article 12 of Regulation (EC) 1333/2008 on food additives, which applies on 20 January 2010.
A producer of a food additive has the obligation to inform the Commission immediately of any new scientific or technical information which might affect the assessment of the food additive\(^6\).

The food area in the EU is one of the most regulated ones, and the cornerstone is that “food shall not be placed on the market if it is unsafe”\(^7\).

**Are current risk assessment methodologies for nano-additives adequate?**

The safety of food additives is evaluated by the European Food Safety Authority (EFSA), who implements specific guidelines for their risk assessment. These guidelines are currently being reviewed to take account of scientific and technological development: hence the EFSA has recommended that when risk assessments guidance documents in the food and feed area are revised, nanotechnology aspects shall be considered\(^8\).

A manufacturer who applies for authorisation of a new substance as food additive is responsible for the provision of detailed toxicological data, including: metabolism/toxicokinetics, subchronic toxicity, genotoxicity, chronic toxicity and carcinogenicity. The design of the related studies can be adjusted in order to take account of the characteristics of the substance, e.g. potential nanocharacteristics.

Combined with the use of the SCENIHR’s exposure assessment decision tree, the usual risk assessment procedure for food additives is sufficient to address the nano-scale aspects, in particular as it includes obligations to the applicant to deliver comprehensive toxicological information. In this way the hazards associated with nano-scale materials, such as reactivity and distribution in the body, are considered within a robust framework for risk assessment. It is inherent to this approach that if the hazards cannot be satisfactorily explored (perhaps due to technical issues when testing or analysing nano-scale materials) the assessment is not complete and safety is not assured. The food additive is consequently not put on the market.

**Are nano-additives produced in the EU?**

ELC represents ca 65 % of the food additives that are permitted in the EU. All food additives of ELC membership are legally marketed and compliant with actual purity criteria as set by the European Commission. They all comply with safety assessments performed during the authorisation procedure.

If we take the proposed terms used in the EFSA scientific opinion on the potential risks arising from nanoscience and nanotechnologies of food and feed safety (2009) and in the definition proposed by the European Parliament further to their first reading of the Commission’s proposal for a Regulation on Novel Foods (2009)\(^9\) into account, we conclude

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\(^{6}\) Article 26 of Regulation (EC) 1333/2008 on food additives

\(^{7}\) Article 14 (1) of Regulation (EC) 178/2002 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.

\(^{8}\) EFSA Scientific Opinion on The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety

\(^{9}\) “Engineered nanomaterial” means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or 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 to the nanoscale.
that there is no food additive produced by nanotechnology. We do not object that there are some borderline cases if a definition of nanotechnology focuses on the size only. But small size does not necessarily relate to new properties and new risks. However this discussion is irrelevant if the product in market is compliant with a former risk assessment, as detailed below for a few additives.

ELC is closely monitoring the potential development of a definition in the EU food legislation and would certainly favour an international harmonised approach across food and non-food sectors (e.g. ISO, OECD).

In line with the most recent scientific developments in the matter, ELC considers that the criterion on size is insufficient and inadequate to qualify the nano-status of an additive: many other aspects have to be considered, in particular:
- the intentional production (i.e. the additive is deliberately created as nano-form),
- the properties that are characteristic to nanoscale (i.e. new properties not known for larger counterpart),
- a risk-based approach: focus on insoluble or persistent nanomaterials since materials that are water-soluble or biodegradable materials exhibit no nano-specific risks.

Hence, the final particle size is definitely not the final defining factor to qualify the nano-status of an additive.

In general every permitted food additive has been evaluated and only authorised if its safety was sufficiently demonstrated. Available test systems focus on the different potential hazards of a product, including toxic, mutagenic, carcinogenic, embryo-toxic, developmental toxic effects. The safety studies have to be performed with the product intended to be marketed. Thus, these safety tests and the later risk assessment will cover potential risks of the particular form or size of the material, too.

This is important to note for example for additives of which a minor part of the particle distribution size is in the order of 100 nm as an unavoidable technological consequence of their production method. The risk assessment of the additive covers also this minor particle fraction.

The same is true for microencapsulated food additives (bulk material) which are soluble and biodegradable. From a toxicological point of view there are no indications that the particle size of substances which dissolve sufficiently fast in water or biological systems has a significant influence on their toxicity. A potential effect on the bioavailability of the additive is usually covered by the safety studies already performed.

It shall be noted that a food additive is never consumed as such but always incorporated at low percentage in complex food and drink matrices.

Properties that are characteristic to 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”.


Silicon dioxide (E 551) has for long been approved as an anti-caking agent for certain applications in dry powdered food ingredients. During its production, temporarily nanosized primary particles are formed, which later agglomerate to larger structures. Silicon dioxide in this form has been evaluated and been approved as a safe food additive for many years.

ELC would definitely favour further EFSA work in order to ascertain this approach.
The only potential case where size would be a determining criterion for nano-status is where the size of the additive is deliberately designed for a specific physiological effect, i.e. potentially substances that are both food additives and nutritional substances.

**Will nano-additives be produced in the EU?**

Given the potential interest of nanotechnologies in the development of innovative food additives with enhanced technological properties (e.g. better stability in various food matrices) there may be requests for authorisation of nano-additives in future.

However industry’s investments in this exciting area for the development of safe innovative food ingredients should not be hampered by unpredictable legislative developments that would not be science-based. Appreciating the communication challenge that surrounds the acceptability by consumers of any new food technology, ELC is committed, on a continuous basis, to deliver transparent and accurate information on the potential nano-status of the food additives produced throughout their membership.

ELC members will inform the European Commission of any new scientific or technical information which might affect the assessment of a food additive with regard to nano-properties.

**Shall a “nano-label” be mandatory?**

A voluntary labelling of the use of nanotechnology in a certain product should be possible to give operators the possibility of promoting a reference to the use of this advanced technology in their food products, as long as claims made on foods are true and not misleading. However, an obligatory labelling system for nanomaterials or foods obtained by nanotechnology may unduly ostracize foods that are produced with this technology compared to other (now) common manufacturing processes. ELC members do not support such an approach.

**Annexes - Case studies**

1. Factsheet [Titanium dioxide E 171](#)
2. Factsheet [Silicon dioxide E 551](#)
3. Factsheet [Silicates - E 552/559](#)
4. Factsheet [Colour Emulsion](#)

Rev.1 - October 2009
Titanium Dioxide Manufacturers Association - TDMA

Response to Customers concerning the Presence of Nanoparticles in Titanium Dioxide Pigment

Titanium Dioxide pigment is manufactured as a fine particulate powder with major uses in paints, plastics, fabrics and high quality papers. It is supplied in a range of grades with different surface coatings that are tailored for the particular consumer end use.

The average primary particle size for all Titanium Dioxide pigments is larger than the nanoparticle size range as defined by ISO/TC 229\(^1\). The pigments should therefore not be considered as nanoparticles, manufactured nanoparticles, nanostructured or nanomaterials.

As with other particulate materials there will be a distribution of primary particle sizes around the average value and it is possible that a small fraction of the primary particles are covered by the nanoparticle definition, that is with all external dimensions in the range,1 to 100nm\(^1\).

However the primary particle size does not represent the size of particles in the products supplied by the industry, since in practical systems these are aggregated or agglomerated into larger particles.

TDMA 20\(^{th}\) January 2009

\(^1\) ISO/TC 229 Nomenclature system for nanoparticles
Annex 2 - Fact Sheet Silicon dioxide E 551

According to the ISO Technical Committee 229 “Nanotechnologies”, nanomaterials are understood to be either nano-objects (ISO / TS 27687:2008) or nanostructured materials (ISO working draft document TS 12921).

Nanomaterials have an internal structure at the nanoscale. Typical examples are aggregates and agglomerates of nano-objects, nano-composites or nanostructured surfaces.

According to this definition, the solid forms of synthetic amorphous silica (SAS: pyrogenic (fumed) silica, precipitated silica, silica gel, colloidal silica) commercialized for decades are nanostructured materials with external dimensions typically above nanoscale. Under conditions of normal handling and use, agglomerates are the relevant particles, for both pyrogenic and precipitated SASs.

Colloidal silicas based on the sol-gel-technology are suspended particles in a liquid, mostly water. They may fulfill the requirements of nano particle definition in the liquid phase. After evaporation of the liquid, the particles condense to much larger sizes.

The existing toxicological and ecotoxicological studies have been performed with these substances described above. Furthermore, we have to stress that the above described substances are manufactured and are commercialized without changing the production processes for decades. Therefore, they do not represent a new functional nanotechnology.

Manufacture

Thermal Route: Production of pyrogenic synthetic amorphous silicas

Synthesis of pyrogenic synthetic amorphous silica can be described as flame hydrolysis of silicon tetrachloride (SiCl₄). SiCl₄ is converted to the gaseous phase and reacts completely in a flame (> 1,000 °C) with the intermediately formed water to form silicon dioxide. The size of the SiO₂ particles are in the range between 5 and 50 nm, which in the temperature gradient of the reactor grow into larger chemically bonded aggregates within about 100 ms and then form even larger agglomerates (1-250 μm). This process takes place in a completely closed system. No particles or gases are released. Hence, the product is nanostructured, but cannot be counted as nanoparticles. Mechanical comminution of the agglomerates requires a high amount of energy.

Wet-Route: Production of precipitated synthetic amorphous silicas and silica gels

In the precipitation method, which is generally carried out discontinuously in precipitation tanks (in batches), sodium silicate solution is mixed with mineral acids (usually sulfuric acid) in water. The synthetic amorphous silica forms in a time frame of up to two hours. The precipitated synthetic amorphous silica (solid proportion of 7-9% in the precipitation tank) is separated from the liquid in a filter press; the by-product, sodium sulfate, is washed out and the product is then flash dried or slow dried. The structures are stabilized during drying. The particle size is about 500-600 μm; the inner structure of the

precipitated synthetic silica depends on the underlying conditions (such as pH, temperature, reactor geometry, agitation).

The gel process, which is done in batches, is based on the same basic chemicals. After the gel has formed it is aged for a defined time and is then roughly milled for the required washing process. The by-product of the reaction, sodium sulfate, is washed out and the inner structures of the gel are also formed during the washing process. This happens due to the shifting of the pH and the washing phases. The washed gel (a so-called hydro gel with about 65% water by weight) can then be further processed or be dried (flash drying (aerogel) or slow drying (xerogel)). Depending on which drying process is chosen, the inner structures are frozen or shrunk. The synthetic amorphous gels are then milled according to their areas of application.

For formulation, the synthetic amorphous silica is milled in a very energy-intensive process from 2-3 mm (gels) or approx. 600 µm for precipitated silica to the required size (hammer mill, jet mill (steam or air jet)). The particle size can be determined by the geometry of the mill; however, for energy reasons a particle size below 1 µm is economically not feasible. A size of 2-20 µm is typical for food additives.

**Application as food additive**

Silicon dioxide has no nutritional value. In food applications it is mainly used as a technical additive for food processing. Silicas are especially used as free flowing agents (e.g. tomato powder, table salt and spices). They are also used as input and dispersion aids in vitamin additives, for example. In powder-type foods, synthetic amorphous silicas prevent clumping and maintain the pouring properties.
Annex 3 - Fact sheet silicates E 552-E559

Manufacture

Sodium aluminum and (sodium) calcium silicate are manufactured with the same technology like precipitated silica or in a second processing step of synthetic amorphous silica through a hydrothermal induced chemical process (see Annex 2). Process conditions are adjusted slightly and the main differences are the replacement of mineral acids by metal salt solutions, e.g. aluminium sulfate, calcium sulfate or calcium hydroxide. The adjusted process or the hydrothermal treatment does not change the forming conditions of particles and the products are very comparable to pure synthetic amorphous silica.
Annex 4 - Fact sheet Colour Emulsion

Technical reasons for colour emulsions:

Natural pigments that are permitted under the Commission Directive 2008/128/EC include a range of naturally oil soluble pigments. It is necessary to produce emulsion using food approved emulsifiers that will render these pigments water dispersible as well as water soluble and suitable for a wide variety of food and beverages applications.

All pigments part of the carotenoid group (such as carotene (E160a), lutein (E161b), paprika (160c) and lycopene (E160d) as well as turmeric and curcumin products are naturally oil soluble and commonly used in the food and beverage industry to deliver a range of colour shade from bright yellow to red/orange. Other naturally oil soluble pigments are the group of chlorophylls (E140 / E 141).

Colour formulation:

Carotene in the form of an emulsion is used in numerous applications within the food industry. Those emulsions are complex systems that require stability both in their concentrated and diluted form.

Oil soluble molecules are first dissolved in vegetable oil before being emulsified in water phase. Emulsifiers may be present either in water or oil phase (or both). The oil phase is first pre-mix with the water phase to make a crude emulsion or pre -mix. Usually this step can be achieved by the use of traditional standard homogenisation and dispersion equipment.

![Diagram of Colour Emulsion Process]

The difference between a cloudy and a clear emulsion is basically the result of the type and quantity of emulsifier used within the formulation.
All emulsifiers used for the preparation of food colours have been authorised within the EC since 25th September 1996 to the so called Miscellaneous Directive 95/2/C on food additives other than colours and sweeteners. Examples of emulsifiers: polysorbates (E432-436), esters of distilled monoglycerides (E472 a-f) and lecithins (E322).

Emulsion technology:
Techniques typically used to produce colour emulsions are traditional processes as described in Annex II of EC Directive 1334/08, such as emulsification and mixing techniques.
The crude emulsion can be further pumped through the homogenisation valve and its the high velocity which creates turbulence and cavitation forces that disperse the oil droplets into finer particles.
This homogenisation technique is also widely employed in the food industry, in particular dairy industry for milk, but also to manufacture coffee cream and whitener, salad dressing and mayonnaise.

\textbf{Oil droplets coloured with carotene finely dispersed in water phase}

In the given example below (Carotene emulsion), the coloured oil droplet size is centred on 0.1\micron (=100nm), however the droplet size distribution covers a range from less than 60nm to above 300nm, even up to 800 nm is possible.

Conclusions:
Colour emulsions have been developed over the last decades to enable natural colours to be used widely within the food and beverage industry. Emulsifiers are all from the permitted list of food additives and the techniques are based on traditional food processes.