Statement for Synthetic Amorphous Silica regarding the definition of "engineered nanomaterials" for use in food in the European Union

The purpose of this statement is to provide the position of the Association of Synthetic Amorphous Silica Producers (ASASP) with respect to the substance Synthetic Amorphous Silica (SAS), E 551, related to " engineered nanomaterials" as provided in Regulation (EU) No 1169/2011 on food information to consumers (FIC), Regulation (EU) No2015/2283 on novel foods and the French Order of 5 May 2017 laying down the conditions for the labelling of manufactured nanomaterials in foodstuffs.

SAS is approved as Silicon Dioxide, E 551, in the Regulations (EC) No 1333/2008 on food additives and (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008. E 551 (SAS) includes precipitated silica, pyrogenic silica and silica gel.

Background

There is no consistent causal link between nano size alone and hazards associated with a substance. It has clearly been expressed by Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in its final position in 2010 and in recent JRC reports (http://dx.doi.org/10.2788/36237, http://dx.doi.org/10.2787/97286, http://dx.doi.org/10.2788/678452)that "It should be stressed that "nanomaterial" is a categorisation of a material by the size of its constituent parts. It neither implies a specific risk nor does it necessarily mean that this material actually has new hazard properties compared to its constituent parts." This is also supported by peer review publications (Donaldson and Poland, 2013; Gebel, T., Marchan, R. & Hengstler, J.G. Arch Toxicol, 2013; Gallud, Audrey and Bengt Fadeel. 2015). Additionally, the physicochemical and toxicological properties of SAS used as E551 for food applications were extensively discussed in a review in Archives of Toxicology (Fruijtier-Pölloth, 2016).

Currently, there is no harmonised definition of a nanomaterial. For the purposes of assessing nano-labelling requirements in food to inform consumers, only the definition of an "engineered nanomaterial" in Article 3,2(f) of the Regulation (EU) No 2015/2283 on novel foods and Article 1 of French Order of May 5, 2017, has to be considered in this statement and it states:

"*engineered nanomaterials 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*."

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"*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".

Article 18(3) of Regulation (EU) No 1169/2011 on food information to consumers and Article 1 of French Order of 5 May 2017 laying down the conditions for the labelling of manufactured nanomaterials in foodstuffs referring to the definition noted above require indication of the presence of any "engineered nanomaterial" ingredient in the food; such an ingredient shall be labelled with the word "[nano]" after the ingredient name.

Interpretation

When placed on the market, SAS is present as agglomerated aggregates in the micrometre scale (> 1 µm). During food processing, SAS agglomerates can be downsized to the sub-micrometre scale. The smallest indivisible unit in SAS is the aggregate which is comprised of fused particles that have no physical boundaries among them. SAS aggregates can only be destroyed by extremely high energies, resulting in fragmented aggregates of smaller size (Gray and Muranko, 2006). Single primary particles are not observed in commercially available SAS which is suitable as E 551 in Europe. (Fruijtier-Pölloth, 2016) is a recent and comprehensive review on the physico-chemical properties of SAS in food market.

Furthermore, it has to be emphasised that it is not the intention of the manufacturers of SAS to intentionally produce a nano-scaled material to exhibit a nano-specific effect for the use in food. More precisely, in food applications, SAS is not designed to present nano-specific properties. In fact, one of the technical functions of SAS is to act as a spacer between food components in order for them to remain in a free flowing state, nano-sized particles are not desired because they are too small to enable this effect. Additionally, the anti-caking function can only be achieved by the SAS agglomerated aggregates having size ranges which are required to be greater than the nanoscale (Jonat et al., 2004; Peters et al., 2016); particles of smaller size would not contribute sufficiently to this function.

Conclusion

In light of the information provided above and based on the current regulatory framework, ASASP has come to the interpretation and recommendation that SAS does not fall within the scope of the definition of an "engineered nanomaterial" as SAS does not meet all components of the definition. Therefore, in our opinion, synthetic amorphous silica does not meet the labelling provisions applicable to "engineered nanomaterials" specified by the FIC Regulation (EU) No 1169/2011, the Regulation (EU) No 2015/2283 on novel foods or by the French Order of 5 May 2017 in their current versions. If you need more

information, please contact your supplier. The current regulatory framework on nanomaterials is continuously evolving and this statement may be updated based on relevant new information, which may impact this conclusion.

References:

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