EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Health Technology and Cosmetics

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific opinion on Solubility of Synthetic Amorphous Silica (SAS)

Commission Department requesting the Opinion: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

1. Background

Article 2(1)(k) of Regulation (EC) No 1223/2009 (Cosmetics Regulation) establishes that "nanomaterial" means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.

That definition covers only materials in the nano-scale that are intentionally made and are insoluble/partially-soluble or biopersistent (e.g. metals, metal oxides, carbon materials, etc.). It does not cover those that are soluble or degradable/non-persistent in biological systems (e.g. liposomes, emulsions, etc.). Article 16 of the Cosmetics Regulation requires cosmetic products containing nanomaterials other than colorants, preservatives and UV-filters and not otherwise restricted by the Cosmetics Regulation to be notified to the Commission six months prior to being placed on the market. Article 19 of this Regulation requires nano-scale ingredients to be labelled (name of the ingredient, followed by 'nano' in brackets). If there are concerns over the safety of a notified nanomaterial, the Commission shall refer it to the Scientific Committee on Consumer Safety (SCCS) for a full risk assessment.

The Commission received several notifications under Article 16 of the Cosmetics Regulation on four types of nano silica and consequently a safety assessment on Silica, Hydrated Silica, and Silica Surface Modified with Alkyl Silylates (nano form) was requested to the SCCS.

The SCCS adopted an opinion (SCCS/1545/15) in September 2015 with the following conclusion:

After detailed evaluation of the current submission, the SCCS has concluded that the evidence, both provided in the submission and that available in scientific literature, is inadequate and insufficient to allow drawing any firm conclusion either for or against the safety of any of the individual SAS material, or any of the SAS categories, that are intended for use in cosmetic products.

In January 2018 the Association of Synthetic Amorphous Silica Producers (ASASP), a Cefic Sector Group, submitted a dossier with the purpose to demonstrate that SAS does not fall under the nanomaterial definition of the Cosmetic Regulation. Therefore, according to the applicant no further actions required for nanomaterials as defined in the Cosmetics Regulation would apply to SAS.

2. Terms of reference

(1) Does the SCCS consider that Synthetic Amorphous Silica (SAS) are soluble (100 mg/L or higher) or degradable/non-persistent in biological systems, in light of the nanomaterial definition of the Cosmetic Regulation?

(2) Can the SCCS indicate to which kind of Silica this solubility applies?

(3) Does the SCCS have any further scientific concerns with regard to solubility of Synthetic Amorphous Silica (SAS)?

3. Deadline: October 2018

The SCCS adopted this mandate at the SCCS plenary meeting on 21/22 February 2018.