



EUROPEAN COMMISSION

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

Resources Based, Manufacturing and Consumer Goods Industries
Consumer Industry

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a scientific advice on the safety of nanomaterials in cosmetics

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

1. Background

1.1 Establishing the concerns

Article 16(4) of the Cosmetics Regulation provides that ‘*In the event that the Commission has **concerns** regarding the safety of a nanomaterial, the Commission shall, without delay, request the SCCS to give its opinion on the safety of such nanomaterial for use in the relevant categories of cosmetic products and on the reasonably foreseeable exposure conditions*’.

Thus far, the ‘*concerns*’ of the Commission that gave origin to previous mandates to SCCS have been based on the intrinsic properties of nanomaterials, as a category, in light notably of their nano-scale dimension, bio-persistence and insolubility.

1.2 Establishing potential risk to human health

According to the Cosmetics Regulation, once a risk assessment for a nanomaterial has been performed, the Commission shall proceed with risk management measures provided that the risk assessment has established the presence of a potential risks to human health.

In this respect, Article 16(6) of the Cosmetics Regulation states that ‘*taking into account the opinion of the SCCS, and where there is a **potential risk to human health**, including when there is insufficient data, the Commission may amend Annexes II and III*’. The risk of having “*insufficient data*” materialised in the recent experience with the inconclusive SCCS opinions on nanomaterials (as notified through CPNP)¹. In these cases, due to the lack of relevant information from the applicants both in the original notifications and in the additional information requested by the SCCS the ‘*potential risk to human health*’ could not be established nor excluded by SCCS.

In the cases mentioned above, even if the ‘*insufficient data*’ provision is fulfilled, the ‘*potential risk to human health*’ is not fully established and the Commission is not in a position to take potential regulatory measures, in accordance with Article 16(6) of the Cosmetics Regulation.

¹ Colloidal Silver (nano) (SCCS/1596/18), Styrene/Acrylates copolymer (nano) + Sodium styrene/Acrylates copolymer (nano) (SCCS/1595/18) and Silica, Hydrated Silica, and Silica Surface Modified with Alkyl Silylates (nano form) (SCCS/1545/15).

The general principle of precaution allows the adoption of restrictive measures even when it is not possible to determine with certainty the existence and/or extent of an alleged risk, but the likelihood of a real harm persists should the risk materialise. Consequently, even if conclusive evidence is not required, the risk addressed by the measure shall be more than hypothetical and based on a scientific risk assessment as thorough as possible.

Therefore, a key question is to determine the minimum level of '*potential risk*', which could justify a restrictive regulatory measure for those substances with inconclusive opinions issued. In view of the current situation, the Commission considers that, regardless of the data submitted by the applicants, evidence in scientific literature could be used to assess if a '*potential risk*' to human health can, nevertheless, be identified and can reasonably justify the adoption of regulatory measures in accordance with Article 16(6) of the Cosmetics Regulation.

Such evidence at the level of substances or group of substances may include, but are not limited to the following:

- systemic or local availability;
- harmful effects specifically related to nano-form;
- surface catalysed reactions in nano-form;
- absorption (or potential absorption) from dermal and inhalation routes;
- potential of nano-form to deliver ionic forms.

2. Terms of reference

*1. The SCCS is requested to determine the nanomaterials, as published in the recent catalogue of nanomaterials of 2019, for which specific concerns can be identified and justified in order to establish a priority list of nanomaterials for risk assessment (Article 16(4) Reg.1223/2009). More specifically, the SCCS is requested to provide a description of the specific concerns that have been identified for the nanomaterials mentioned above. This process should be based on the currently available scientific literature and SCCS' expert judgement.**

*2. For the nanomaterials with inconclusive SCCS opinions, such as [Colloidal Silver (nano) (SCCS/1596/18), Styrene/Acrylates copolymer (nano) + Sodium styrene/Acrylates copolymer (nano) (SCCS/1595/18) and Silica, Hydrated Silica, and Silica Surface Modified with Alkyl Silylates (nano form) (SCCS/1545/15)], the SCCS is requested to assess if a potential risk can be identified according to Article 16(6) Reg.1223/2009. Such assessment, regardless of the data previously submitted by the respective applicants, should be based on the available scientific literature and SCCS' expert judgement (i.e. systemic or local availability; harmful effects specifically related to nano-form; surface catalysed reactions in nano-form, absorption (or potential absorption) from dermal and inhalation routes, potential of nano-form to deliver ionic forms, etc.).**

* In the assessment of the above question and in order to avoid conflicting opinions with other bodies, SCCS is invited to consult SCHEER.

The SCCS adopted this mandate by written procedure on 5 February 2020.