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The SCCS scientific advice on the safety of nanomaterials in cosmetics

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ABSTRACT

The Cosmetic Regulation (EC) No 1223/2009 specifically covers the risk of nanomaterials used in cosmetic products. If there are concerns regarding the safety of a nanomaterial, the European Commission refers it to the SCCS for a scientific opinion. The Commission mandated the SCCS to identify the scientific basis for safety concerns that could be used as a basis for identifying and prioritising nanomaterials for safety assessment, and to revisit previous inconclusive SCCS opinions on nanomaterials to identify any concerns for potential risks to the consumer health.

The SCCS Scientific Advice identified the key general aspects of nanomaterials that should raise a safety concern for a safety assessor/manager, so that the nanomaterial(s) in question could be subjected to safety assessment to establish safety to the consumer. The Advice also developed a list of the nanomaterials notified to the Commission for use in cosmetics in an order of priority for safety assessment, and revisited three previous inconclusive opinions on nanomaterials to highlight concerns over consumer safety that merited further safety assessment.

The use of nanomaterials in cosmetic products is subject to a high level of protection of consumer health under the European Cosmetic Regulation (EC No 1223/2009) (hereafter: EU Cosmetic Regulation).

The Regulation provides a definition of nanomaterial, and lays down the requirements for pre-market notification, safety assessment, authorisation and labelling of nanomaterials intended to be used as cosmetic ingredients.

Article 16 (4) of Cosmetic Regulation stipulates that in a case where the European Commission has concerns regarding the safety of a nanomaterial, it will seek scientific advice from the [Scientific Committee](#)

[on Consumer Safety \(SCCS\)](#) on the safety of the nanomaterial to the consumer. Article 16(6) further 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'*.

In recent years, the SCCS published scientific opinions on the safety of several nanomaterials intended for use in cosmetic products. However, a number of these opinions were inconclusive, because the available data were insufficient to allow the SCCS to reach a conclusion on whether a risk to consumer health could be established or excluded. In

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view of this, the Commission mandated the SCCS to identify the scientific basis for safety concerns for nanomaterials that could be used by the Commission as a basis for identifying and prioritising nanomaterials for safety assessment. The SCCS was further requested to revisit the inconclusive SCCS opinions on nanomaterials to identify any concerns for potential risks to the consumer health that would need further safety assessment.

Since the use of any nanomaterial in a cosmetic product could potentially raise a concern over safety of the consumer, it was important to rationalise such concerns and identify the nanomaterials that would need priority attention for safety assessment. In this regard, the SCCS Scientific Advice briefly summarised those key general aspects of nanomaterials that should raise a safety concern for a safety assessor/manager, so that the nanomaterial(s) in question could be subjected to appropriate safety assessment in the context of use in cosmetics to establish safety to the consumer.

It is well known that nanomaterials with particle size range in the nano-scale (1–100 nm) may exhibit distinctive characteristics compared to conventional (non-nano) form of the same materials. It was also noted at early stages of the development and application of nanomaterials that the same nano-scale features that make them desirable for a wide range of industrial and consumer applications, may also render them harmful for human health and/or the environment. Whilst the science of safety assessment of nanomaterials is still evolving, and there are several knowledge gaps, a number of characteristics have been identified as important in relation to the distinctive properties, behaviour and potential toxicological effects of nanomaterials. These were discussed and summarised by the SCCS.

In brief, the SCCS Scientific Advice identified that, in the first place, the presence of small particles (in the nanometer range) in an ingredient should draw attention of the risk assessors/managers to look more closely to the information on physicochemical characterisation of the nanomaterial. In particular, the presence of a significant proportion of nano-sized particles in consumer products should raise the first alert for potential concerns over safety. It noted that, although there are currently no hard and fast rules for working out the safety concerns for nanomaterials, as a general principle, each of the following attributes should add a further degree of safety concern. For example, where:

1. The nanomaterial has constituent particles that have sizes in the lower range of the nano-scale (1–100 nm),
2. The nanomaterial is insoluble, or only partially-soluble,
3. The chemical nature of the nanomaterial suggests the potential for a toxicological hazard,
4. The nanomaterial has certain physical/morphological features (e.g. needle shape, rigid long fibres) that point to potential for harmful effects,
5. The nanomaterial has surface reactivity in terms of catalytic (including photocatalytic) activity, potential for radical formation, or other surface properties (e.g. that can enhance cellular uptake, or confer allergenicity due to proteinaceous surface),
6. The nanomaterial has a different biokinetic behaviour than the conventional equivalent. For example, on the surface a modification/coating (e.g. hydrophobic coatings, encapsulation) has been applied to the core nanoparticles to alter their ADME (absorption, distribution, metabolism, elimination) properties and as a result make them more accessible systemically, or enable them to reach different tissues compared to the neat nanoparticles and/or their conventional chemical forms,
7. The nanomaterial is used as vehicle to carry other substances - which have not been assessed for safety as individual components, or together in the nano-scale entity,
8. There is a likelihood of systemic exposure of the consumer to nanoparticles through the use of final products, especially those that may alter surface characteristics of the nanoparticles and thereby enhance their absorption in the skin (skin penetration),

9. The frequency of use, and/or the amounts of the consumer product are relatively high,
10. There is evidence for persistence/accumulation of nanoparticles in the body,
11. Nanoparticles have other distinctive properties not present in conventional form of the same material or a new activity/function (e.g. a smart/functional nanomaterial),
12. The nanomaterial is so novel that it does not have a conventional comparator to allow assessment of changes in properties, behaviour or effects,
13. The nanomaterial is used in a product that is inhalable (taken up by inhalation into respiratory tract and lung), and the particles are respirable (can reach respiratory epithelium i.e. alveoli),
14. The assessment of genotoxicity is inadequate, e.g. in vitro studies are without information on stability of the test suspension, or evidence of cell exposure (internalisation).

Each of the individual aspects discussed above provide a scientific basis for safety concerns that may arise from the use of a nanomaterial in a cosmetic product. However, the overall concern for consumer safety would require combining all the aspects relevant to a specific nanomaterial. In the absence of any agreed rules on how to combine the individual 'alerts' to obtain an overall concern for safety, the SCCS used a scoring system proposed by [Brand et al. \(2019\)](#), along with expert judgement, to assign notional overall scores for risk potential of different nanomaterials. The scoring system combines consideration of the key aspects of nanomaterials that can trigger a 'signal' for risk, which when combined with expert judgment can help assign an arbitrary score for prioritisation of the nanomaterials on the basis of risk potential for human health. This allowed the SCCS to develop an order of priority for the nanomaterials that had been notified to the Commission for use in cosmetic products by industry applicants (<https://ec.europa.eu/docsroom/documents/38284>).

The SCCS also revisited three of the previous opinions on nanomaterials that were inconclusive (SCCS/1596/18 on colloidal silver (nano); SCCS/1595/18 on (sodium) styrene/acrylates copolymer (nano) and SCCS/1545/15 on silica, hydrated silica, and silica surface modified with alkyl silylates (nano)), and highlighted the basis for concerns over their safety to consumer health that merited further safety assessment.

The SCCS emphasised that the scoring system used in the Scientific Advice was not meant to be an alternative to safety assessment, but was only used to identify nanomaterials in an order of priority so that they could be subjected for proper evidence-based safety assessment.

Scientific Advice to be cited as

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Transparency document

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