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Commentary

The SCCS guidance on the safety assessment of nanomaterials in cosmetics

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

Where a cosmetic ingredient fulfils the criteria defining a nanomaterial as set out in the European Cosmetic Regulation, Article 2 (1) (k), the cosmetic products containing nanomaterials shall be notified to the Commission along with (inter alia) information on identification, specification, toxicological profile and safety data relating to the category of cosmetic product, as used in such products (Art. 16 (3)).

The EU Cosmetic Regulation states that "At present, there is inadequate information on the risks associated with nanomaterials. In order to better assess their safety the SCCS should provide guidance in cooperation with relevant bodies on test methodologies which take into account specific characteristics of nanomaterials." (Recital 30 of the EU Cosmetic Regulation). This led the SCCS to publish a Guidance on the Safety Assessment of Nanomaterials in Cosmetics (SCCS/1484/12), which has been updated in 2019 (SCCS/1611/19).

The update takes into account any new developments in the area of nanotechnology and nanosafety, the issues noted by the SCCS in relation to safety dossiers on nanomaterials assessed so far, as well as the challenges in safety assessment due to the EU ban on animal testing for cosmetic ingredients and products. Safety assessment of cosmetic ingredients has historically been based on data from a series of in vivo studies in animals. However, due to the animal-testing ban, safety data from in vivo studies can only be used if the tests had been performed before the animal testing ban deadlines of March 11, 2009 and March 11, 2013, as given under Recital 43 of the EU Cosmetic Regulation. It is also possible that animal data is accepted for the purpose of cosmetic safety assessment for some ingredients, if they are also used in other (non-cosmetic) consumer and industrial sectors, and have been tested on animals to fulfil requirements under other regulatory frameworks.

The SCCS Guidance on the Safety Assessment of Nanomaterials in Cosmetics (SCCS/1611/19) specifies the requirements for safety assessment of nanomaterials intended to be used as cosmetic ingredients in consideration of nano-specific properties and the animal testing bans.

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Detailed characterisation and identification of nanomaterials is an essential requirement of safety assessment. The data provided in a safety dossier therefore need to contain detailed characterisation in relation to the unequivocal/unambiguous identity and composition of the nanomaterial(s) that are intended for use in the final product. The characterisation must also include measurement of the important physicochemical parameters that are described in detail in the Guidance.

It is important that characterisation of nanomaterials is carried out using mainstream techniques with due consideration of the nano-aspects, and results are backed up by appropriate documentation. A particular challenge in regard to characterisation of nanomaterials is the fact that different analytical methods can yield different measurement values, e.g. particle size, because they can be based on very different principles for measurement of the same aspect. Preference should therefore be given to the use of standardised mainstream analytical methods. However, it is also important to note that currently there is no single method that can be regarded a 'gold' standard for characterisation of the different physicochemical parameters of a nanomaterial as such, nor is there one suited to fully assess a nanomaterial in a cosmetic product. The exact choice of appropriate analytical method(s) to measure a parameter will be dependent on the chemical composition and the physical form of individual nanomaterials.

In the first place, safety assessment of a nanomaterial used as cosmetic ingredient need to be driven by considerations of exposure, which should include aspects such as function and use of the particular nanomaterial and describe relevant exposure scenarios. The type and amount of external exposure (dermal, inhalation, oral) need to be described, and the systemic uptake by the relevant exposure route(s)/exposure scenario(s) determined. This means, information on the possibility of translocation through biological barriers (skin, gastrointestinal tract, lung) has to be provided by experimental data (e.g. dermal absorption studies), or by other convincing information (e.g. based on physicochemical properties). In the absence of experimental data for systemic exposure, default values will be used to describe the amount systemically available. If systemic availability is likely, consideration of toxicokinetics, especially uptake and distribution, as well as systemic effects have to be addressed, keeping in mind that toxicokinetics of nano form of a substance may differ from that of conventional chemical form of the same substance.

For the assessment of toxicity, the guidance provides a list of non-animal methods that could be used for nanomaterials while taking nano-specific aspects into consideration. The test design needs to be oriented on the relevant exposure scenario (oral, dermal, inhalation) using adequate context-specific doses. In the first instance, in vitro testing can be targeted to assess overt toxicity that might be exerted even at the port of entry (e.g. cytotoxicity, production of ROS, inflammation, cytokine induction, local genotoxicity). It is recommended that more than one assay is used for one specific endpoint/parameter to circumvent any limitations of the individual assay and to check for interference of the nanomaterial with the assay. If there is a potential for systemic uptake of the nanomaterial, systemic toxicity will need to be investigated. For in vitro tests addressing systemic effects, kinetic aspects (e.g. absorption via the relevant uptake route, dissolution rate in relevant body fluids, protein binding and protein corona formation, distribution) should also be taken into consideration to enable in vitro to in vivo extrapolation. For the investigation of systemic effects in tissues, 3D cell co-culture models and microfluidic models need to be described, and the use of ex-vivo models may provide further understanding of the systemic toxicity of nanomaterials. In this regard, the use of a battery of alternative testing methods will be more useful, where results are used together in a Weight-of-evidence approach.

Further aspects that are covered in the Guidance include considerations of different surface coatings of the same core nanomaterial, nano-carriers and nano-encapsulated materials, in silico modelling, grouping and read-across, immunotoxicity. Also included in the Guidance is a checklist for hazard identification (toxicological data) needed for safety evaluation of nanomaterials intended to be used in cosmetic products.

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Declaration of competing interest

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Further reading

. The guidelines in full may be read on the website of the European Commission's independent Scientific Committees: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_233.pdf