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EC Committee Publishes Guidance on Safety Assessment of Nanomaterials in Cosmetics

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On November 4, 2019, the European Commission's (EC) Scientific Committee on Consumer Safety (SCCS) published an updated *Guidance on the Safety Assessment of Nanomaterials in Cosmetics*. The Guidance updates SCCS's 2012 Guidance (SCCS/1484/12) on the safety assessment of nanomaterials in cosmetic products. It covers the main elements of safety assessment — general considerations (Section 2), material characterization (Section 3), exposure assessment (Section 4), hazard identification and dose-response characterization (Section 5), and risk assessment (Section 6). The Guidance includes key recommendations for the safety assessment of nanomaterials intended for use in cosmetics on the following topics:

- Definition: The regulatory definition of nanomaterial is provided in the

Cosmetic Regulation (EC) No. 1223/2009, under Article 2(1)(k). SCCS suggests that when assessing the safety of a material consisting of small particles, applicants should also take into account the EC's Recommendation (2011/696/EU). SCCS notes that "[w]here a new or an already-approved cosmetic ingredient fulfils the criteria for defining it as NM, it will be subject to safety assessment based on the data relevant to nano-scale properties."

- Material characterization: At a minimum, applicants must provide characterization data on all the specified parameters that are relevant to a given nanomaterial. According to the Guidance, the nanomaterial characterization needs to be carried out at the raw material stage, in the cosmetic formulation, and during exposure for toxicological evaluations. The Guidance notes that SCCS may request a detailed description of the production processes, any surface modifications, and the preparatory steps carried out for integrating the nanomaterials in the final cosmetic products as input into the safety assessment process.

- Exposure assessment: Safety assessment of nanomaterials follows the same procedure as for non-nanoscale ingredients, but with special considerations of the nanoscale aspects. According to the Guidance, SCCS is of the view that the method for calculating dermal and oral exposure to nanomaterials will not be substantially different from the calculation of exposure to conventional cosmetic ingredients. The Guidance notes that calculation of exposure to aerosols containing nanomaterials may be more challenging, however.

- Hazard identification/dose-response characterization: SCCS will require data from toxicological studies for local and — in case of systemic absorption — systemic effects. According to the Guidance, testing of nanomaterials for hazard identification/dose-response characterization must be carried out in consideration of the nano-related aspects.

- Safety assessment: The Guidance notes that historically, calculation of the margin of safety of a cosmetic ingredient has been based on a measured toxicological point of departure (POD), along with an estimate of internal exposure in terms of systemic exposure dose (SED). The Guidance acknowledges that with the European Union's ban on animal testing of cosmetic ingredients and/or products, derivation of POD_{sys} for systemic adverse effects of a new cosmetic ingredient may not be possible, or possible only in exceptional cases. Data obtained to comply with other non-cosmetic regulations should be used and submitted when available, however. For other cases, the applicant will need to assemble relevant information and data from different alternative (non-animal) methods and integrate the data to build an overall weight of evidence to support the safety of the cosmetic ingredient.

SCCS notes that due to the evolving nature of nanomaterials safety research, it may revise the Guidance in the future to take account of any new scientific knowledge.

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