

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Request for a guidance document: Guidance on Safety Assessment of Nanomaterials in Cosmetics

1. Background:

Nanotechnologies open new perspectives for useful innovation in cosmetics. A number of documents provide general guidance on the health risk assessment of manufactured nanomaterials (SCENIHR opinions on *the appropriateness of the risk assessment methodology in accordance with the technical guidance documents for new and existing substances for assessing the risks of nanomaterial* 2007; *Risk Assessment of Products of Nanotechnologies* 2009). Yet, experience with the assessment of specific substances is limited. The ongoing risk assessments being carried out by the European Commission Scientific Committee on Consumer Safety (SCCS) on three specific manufactured nanomaterials for their inclusion in Annex VII (ultraviolet (UV) filters) of the Cosmetics Directive (76/768/EEC), are the first instances in the EU and worldwide with regulatory implications.

This work has made possible the identification of a number of issues and questions regarding the types of information and data unique to nanomaterials that must form part of future submissions of safety dossiers. It has also highlighted the need for developing specific guidance for the development of similar, consistent and, to the extent possible standardised, safety evaluation dossiers of manufactured nanomaterials.

This will not only facilitate the submission of safety dossiers at present, but will also assist in the implementation of the provisions of article 16 of the Cosmetics Regulation (EC) No 1223/2009/ which will impose strict conditions and timelines for the notification and the assessment of cosmetic products containing nanomaterials on the responsible persons and the SCCS respectively, starting on January 2013.

On the basis of the evolving knowledge based on the health risk assessment of specific manufactured nanomaterials, the Commission considers appropriate to request the SCCS to develop guidance on the essential elements that would be required in a manufactured nanomaterial safety dossier i.e. physicochemical characterisation; toxicological evaluation, exposure assessment etc.

This guidance should be revised and updated as considered appropriate by the SCCS, taking into consideration scientific advances and growing experience on this matter.

2. Terms of reference:

On the basis of the present experience, the SCCS is requested to develop guidance on:

1. The essential elements that must form part of safety dossiers for the assessment of nanomaterials in cosmetic products, based on the data requirements for the pre-market notification listed in article 16 of Regulation (EC) No 1223/2009, i.e. taking into

account points 3a to 3f of article 16 (identification of the nanomaterial; specification; quantity; toxicological profile; safety data and exposure).

2. The possibility to develop criteria and conditions that would allow the safety assessment of nanomaterials on a category based approach rather than on a case-by-case basis.
3. The suitability of alternative methods already validated for the assessment of conventional chemical substances for the assessment of nanomaterials in light of the current (as of 2009) ban on animal testing in the EU.
4. The set of attributes unique to manufactured nanomaterials that will need to be addressed by newly developed and/or newly validated alternative methods for the testing of toxicological end points for which there will be a ban on the testing on animals after March 2013.

In elaborating this guidance, and taking into account the growing experience on the matter the SCCS is asked to consider all available documentation on the subject such as the SCCP scientific opinion¹ on safety of nanomaterials in cosmetic products; the documents issued by the OECD Working Party on Manufactured Nanomaterials²; the EFSA scientific opinion on guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain³.

5. Deadline:

The document should be finalised before the end of the current SCCS term (February 2012).

¹ Scientific Committee on Consumer Products (2007) SCCP - Opinion on the safety of nanomaterials in cosmetic products adopted by the SCCP after the public consultation on the 14th plenary of 18 December 2007, SCCP/1147/07. http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf

² OECD (2010) OECD Environment, Health and Safety Publications Series on the Safety of Manufactured Nanomaterials: Guidance Manual for the Testing of Manufactured Nanomaterials: OECD's sponsorship programme; first revision, 02 June 2010, ENV/JM/MON.

³ EFSA Scientific Committee; Scientific Opinion on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. EFSA Journal 2011;9(5):2140 [36 pp.]. Available online: www.efsa.europa.eu/efsajournal.htm