SCCS/1524/13
Revision of 27 March 2014

Scientific Committee on Consumer Safety

SCCS

MEMORANDUM on

"Relevance, Adequacy and Quality of Data in Safety Dossiers on Nanomaterials"

The SCCS adopted this opinion at its 4th plenary on 12 December 2013

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.
They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCCS

The Committee shall provide opinions on questions concerning all types of health and safety risks (notably chemical, biological, mechanical and other physical risks) of non-food consumer products (for example: cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products such as detergents, etc.) and services (for example: tattooing, artificial sun tanning, etc.).

Scientific Committee members

Ulrike Bernauer, Qasim Chaudhry, Pieter-Jan Coenraads, Gisela Degen, Maria Dusinska, David Gawkrodger, Werner Lilienblum, Andreas Luch, Elsa Nielsen, Thomas Platzek, Suresh Chandra Rastogi, Christophe Rousselle, Jan van Benthem.

Contact
European Commission
Health & Consumers
Directorate C: Public Health
Unit C2 – Health Information/ Secretariat of the Scientific Committee
Office: HTC 03/073 L-2920 Luxembourg
SANCO-C2-SCCS@ec.europa.eu

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This opinion has been subject to a commenting period of eight weeks after its initial publication. Comments received during this time have been considered by the SCCS and discussed in the subsequent plenary meeting. Where appropriate, the text of the relevant sections of the opinion has been modified or explanations have been added. In the cases where the SCCS after consideration and discussion of the comments, has decided to maintain its initial views, the opinion (or the section concerned) has remained unchanged. Revised opinions carry the date of revision.

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1. PREAMBLE

Nanotechnologies open new perspectives for useful innovation in cosmetics. However, manufactured nanomaterials may also have certain properties, interactions with biological systems, and/or effects that are different from conventional ingredients in insoluble bulk form with larger characteristic particle size. In the EU, the use of nanomaterials in cosmetic products is specifically covered under the Cosmetics Regulation (Regulation (EC) No 1223/2009). The Regulation provides a definition of nanomaterial, as well as a mechanism for notification, labelling, and safety evaluation of cosmetic products containing nanomaterials.

The risk assessment of specific nano substances is currently limited, and the ongoing risk assessments being carried out by the European Commission's Scientific Committee on Consumer Safety (SCCS) on manufactured nanomaterials represent the first examples in the EU and worldwide with regulatory implications. This ongoing 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 submissions of safety dossiers. These aspects have been detailed in the SCCS Guidance on *the Safety Assessment of Nanomaterials in Cosmetics* (SCCS/1484/12) to enable a consistency and, to the extent possible, standardisation of the safety evaluation dossiers of manufactured nanomaterials. The Nano-Guidance (SCCS/1484/12) covers the essential elements that would be required in a safety dossier on manufactured nanomaterial, i.e. physicochemical characterisation, toxicological evaluation, exposure assessment, and risk characterisation. The Guidance is also meant to facilitate submission of safety dossiers by the applicants, and assist the SCCS in the evaluation process and in the implementation of the provisions of article 16 of the Cosmetics Regulation (EC) No 1223/2009. Further notes in relation to nanomaterials are provided in the SCCS Notes of Guidance (SCCS/1501/12).

As mentioned in the Nano-Guidance (SCCS/1484/12), it is also intended for revision and updating as considered appropriate by the SCCS, taking into consideration scientific advances and growing experience on this matter. In this context, a number of issues have so far been noted by the SCCS during the evaluation of nanomaterials, especially in relation to the relevance, adequacy, and quality of the data presented in the safety dossiers. These have been briefly highlighted in the recently published "Memorandum on Scientific Evaluation and Opinions to be adopted by the SCCS" (SCCS/1517/13) which states that:

"*A specific problem is evident with regard to safety dossiers on nanomaterials. The supporting evidence submitted for a given nanomaterial under assessment is sometimes provided for materials with distinctly different size characteristics. Thus, a dossier may include information on e.g. non-nano forms, characterized by entirely different physico-chemical properties and morphological forms which do not necessarily correspond to the actual material used in cosmetic products*".

The current Memorandum is therefore aimed at highlighting the main considerations in relation to the relevance, adequacy and quality of the data presented in safety dossiers on nanomaterials. In this respect, it is also meant to provide further guidance and clarity to future applicants so that preparation and evaluation of the safety dossiers can proceed without an undue burden on the part of either the applicants or the evaluators in the Committee.

RELEVANCE, ADEQUACY AND QUALITY OF THE DATA IN SAFETY DOSSIERS ON NANOMATERIALS

1.1. It is important to highlight at the outset that nanomaterials, irrespective of the type, have a chemical as well as a physical/morphological form. Nanomaterials are generally marked by a greater surface area, certain distinctive physicochemical properties and by their distinct behaviour (e.g. particle agglomeration/aggregation and biokinetics), and potentially different biological interactions and effects, compared to conventional (i.e. non-nanoparticle containing) insoluble bulk ingredients with the same chemical composition. However, any nano-related properties and behaviour of nanomaterials are intrinsically linked to the physical integrity of the nano-structure of the material under consideration. Where a nanomaterial loses its nano-structure, e.g. by solubilisation in a formulation, test medium, or biological environment, it will no longer be expected to behave any differently from its non-nano (chemical) equivalent. However, where dissolution/solubility of a nanomaterial is claimed, sufficient supporting evidence needs to be provided.

1.2. Any material is characterized by its chemical composition and its physical aggregation state and structure/ phase. Consideration of both chemical and physical/morphological aspects is therefore important in relation to assessing the potential risk of any nanomaterial, its nano-related properties, behaviour, and effects. It is therefore important when data are presented in a nanomaterial safety dossier that both aspects are covered adequately. This means that safety of a nanomaterial must not be assumed or argued simply on the basis of its chemical composition alone. The same applies to the aspects relating to physical/morphological form.

1.3. It is important that a safety dossier on nanomaterial(s) contains sufficient data and supporting information to enable adequate risk assessment. The dataset should be complete in relation to physicochemical properties, exposure, toxicological effects, and safety evaluation, as indicated in the SCCS Nano-Guidance (SCCS/1484/12).

1.4. All data presented in a dossier should be presented in conjunction with a specific argument to what extent it provides a case in favour of the safe use of that same material. In these arguments all properties i.e. the chemical composition, the physical aggregation state and crystallographic/ grain structure need to be covered. For example, safety of a nanomaterial cannot be assumed on the argument that the bulk form of the materials is safe (and vice versa), without specific evidence to support it.

1.5. Another important aspect relates to inclusion of the data and information that are relevant to the assessment of the nanomaterial(s) under evaluation. The inclusion of irrelevant data – for example from unrelated materials, or materials with unknown characterisation – will waste valuable time and resources on the part of the applicant and the Committee. Also, such 'bulking up' of the dossier does not help or influence the overall outcome of evaluation by the Committee.

1.6. If data from other materials are included (e.g. a bulk material as a comparator), it should be clearly defined and segregated, and not presented mixed-up with specific data on nanomaterial(s) under evaluation.

1.7. Each submission should contain comprehensive data from applicants' studies as well as from the open literature. To facilitate the evaluation, the contents should be divided into general aspects and specific aspects. The submission should be in the form of a searchable text or pdf file with page numbering and appropriate indexing of the

contents and supporting studies and publications into clear sections and separated appendices/annexes. Scanned files that are not searchable, and embedded files within documents will not be accepted.

1.8. Unless there is a close similarity between different nanomaterials, it is advisable to include a complete set of supporting data on each nanomaterial, rather than presenting several different nanomaterials in a single, patchy, and data-poor submission. If more than one nanomaterial is included in the dossier, the basis for 'close similarity' to allow data read-across between the nanomaterials must also be provided. This should not only relate to the chemical composition of the core nanomaterial, but also the physical/morphological features and other characteristics, such as surface coating or other modifications. The guidance on the types of data important for safety evaluation of nanomaterials in cosmetic products is detailed in the SCCS Nano-Guidance (SCCS/1484/12).

1.9. As explained in the SCCS Nano-Guidance (SCCS/1484/12), risk assessment of nanomaterials is carried out by the Committee on a case-by-case basis, and arguments based on history of safe use as a surrogate to test data are not acceptable for nanomaterials.

1.10. The SCCS is bound by the rules of procedure, and can only give an opinion in line with the boundaries set by the Commission in terms of a specific mandate. The Committee forms its opinions in consideration of the data provided as part of a submission by the applicants, as well as other relevant information from the published scientific literature. It is therefore important to note that the Committee cannot give any generalised opinion on nanomaterial(s) for which data are neither provided in the submission, nor available in the scientific literature.

1.11. Generally, only data from validated tests are accepted by SCCS. It should, however, be of note that the currently available *in vitro* tests are generally designed and validated for chemical substances in non-nano forms, and therefore data from these tests cannot be accepted for nanomaterials as such. Further supporting evidence should be provided to demonstrate that the tests were carried out with due consideration of the nano aspects as described in the SCCS Nano-Guidance (SCCS/1484/12).

1.12. Data from valid *in vitro* tests may be accepted as additional supporting evidence for hazard identification, provided that there is evidence to show that the tests were appropriately conducted in consideration of the nano-related aspects (see Nano-Guidance (SCCS/1484/12)).

1.13. The data provided in a safety dossier must also be accompanied with detailed description of the materials and methods used, and appropriate statistical indicators of the quality and reliability of the results.

1.14. In pursuance of the Cosmetics Regulation (EC) No 1223/2009, Article 16 (3) a) "identification of the nanomaterial…", the data should provide detailed characterisation in relation to the unequivocal/unambiguous identity and composition of the nanomaterial(s) that are intended for use in the final product.

1.15. In pursuance of the Cosmetics Regulation (EC) No 1223/2009, Article 16 (3) b) "specification of the nanomaterial...", the data should provide the physicochemical parameters listed in the SCCS Guidance on the Safety Assessment of Nanomaterials in Cosmetics (SCCS/1484/12).

1.16. Any data relating to testing of nanomaterials for hazard identification/ dose response characterisation must be derived in consideration of the nano-related aspects as described in the SCCS Nano-Guidance (SCCS/1484/12).

1.17. Provision of insufficient data, or data from inadequate tests, will lead to non-acceptance by the Committee, or recommendation for a higher safety margin than that normally applied.

1.18. Irrespective of the presence of nanomaterials, the existing regulations and the SCCS Notes of Guidance (SCCS/1501/12) must be followed.

2. CONCLUSIONS

The relevance, adequacy and quality of the data presented in a dossier are of utmost importance in relation to the smooth and transparent evaluation of safety of nanomaterials used in cosmetic products. In this regard, the key message in this Memorandum is that the data provided in a dossier in support of nanomaterial safety must be relevant to the types of nanomaterials under evaluation, sufficiently complete, and of appropriate standards to allow adequate risk assessment. Further details on the aspects to be considered in relation to safety assessment of nanomaterials in cosmetic products are provided in the SCCS Nano-Guidance (SCCS/1484/12).

3. REFERENCES

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