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Scientific Committee on Consumer Safety
Email: **SANCO-C2-SCCS @ ec.europa.eu**

To Whom It May Concern:

RE: Comments on Memorandum on "Relevance, Adequacy and Quality of Data in Safety Dossiers on Nanomaterials" by the Scientific Committee on Consumer Safety (SCCS)

These comments are submitted on behalf of the PETA International Science Consortium, Ltd., which directs the scientific and regulatory expertise of PETA U.S. and its international affiliates to promote reliable and relevant strategies that eliminate the use of animals in experiments and coordinates the affiliates' funding of nonanimal method development. We thank the Scientific Committee on Consumer Safety (SCCS) for the opportunity to comment on the "Relevance, Adequacy and Quality of Data in Safety Dossiers on Nanomaterials". We have the following comments that we hope will help accomplish the goal of this memorandum to provide further guidance and clarity to future applicants regarding preparation and evaluation of the safety dossiers on nanomaterials:

- We agree with the comments made by the SCCS in this memorandum regarding the evaluation of nanomaterials used in cosmetic products. However, characterization of nanomaterials should not be limited to their pristine form. Rather, thorough analysis of nanomaterial characteristics should be conducted throughout the process of toxicity evaluation.

- Regarding comment #1.11 in the memorandum, it should be stressed that existing validated *in vitro* tests are well suited for assessing nanomaterial effects, provided that relevant controls and characterization data are included. The SCCS Nano-Guidance (SCCS/1484/12) that this memorandum refers to lists the *in vitro* methods that are used for traditional chemicals along with recommendations on parameters to consider while testing nanomaterials. In the absence of scientific evidence proving otherwise, the *in vitro* assays could provide valuable information regarding the toxicity of nanomaterials. For example, the *in vitro* cell transformation assays recently recommended by the European Union Reference Laboratory for alternatives to animal testing (EURL ECVAM), could potentially predict the carcinogenic potential of nanomaterials when appropriate controls and characterization parameters are used . Also, while no official validations of the bovine corneal opacity and permeability or isolated rabbit eye tests have been performed for nanomaterials, there is no scientific basis against the use of existing protocols for solid substances. Therefore, we recommend rephrasing comment #1.11 to more accurately reflect the nano-guidance (SCCS/1484/12).

- We agree with comment #1.13 in the memorandum, stating that a detailed description of the materials and methods should be provided with the data, and we suggest that the limitations of the techniques used in the studies should also be described. For instance, dynamic light scattering is widely used to assess hydrodynamic diameter of nanomaterials; however, presence of salts or aggregates could skew the size measurement.

Adding the above information to this memorandum would further help guide applicants and evaluators in the Committee on preparation and evaluation of safety dossiers on nanomaterials.

Sincerely,

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