EXPLANATORY NOTE ON THE MODIFICATIONS OF THE SCCS/SCHER/SCENIHR OPINION ON USE OF THE THRESHOLD OF TOXICOLOGICAL CONCERN (TTC) APPROACH FOR HUMAN SAFETY ASSESSMENT OF CHEMICAL SUBSTANCES WITH FOCUS ON COSMETICS AND CONSUMER PRODUCTS

This note sets out the rationale for the modifications made to the joint opinion of the European Commission Scientific Committees on Consumer Safety (SCCS), on Health and Environmental Risks (SCHER) and on Emerging and Newly Identified Health Risks on the Use of the Threshold of Toxicological Concern (TTC) Approach for Human Safety Assessment of Chemical Substances with focus on Cosmetics and Consumer Products following a public consultation conducted between 24 November 2008 to 2 January 2009.

Introduction

The European Commission requested the Scientific Committees to critically review the available scientific literature and to assess whether the TTC approach is appropriate for the human health risk assessment of chemical substances, with a focus on chemicals used in Cosmetics and Consumer Products. A Working Group with members of all three Committees as well as external experts was set up for development of the document. The WG produced a draft opinion which was discussed and adopted by the three Committees in November 2008 as a preliminary opinion suitable for public consultation (pre-consultation opinion).


Results/participation

By the deadline, DG SANCO received a total of 21 contributions. A targeted hearing with the stakeholders who contributed to the public consultation took place on 24 September 2009. This hearing aimed to allow for a further exchange of views between the members of the Working Group and the stakeholders who contributed to the public consultation.

All documents received during the public consultation and the hearing were reviewed by the Working Group and carefully considered if they fulfilled the following conditions: (i) concerned issues that are under the remit of the Scientific Committees, (ii) referred directly to the content of the report and was related to the issues addressed in the report (iii) contained specific comments and suggestions on the scientific basis of the opinion, (iv) had the potential to add to the preliminary opinion of Scientific Committees.
Modifications to the opinion

Due to the prolonged work on this opinion, changes to the setup of the Working group caused by the renewal of the Scientific Committees in 2009 and the availability of new information in the general literature and in the context of the opinion on the use of the TTC approach in the food area, developed by EFSA in parallel, the pre-consultation draft has been subject to extensive changes. Although comments received during the public consultation and the hearing, when fulfilling the criteria above, were taken into account during the revision, in this particular case, due to the general redrafting, it is not possible to document individual modification that have been made based on certain comments.