GUIDANCE ON A HARMONISED APPROACH TO THE DEVELOPMENT AND USE OF OVERALL EXPOSURE ESTIMATES IN ASSESSING THE SAFE USE OF CMR SUBSTANCES IN COSMETIC PRODUCTS

I. Background

1. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products[1] (Cosmetics Regulation) contains in its Article 15 provisions on the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR substances) under Part 3 of Annex VI to Regulation (EC) 1272/2008[2]. These provisions apply from 1 December 2010.

2. As a general rule, the substances classified as CMR substances of category 1A, 1B and 2 under Part 3 of Annex VI to Regulation (EC) 1272/2008 are prohibited for use in cosmetic products. This ban is automatic as from the date of application of their classification under Regulation (EC) No 1272/2008.

3. However, exceptions to this rule are foreseen by the Cosmetics Regulation. Indeed, a substance classified as a CMR substance of category 2 may be used in cosmetic products where the substance has been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found safe for use in cosmetic products on the basis of the data submitted.

4. Also, CMR substances of category 1A or 1B may be used in cosmetic products by way of exception where, subsequent to their classification as CMR substances of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008, all of the following conditions are fulfilled:

   (a) they comply with the food safety requirements as defined in Regulation (EC) No 178/2002 of the European Parliament and the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;[3]

   (b) there are no suitable alternative substances available, as documented in an analysis of alternatives;

   (c) the application is made for a particular use of the product category with a known exposure; and

   (d) they have been evaluated and found safe by the SCCS for use in cosmetic products, in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, taking particular account of vulnerable population subgroups.

II. Scope and objectives

5. Article 15, paragraph 3 of the Cosmetics Regulation foresees that the Commission shall ensure that appropriate guidance is developed with the aim of enabling a

[1] OJ L 342, 22.12.2009, p. 59.
[2] OJ L 353, 31.12.2008, p. 1.
[3] OJ L 31, 1.2.2002, p. 1.

harmonised approach to the development and use of overall exposure estimates in assessing the safe use of CMR substances.

6. To authorise the use of CMR substances of category 1A or 1B in cosmetic products, one of the conditions to be fulfilled is that they have been evaluated and found safe by the SCCS for use in cosmetic products, in particular in view of exposure to cosmetics products and taking into consideration the overall exposure from other sources and vulnerable population subgroups.

7 On a case by case basis and at the request of the SCCS, it may also be necessary to perform an overall exposure from other sources for CMR 2 substances. Therefore the procedure developed below for the overall exposure assessment of CMR 1A and 1 B substances should, where necessary, also apply to CMR 2 substances (condition (d) only).

8. Appropriate consultations with the SCCS and other relevant stakeholders have been carried out in order to develop this guidance. In addition, administrative agreements have been established with relevant EU Agencies - European Chemicals Agency (ECHA), European Food Safety Authority (EFSA), European Medicines Agency (EMA) - to ensure the appropriate exchange of data between them and the SCCS Secretariat.

III. Procedure

9. The aim of this guidance is to outline the mechanisms necessary for ensuring the generation and the exchange of the appropriate data for the assessment by the SCCS of the overall exposure to a CMR 1A or 1B substance stemming from other sources than cosmetics (such as food, biocides, etc.).

10. When a substance of interest for the industry is indicated in the Registry of Intentions for the purpose of its harmonised classification as CMR substance under Part 3 of Annex VI to Regulation (EC) No 1272/2008, it is for the industry to inform the Commission in due time of its intention to defend a substance under discussion for future (re)classification as CMR substance, so as to allow that any possible derogation measure is adopted by the Commission within 15 months following the adoption of the classification as CMR substance.

11. The Commission responsible Services should inform the SCCS that the industry intends to defend the substance. They should also inform the Member States of this intention, so that any relevant data available in public or state laboratories, or elsewhere, may be considered for the scientific assessment. In parallel, they may also organise a call for scientific data from anyone holding or being aware of further relevant information, in order to gather additional scientific data.

12. It is the industry's responsibility to demonstrate that the first three conditions (a), (b) and (c) for derogation laid down in Article 15 paragraph 2 of Cosmetics Regulation are fulfilled. For justifying compliance with each of the above conditions, the industry should submit appropriate dossiers for examination by the Commission responsible Services.

13. The Commission responsible Services should verify the compliance with the food safety requirements, where necessary by consulting the EFSA and the absence of suitable alternative substances and the fact that the application is limited for a particular use of the product category with a known exposure, where necessary by consulting the COSCOM.

14. Subsequently, the procedure for the exchanges of data between the relevant entities can be started as regards to the overall exposure assessment by the SCCS (condition d). Requests for data sharing with the relevant EU Agencies (ECHA, EFSA and EMA[4]) should be initiated and managed by the SCCS Secretariat. On a case by case basis, the Commission responsible Services can, where relevant, ask for data to Member States or third countries.

15. The "Declaration of Commitment by the Commission with respect to security aspects for ECHA's information systems" has been signed by the responsible Commission Services[5] and sets up the conditions under which exchange of confidential data from REACH dossiers can be ensured with ECHA.

16. Upon request by the SCCS Secretariat, the Commission responsible Services should grant access to relevant data in REACH registration dossiers to a designated SCCS expert who adheres to the security rules for users of ECHA's Information System.

17. The extraction of relevant data from REACH dossiers and their processing to establish aggregated exposure levels should be completed by the designated SCCS expert within the secure room of the Commission responsible Services and in accordance with all applicable security rules. In case an evaluation of the CMR substance has already been completed under REACH, exposure levels that have been established can also be used straightaway where appropriate.

18. The EFSA should be consulted by the SCCS Secretariat to provide, if available, data or estimates on exposure from food and other relevant sources.

19. Additionally, the EMA could be consulted by the SCCS Secretariat on a case by case basis on exposure from substances used as pharmaceuticals.

20. The applicant should include in their submission all exposure information they have. In addition to the exposure information gathered as mentioned above, e.g. exchange of data with the Agencies, public call for information, consultation with Member States, the SCCS will consider the exposure information provided by the applicant.

21. It is necessary that the exchange of data takes place in a smooth and timely manner as, for CMR 1A and 1B substances, the measure necessary for the derogation must be adopted by the Commission within 15 months starting from listing of the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

22. The SCCS, once it has received the scientific data from ECHA, EFSA, EMA and has taken into consideration the data submitted by the industry and other available sources (such as information gathered from Member States or following public consultation), shall assess the specific CMR substance(s) for safety of use in cosmetic products

[4] The need to consult EMA will be checked by the Commission on a case by case basis.
[5] DG ENTR and DG ENV co-managed the REACH legislation.

taking into account the overall exposure from other sources and vulnerable population groups within a timescale of at least six months for finalising their Opinion after an adequate submission and a complete set of exposure data is received.

23. It should be noted that, where the work of other scientific/regulatory bodies contains information on exposure to humans via the environment, this may have been incorporated in their overall estimates of exposure. However, Cosmetic Regulation (EC) No 1223/2009 only covers the aspects of safety to human health. As indicated in recital 5 of that Regulation, the environmental concerns that substances used in cosmetic products may raise are considered through the application of Regulation (EC) No 1907/2006 (REACH).[6]

24. As regards the scientific risk assessment of CMR substances of categories 1A and 1B used in cosmetics, the SCCS will determine the most appropriate methodology for their safety evaluation based on the best scientific knowledge and taking into account the exposure from the specific uses in cosmetic products and the overall exposure from other sources.

25. In order to provide transparency on the applied methodology and guidance to the industry, the SCCS should develop and incorporate this methodology within the next revision of its "Notes of guidance[7] for the testing of cosmetic substances and their safety evaluation".

IV. Final observations

26. This document is only meant to provide guidance for a harmonised approach to the development and use of overall exposure estimates in assessing the safe use of CMR substances in cosmetic products and it is by no means binding.

27. The SCCS evaluation will not automatically trigger action under any legislation other than the Cosmetics legislation. The SCCS conclusions will be publicly available.

28. This document may be revised in the future in the light of further scientific developments.

[6] OJ L 396, 30.12.2006, p. 1.
[7] SCCS/1501/2 of 11 December 2012.