Scientific Committee on Consumer Safety

SCCS

Memorandum on Endocrine Disruptors

The SCCS adopted this memorandum at its 8th plenary meeting

on 16 December 2014

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.).

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ISSN 1831-4767 ISBN 978-92-79-35662-9
Doi: 10.2772/52077 ND-AQ-14-015-EN-N

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http://ec.europa.eu/health/scientific_committees/consumer_safety/index_en.htm

ACKNOWLEDGMENTS

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Keywords: SCCS, memorandum, endocrine disruptor, EC Regulation 1223/2009.

to be cited as: SCCS (Scientific Committee on Consumer Safety), memorandum on Endocrine Disruptors, SCCS/1544/14, 16 December 2014.

MEMORANDUM

REGULATION (EC) No 1223/2009 on cosmetic products states in Article 15 No. 4. "When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties."

The European Commission established two expert groups with orientation on various scientific and policy aspects related to this topic. The "Ad hoc group of Commission Services, EU Agencies and Member States" focused on policy issues. The "Endocrine Disruptors Expert Advisory Group" reflected on scientific issues relevant to endocrine disruptors, not specific to any regulatory framework, including advice/orientation on scientific criteria for the identification of endocrine disrupting chemicals. In both groups, industry associations, non-governmental organisations, European Commission staff, EU Agencies and Member States were represented. The outcome of "the Endocrine Disruptors Expert Advisory Group" meetings is summarised in two reports [JRC 2013a, b].

For preparing the definition of the criteria in the EU, the Commission asked the European Food Safety Authority (EFSA) to deliver a Scientific Opinion on the hazard assessment of endocrine disruptors (EDs) which was published in 2013 [EFSA 2013].

ECHA has set up a working group of experts on ED to deal with this issue under REACH regulation. Endocrine disruptors may be identified on a case-by-case basis as substances of very high concern (SVHCs), where there is scientific evidence of probable serious effects to human health or the environment, which give rise to an equivalent level of concern to CMR or PBT/vPvB substances (under Article 57(f) of REACH Regulation).

In June 2014, the EU Commission initiated a roadmap defining criteria for identifying endocrine disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation. However, also other sectorial legislations were mentioned, and the various approaches foreseen for the regulation of EDs in different pieces of legislation were compiled in the roadmap including the cosmetics sector. In the context of the implementation of the plant protection product regulation and the biocidal products regulation, a public consultation was started (period of consultation from 26.09.2014 to 16.01.2015). This Memorandum is also meant as the SCCS's contribution to that public consultation.

By Commission Decision of 5 August 2008, an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment was set up (2008/721/EC) and three Scientific Committees were established. The Scientific Committee on Consumer Safety (SCCS) shall provide opinions on questions concerning all types of health and safety risks of non-food consumer products (for example: cosmetic products and their ingredients, etc.) and services.

The "*Notes of Guidance for Testing of Cosmetic Ingredients and Their Safety Evaluation by the SCCS*" are compiled by the members of the SCCS. The document is designed to provide guidance to public authorities and cosmetic industry, in order to improve harmonised compliance with the actual cosmetic EU legislation. It contains relevant information on the different aspects of testing and safety evaluation of cosmetic substances in Europe. The "Notes of Guidance" are regularly revised and updated in order to incorporate the progress of scientific knowledge [SCCS/1501/12].

The SCCS, in accordance with EFSA and JRC, endorses the WHO/IPCS definition:

*"An **endocrine disruptor** (ED) is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations".*

It is emphasized that an ED is defined by a set of three criteria: the presence of *i)* an adverse effect in an intact organism or a (sub)population; *ii)* an endocrine activity; and *iii)* a plausible causal relationship between the two. Moreover, the SCCS supports the conclusions of EFSA that: *"Critical effect, severity, (ir)reversibility and potency aspects are part of the hazard characterisation of EDs. To inform on risk and level of concern for the purpose of risk management decisions, risk assessment (taking into account hazard and exposure data/predictions) makes best use of available information. EDs can therefore be treated like most other substances of concern for human health and the environment, i.e. be subject to risk assessment and not only to hazard assessment."* [EFSA 2013].

This position is in agreement with past and present practices of the SCCS and its predecessors (SCCP and SCCNFP) with regard to a safety assessment for substances with endocrine disrupting properties. Examples are organic UV filters with weak estrogenic activity *in vitro* and *in vivo* in mice. In 2001 the SCCNFP issued an opinion on the matter and after analysis of all the available information, the SCCNFP concluded that the UV filters used in cosmetic sunscreen products allowed on the EU market, showed no estrogenic effects that could adversely affect human health [SCCNFP/0483/01]. More recent safety assessments of the UV filters 4-methylbenzylidene camphor [SCCP/1183/08] and 3-benzylidene camphor [SCCS/1513/13] used the NOAELs derived from animal studies in the MoS calculations, after careful evaluation of possible endocrine-related adverse effects as well as human exposure data. Ingredients used as preservatives or for other functions in cosmetic products have been evaluated by SCCP and SCCS, *i.e.* parabens [SCCP/1017/06, SCCP/1183/08, SCCS/1348/10, SCCS/1446/11, SCCS/1514/13], triclosan [SCCP/1192/08, SCCS/1414/11], homosalate [SCCP/1086/07], and cyclomethicone [SCCS/1241/10]. These opinions came to the conclusion that endocrine activities were not the critical endpoint for assessing the safety of these substances. Nonetheless, these opinions illustrate the types of *in vitro* studies suitable to detect different endocrine activities and *in vivo* studies relevant for detection of related developmental and reproductive toxicity. Thereby these opinions provide some guidance on the types of data needed in a scientific evaluation of substances with endocrine disrupting properties.

Due to the ban on animal testing for cosmetic ingredients effective since 2013, it will be extremely difficult in the future to differentiate between a **potential ED** and an **ED**, if the substance is registered *solely* for use in cosmetic products [Factsheet ECHA-14-FS-04-EN, http://echa.europa.eu/documents/10162/13628/reach_cosmetics_factsheet_en.pdf]. Yet, for substances registered under REACH and also for other (mixed) uses, crucial information from animal tests is necessary for the time being.

The replacement of animal test methods by alternative methods in relation to complex toxicological endpoints remains scientifically difficult, despite the additional efforts launched at various levels [SCCS/1294/10, Adler et al. 2011, JRC 2014]. With regard to substances with endocrine activity (potential endocrine disruptor), the assessment of their impact to human health without animal data remains a challenge.

REFERENCES

Adler S, Basketter D, Creton S, Pelkonen O, van Benthem J, Zuang V, Andersen KE, Angers-Loustau A, Aptula A, Bal-Price A, Benfenati E, Bernauer U, Bessems J, Bois FY, Boobis A, Brandon E, Bremer S, Broschard T, Casati S, Coecke S, Corvi R, Cronin M, Daston G, Dekant W, Felter S, Grignard E, Gundert-Remy U, Heinonen T, Kimber I, Kleinjans J, Komulainen H, Kreiling R, Kreysa J, Leite SB, Loizou G, Maxwell G, Mazzatorta P, Munn S, Pfuhler S, Phrakonkham P, Piersma A, Poth A, Prieto P, Repetto G, Rogiers V, Schoeters G, Schwarz M, Serafimova R, Tähti H, Testai E, van Delft J, van Loveren H, Vinken M, Worth A, Zaldivar JM (2011). Alternative (non-animal) methods for cosmetics testing: current status and future prospects-2010. Archives of Toxicology 85(5), 367-485

EFSA (2013). Scientific Opinion on the hazard assessment of endocrine disruptors: scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013;11(3):3132. European Food Safety Authority. Available at:
http://www.efsa.europa.eu/en/efsajournal/doc/3132.pdf

JRC (2013a). JRC Scientific and Policy Reports: Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances. Report of the Endocrine Disruptors Expert Advisory Group (Munn S & Goumeneau M, Eds.), Report. EUR 25919 EN (2013).
Available at:
http://ihcp.jrc.ec.europa.eu/our_activities/food-cons-prod/endocrine_disrupters/jrc-report-scientific-issues-identification-endocrine-disrupting-substances

JRC (2013b). JRC Scientific and Policy Reports: Thresholds for endocrine disruptors and related uncertainties. Report of the Endocrine Disruptors Expert Advisory Group (Munn S & Goumeneau M, Eds.), Report. EUR 26068 EN (2013).
Available at:
https://ec.europa.eu/jrc/sites/default/files/lb-na-26-068-en-n.pdf

JRC (2014). JRC Scientific and Policy Reports: Alternative methods for regulatory toxicology – a state-of-the-art review. A. Worth, J. Barroso, S. Bremer, J. Burton, S. Casati, S. Coecke, R. Corvi, B. Desprez, C. Dumont, V. Gouliarmou, M. Goumenou, R Gräpel, C. Griesinger, M. Halder, A. Janusch Roi, A. Kienzler, F. Madia, S. Munn, M. Nepelska, A. Paini, A. Price, P. Prieto, A. Rolaki, M. Schäffer, J. Triebe, M. Whelan, C. Wittwehr, V. Zuang.
Available at:
http://bookshop.europa.eu/en/eurl-ecvam-status-report-on-the-development-validation-and-regulatory-acceptance-of-alternative-methods-and-approaches-2013-april-2014--pbLBNA26702/

SCCNFP/0483/01: Opinion on the Evaluation of Potentially Estrogenic Effects of UV-filters adopted by the SCCNFP during the 17th Plenary meeting of 12 June 2001

SCCP/1017/06: Opinion on Parabens (Colipa n° P82), *adopted by the SCCP during the 9th plenary meeting of 10 October 2006*.

SCCP/1086/07: Opinion on Homosalate (Colipa n° S12), *adopted by the SCCP during the 11th plenary meeting of 21 March 2007*.

SCCP/1183/08: Opinion on 4-Methylbenzylidene camphor, 4-MBC (Colipa n° P82), *adopted by the SCCP during the 16th plenary of 24 June 2008*.

SCCP/1184/08: Opinion on Parabens (Colipa n° S60), *adopted by the SCCP during the 16th plenary of 24 June 2008*.

SCCP/1192/08: Opinion on Triclosan (Colipa n° P32), *adopted by the SCCP during the 19th plenary meeting of 21 January 2009*.

SCCS/1501/12: The SCCS's notes of guidance for the testing of cosmetic substances and their safety evaluation 8th revision. *The SCCS adopted this opinion at its 17th plenary meeting of 11 December 2012.*
Available at:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_006.pdf

SCCS/1241/10: Opinion on Cyclomethicone – Octamethylcyclotetrasiloxane (Cyclotetrasiloxane, D4) and Decamethylcyclopentasiloxane (Cyclopentasiloxane, D5), *adopted by the SCCS during the 7th plenary meeting of 22 June 2010*.

SCCS/1294/10: Memorandum on alternative test methods in human health safety assessment of cosmetic ingredients in the European Union, *adopted by the SCCS during the 5th plenary meeting of 8 December 2009*.

SCCS/1348/10: Opinion on Parabens (Colipa n° P82), *adopted by the SCCS during the 9th plenary meeting of 14 December 2010.*

SCCS/1414/11: Opinion on Triclosan (Colipa n° P32) – Addendum to the SCCP opinion on Triclosan (SCCP/1192/08) from January 2008; *adopted by the SCCS during the 10th plenary meeting of 22 March 2011*.

SCCS/1446/11: Clarification on Opinion SCCS/1348/10 in the light of the Danish clause of safeguard banning the use of parabens in cosmetic products intended for children under three years of age, *adopted by the SCCS by written procedure on 10 October 2011.*

SCCS/1513/13: Opinion on 3-Benzylidene camphor (Colipa n° S61), *adopted by the SCCS during the 2nd plenary meeting of 18 June 2010.*

SCCS/1514/13: Opinion on Parabens - Updated request for a scientific opinion on propyl- and butylparaben (Colipa n° P82), *adopted by written procedure on 3 May 2013.*