



Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety

Comments from the Norwegian Scientific Committee for Food Safety (VKM) on various position documents related to risk assessment of parabens in cosmetic products

Opinion of the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of the Norwegian Scientific Committee for Food Safety

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Contributors

Persons working for VKM, either as appointed members of the Committee or as *ad hoc* experts, do this by virtue of their scientific expertise, not as representatives for their employers. The Civil Services Act instructions on legal competence apply for all work prepared by VKM.

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Assessed by

The answer to the request from the Norwegian Food Safety Authority has been provided by the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of VKM.

Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics*:

Inger-Lise Steffensen (Chair), Jan Alexander, Knut Helkås Dahl, Berit Granum, Ragna Bogen Hetland, Trine Husøy, Jan Erik Paulsen, Vibeke Thrane.

Scientific coordinator from the secretariat

Tor Øystein Fotland

***Conflict of interest:** Panel member Tore Sanner declared an interest as he has chaired the Working Group preparing the SCCS opinion on parabens (SCCS/1348/10) and the SCCS opinion “Clarification on Opinion SCCS/1348/10 in the light of the Danish clause of safeguard banning the use of parabens in cosmetics intended for children under three years of age”. Panel member Mona-Lise Binderup declared an interest since her employer, the National Food Institute, Technical University of Denmark, has given advice to Danish authorities on the safety of parabens in cosmetics. Tore Sanner and Mona-Lise Binderup have not participated in this opinion from VKM.

Background

The European Commission received on 21 March 2011 the notification of a decision taken by the Minister of the Environment in Denmark to ban propyl and butyl parabens, their isoforms and their salts in cosmetic products for children up to three years of age, in light of article 12 of the Cosmetic Directive (1). The ban entered into force on 15 March 2011. The Danish ban on these parabens opened the question of whether the same measure should be taken at EU level or not. The Commission's Service therefore requested of the Scientific Committee on Consumer Safety (SCCS) under the European Commission a position on scientific justification for the Danish measure. The SCCS gave its opinion in the document "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", SCCS/1446/11 (2). Thereafter, the Danish Ministry of the Environment in Denmark (3), Agence française de sécurité sanitaire des produits de santé (AFSSAPS) in France (4) and Santé Belgique (personal communication) in Belgium (5) gave their comments on the SCCS/1446/11 document.

Terms of reference

The Norwegian Scientific Committee for Food Safety (VKM) Scientific Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics was requested by the Norwegian Food Safety Authority (Mattilsynet) to provide general comments on the document from SCCS (2) and the major objections raised by Denmark, France and Belgium in the documents mentioned above (3-5), and especially to comment on whether these objections are of a nature that require an immediate new assessment by SCCS.

Assessment

The responsibility of VKM is risk assessment, and not risk management or political decisions, and VKM will therefore limit its comments to the most important questions related to the risk assessment only.

Inclusion of sunscreens in the exposure assessment of parabens for children

VKM agrees with the comment from Denmark and France that the use of sunscreens should be included in the exposure calculations of parabens to children of the age group up to 3 years if there are data available to do so. VKM is of the opinion that the use of sunscreens also on body areas that can be covered by clothing is a realistic scenario. Therefore, it should be included in the exposure assessment, rather than being excluded on the grounds of it being product misuse because it is recommended that children of this age should not be exposed to direct sunlight. Denmark (3) lists three studies from Sweden, Australia and Canada documenting that 59-93% of children below 5 years of age use sunscreen. However, to be able to include the contribution from sunscreen into the exposure assessment, data on which parabens and concentrations are used in the sunscreens, body area (only face and hands, or the whole body) that is treated with sunscreen, the frequency of use etc., must also be available. If such data are not yet available in Europe, they should be obtained by research.

Dermal absorption of parabens from cosmetics applied on damaged skin in the nappy area

VKM agrees with AFSSAPS' comment (4) that the use of cosmetic products on damaged skin caused by dermatitis in the nappy zone should be included in the exposure calculations of parabens for children of the age group up to 3 years. It is a very likely scenario that parents use cosmetic products such as body lotions on this area under the nappy also in cases with nappy dermatitis. VKM also agrees that in such situations occlusion under a nappy is likely to lead to higher absorption levels than normally reached without occlusion of intact skin. However, VKM finds the suggested 100% absorption to be unrealistic as a worst case scenario. Such a situation will be only temporary and of relatively short duration. SCCS used the value 3.7% for dermal absorption based on three *in vitro* studies because of lack of human *in vivo* skin absorption data. This value is already conservative, as described by SCCS (2; 6).

VKM agrees with the statement from SCCS that high quality *in vivo* studies of dermal absorption of the various parabens in humans should be provided by the cosmetic industry, since the available data from rats may not be sufficient to evaluate human skin absorption.

Conversion factors (skin surface area/body weight ratio)

The default safety factor of 100 is normally meant to cover interspecies differences (factor 10) and interindividual differences (factor 10) in toxicokinetics and toxicodynamics. The default interindividual differences in toxicokinetics and toxicodynamics are $3.2 \times 3.2 = 10$. AFSSAPS was concerned that the factor 10 was not accommodating an additional factor for differences in skin surface area/body weight (SSA/BW) ratio between children and adults. The paper referred to by France published by Renwick 1998 (7), and the consensus summary paper from a workshop on the applicability of the ADI to infants and children (8), concluded that in general there is no need for an additional uncertainty factor for children in setting ADIs. This view was included in the SCCS's Note of guidance for the testing of cosmetic ingredients and their safety evaluation (pages 57-58) (9). Since the difference between SSA/BW for children and adults varied from 1.3 fold for 10 year old children to 2.3 fold at birth, and the toxicokinetic factor for interindividual variability was higher (i.e. 3.2), SCCS concluded that in general there is no need for an additional uncertainty factor for children when intact skin is involved. However, it may be necessary to evaluate this on a case by case basis. VKM suggests that it might be timely to review this issue in light of any new data published after 1998 about differences between adults and children. This is particularly important in cases where exposure takes place through dermal absorption, and for effects especially on complex organ systems such as nervous, reproductive, endocrine and immune systems.

Insufficient data available on metabolism of parabens in children

The comments from Belgium (5) relate to the lack of good data on metabolism of parabens, i.e. glucuronidation and sulfate ester formation, which play critical roles in the inactivation and elimination of free parabens in skin and systemic circulation. However, based on the limited information available no quantitative conclusions can be drawn for such differences between adults and children. This fact was described in detail by SCCS (2; 6). Sante Belgique states that therefore the absence of risk after the age of 6 months is not demonstrated enough.

Complete absence of risk can never be demonstrated. However, acceptable low risk can be demonstrated with reasonable certainty given sufficient relevant good quality data. VKM

agrees that more data on the differences between children and adults, and between children of various ages, on metabolism of parabens, would have been very useful.

Similar risk for children up to 3 years as for children up to 6 months

Denmark (3) emphasizes the remaining uncertainty regarding maturation of metabolic enzymes between the age of 6 months and 3 years and the fact that diapers, potentially causing nappy dermatitis and damaged skin, are generally used up to the age of 3 years. The Margin of Safety (MOS) values were in the same range for the two age groups, i.e. 49 for 3-months-old children and 64 for children 2-3 years of age. Therefore, Denmark argues that the safety concerns raised by SCCS (2) with respect to parabens present in the leave-on cosmetic products designed for application on the nappy area should be applied to children up to the age of 3 years, not only up to 6 months. VKM agrees with this statement.

General comments

The comments from Denmark, France and Belgium do not contain quantitative evaluations that show whether their critical comments would actually change the SCCS's conclusions on risk assessment of parabens. AFSSAPS states that this is because they are awaiting a new study on parabens in juvenile rats to be published by the end of December 2011. It is therefore not clear to VKM if the outcome of SCCS's opinion would have been any different if the critical points had been taken into consideration by SCCS. The impact of these critical comments for the outcome of the risk assessment can therefore not be commented on by VKM. VKM is not aware of the details of the ongoing study mentioned by AFSSAPS.

Risk assessment of parabens in cosmetics has been an ongoing activity for many years in Europe. New opinions have been prepared by SCCS or other risk assessment committees, including VKM, when new studies have been provided. It is the opinion of VKM that the SCCS has handled the risk assessment of parabens in cosmetics, and also expressed uncertainties due to lack of data, according to good practice for such work. From the critical comments mentioned above it is not possible to know if the conclusions of this risk assessment would have been substantially different even if contributions from sunscreens and occlusion of the nappy area with damaged skin were taken into account in the exposure assessment.

Most risk assessments may to a certain extent contain elements of uncertainty because of lack of good quality data, and therefore there will be a need for making assumptions both about the health effects and the exposure related to a chemical. In such situations, it is important to clearly express the assumptions made and the uncertainties detected in the risk assessment.

It is for the risk manager to handle the outcome of the risk assessment and the expressed uncertainties.

Conclusions

Risk assessment of parabens has repeatedly been performed by SCCS for many years. As announced by France, a new study on juvenile rats is under way and will be published at the end of December 2011. This will likely trigger a new risk assessment from SCCS. VKM does

not find that the objections to the risk assessment of SCCS from Denmark, France and Belgium discussed above necessitate an immediate new evaluation of parabens by SCCS.

As mentioned by SCCS and implicated by the comments from Denmark, France and Belgium, VKM also like to stress the need for better paraben data on dermal absorption in humans and metabolism in humans including children of various ages, as well as good quality reproductive and developmental toxicity studies from animals. Furthermore, specific exposure data on the use of cosmetic products on children would also reduce the uncertainty regarding paraben safety. Such data should be provided by the cosmetic industry.

References

1. European Commission. Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products. Available from: URL: <http://ec.europa.eu/consumers/sectors/cosmetics/documents/directive/>
2. SCCS (Scientific Committee on Consumer Safety) (2011). 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, SCCS/1446/11, 10 October 2011. Available from: URL: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_069.pdf
3. Danish Ministry of the Environment (2011). Danish Ministry of the Environment, Environmental Protection Agency. Danish comments to the “Clarification on Opinion SCCS/1348/10”, J. nr. MST-653-00029, 31 October 2011.
4. Agence française de sécurité sanitaire des produits de santé (AFSSAPS) (2011). Afssaps comments on the “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)”, dated 17 November 2011.
5. Sante Belgique (2011). Personal communication, e-mail dated November 14, 2011 from Joëlle Meunier, Sante Belgique, to Hans Jørgen Talberg, The Norwegian Food Safety Authority.
6. SCCS (Scientific Committee on Consumer Safety) (2011). Opinion on parabens, SCCS/1348/10, 14 December 2010, revision of 22 March 2011. Available from: URL: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_041.pdf
7. Renwick AG. Toxicokinetics in infants and children in relation to the ADI and TDI. Food Addit Contam 1998. 15(suppl.):17-35.
8. Larsen JC and Pascal G. Workshop on the applicability of the ADI to infants and children: consensus summary. Food Addit Contam 1998. 15(suppl.):1-9.
9. SCCS (Scientific Committee on Consumer Safety) (2010). The SCCS’s Notes of guidance for the testing of cosmetic ingredients and their safety evaluation. 7th revision, SCCS/1416/11, 14 December 2010. Available from: URL: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_004.pdf