

# Notat

Statens tilsyn for planter, fisk, dyr og næringsmidler



**Til:** VKM

**Fra:** Mattilsynet  
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**Dato:** 29.04.2014  
**Vår ref:**

Som etterlyst av VKM ettersendes herved mandat på engelsk når det gjelder igangsatt hasteoppdrag for Aluminium i lys av SCCS' utkast til «opinion» gitt 27. mars med frist for kommentarer satt til 26. mai 2014

## Background

27 March 2014 the Scientific Committee on Consumer Safety (SCCS) published a draft opinion on "The safety of aluminium in cosmetic products" (SCCS/1525/14). The opinion is open for comments until 26 May 2014.

In the opinion, the SCCS concludes that:

*"due to the lack of adequate data on dermal penetration to estimate the internal dose of aluminium following cosmetic uses, risk assessment cannot be performed". Further, the SCCS recommends that "an internal exposure to aluminium after skin application should be determined using a human exposure study under use conditions".*

5 April 2013, the Norwegian Scientific Committee for Food Safety (VKM), published the risk evaluation entitled "Risk assessment of the exposure to aluminium through food and the use of cosmetic products in the Norwegian population".

In the opinion, VKM concludes that the established tolerably weekly intake (TWI, JECFA 2012), is exceeded by a large margin, and in particular, the use of antiperspirants is of concern. The estimated systemic exposure (SED) is based on skin penetration data from a *in vitro* study of Pineau *et al.* 2012. Regarding the dermal penetration data, VKM states that "*The study by Pineau et al. (2012) fulfils most of the SCCS's requirements and was, therefore, chosen for the estimations of SED in this opinion. Since this study does not significantly deviate from the protocol, the mean+1SD was used*".

The dermal penetration data generated by Pineau *et al.* 2012, is also assessed in the opinion by the SCCS. However, the SCCS rejects the study, since it does not satisfy part of the requirements set by SCCS for such studies. In particular, the SCCS comments that «*Mass balance analysis and recovery data are to be provided. The overall recovery of test substance (including metabolites) should be within the range of 85-115%.*»

According to SCCS, the mass balance of the study of Pineau *et al.* 2012 is in the range of 51 +/- 10 % - 141 +/-29 %. The mass balance data are not mentioned in the publication, so presumably SCCS collected them addressing the authors. Thus, SCCS concludes that the dermal penetration data should be determined using a human exposure study under actual use conditions.

As far as we know, this is the first opinion in which the SCCS has found it necessary to require human data to assess dermal penetration. Otherwise, the recommended method for obtaining sufficient dermal penetration data is established in the OECD Guideline for testing of chemicals No. 428.

## **TERMS OF REFERENCE**

In light of the draft opinion on the safety of aluminium in cosmetics, and with reference to the above explanation, the Norwegian Food Safety Authority requests VKM to clarify the following points:

- Does VKM still think that the dermal penetration data generated by Pineau *et al.* 2012 can be used for estimation of systemic exposure dose (SED)? Please provide justification for the answer.
- Does VKM agree with the SCCS regarding the necessity of human (in vivo) dermal penetration data as a basis for risk assessment of Aluminium in cosmetics?
- Does VKM have other comments pertaining to other aspects of the SCCS opinion?
- What, if any, consequences does VKM think the SCCS draft opinion has for its own risk evaluation of aluminium as published 5 April 2013?