Bestilling fra Miljø- og Fødevareministeriet vedr. SCCS opinion om aluminium i kosmetiske produkter

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Opdrag

Miljø- og Fødevareministeriets departement vil gerne have DTU Fødevareinstituttets input/kommentarer til SCCS opinion om aluminium i kosmetiske produkter.

Opgavespecificering:

SCCS har i deres opinion bl.a. konkluderet følgende (s. 37):

"*In the light of the new data provided, the SCCS considers that the use of aluminium compounds is safe at the following equivalent aluminium concentrations up to:*

- *6.25% in non-spray deodorants or non-spray antiperspirants;*
- *10.60% in spray deodorants or spray antiperspirants;*
- *2.65% in toothpaste and;*
- *0.77 % in lipstick"*

SCCS tilføjer at:

"*The SCCS considers that the systemic exposure to aluminium via daily applications of cosmetic products does not add significantly to the systemic body burden of aluminium from other sources. Exposure to aluminium may also occur from sources other than cosmetic products, and a major source of aluminium in the population is the diet. This assessment has not taken into account the daily dietary intake of aluminium".*

I forhold til ovenstående konklusioner, vil departementet gerne have nedenstående spørgsmål besvaret:

- Hvorvidt DTU Fødevareinstituttet er enige med SCCS i, at aluminium er sikkert at anvende i kosmetiske produkter, under de nævnte betingelser.
- Hvorvidt DTU Fødevareinstituttet mener, at aluminium er sikkert at anvende i kosmetiske produkter, under de nævnte betingelser, hvis man også tager højde for indtag af aluminium via fødevarer?

Conclusion

1. The National Food Institute (DTU FOOD) considers the health risk of using aluminium in the concentrations mentioned in the task specification to be small. DTU FOOD thus agrees with SCCS, even though the wording is a little different.

2. The intake of aluminium from all sources in the Danish population is considered higher than desirable from a toxicological point of view. However, the extra contribution of aluminium from antiperspirant and lipstic is insignificant in relation to the intake from all sources. Toothpaste contributes to the total systemic for aluminium. DTU FOOD Institute in general agrees with SCCS but it could be considered to reduce the amount of aluminium in toothpaste.

Uncertainty assessment

The most significant uncertainty is that DTU FOOD has not had access to the original studies ant that there are not sufficient data on the aluminium exposure in the population from food. However, the studies are well described in SCCS opinion and appear to be well conducted. The overall uncertainty of the conclusions is therefore considered to be average.

The risk assessment /evaluation

Several studies have previously been conducted on the absorption of aluminium after the use of aluminium-containing cosmetics. These studies have yielded conflicting results. In 2014, SCCS concluded that data on this absorption were insufficient and therefore requested data for the internal exposure of aluminium using aluminum-containing cosmetics. Two new studies have since been performed and these are major part of the new opinion from SCCS.

Without going into detail DTU FOOD consider the study design suitable to test the aluminium absorption after use of aluminium containing cosmetics. Also the analytical part where very sensitive and specific methods were applied is well suited for the purpose.

SCCS determined the dermal absorption of aluminium to be 0.00192%.Based on this value and the use of cosmetics SCCS calculated the systemic exposure to aluminium from antiperspirant, lipstic and toothpaste to be 0.007 µg/kg bw, 0.0015 µg/kg bw and 0.057 µg/kg bw respectively. The total systemic exposure from these three sources is 0.0655 µg/kg bw.

Food is the main source of oral exposure to aluminium. Some aluminium compounds are permitted as food additives and aluminium is also a common food contaminant. DTU FOOD has not sufficient data to assess the Danish intake of aluminium from food. Therefore the data collected by EFSA is used to assess this. EFSA has estimated the human exposure to aluminium to be between 0,2 – 1,5 mg/kg bw/week where children has the largest intake. This is above the tolerable weekly intake of 1 mg/kg bw. for a part of the population. EFSA has estimated the absorption of aluminum to be between 0.1% and 0.3% after oral ingestion. The systemic exposure

from food is therefore between 0.2 µg/kg bw/week (0.029 µg/kg bw/day) and 4.8 µg/kg bw/week (0.69 µg/kg bw/day).

If the systemic exposure from cosmetics is compared to the systemic exposure from food, the exposure from antiperspirant and lipstic are considered insignificant, whereas toothpaste contribute to the total systemic exposure to aluminium.

DTU FOOD concludes the human exposure for aluminium exceed the TWI for a large part of the population. Therefore an increase in the exposure should be avoided. Only toothpaste contributes significant to the systemic aluminium exposure espically for persons with a low exposure from food.

SCCS (Scientific Committee on Consumer Safety), Opinion on the safety of aluminium in cosmetic products, preliminary version of 30-31 October 2019, final version of 03-04 March 2020, SCCS/1613/19

Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials on a request from European Commission on Safety of aluminium from dietary intake. The EFSA Journal (2008) 754, 1-122