



## EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Dir F: Ecosystems I: Chemicals, food, Retail

Unit F2: Bioeconomy, Chemicals & Cosmetics

### SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

#### **Request for a scientific opinion on the safety of Aluminium in cosmetic products - Submission III**

**Commission Department requesting the Opinion:** Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

#### **1. Background**

Aluminium (Al) and Al compounds are used in a variety of cosmetic products, predominantly in deodorants, antiperspirants, lipsticks and toothpastes. Several Al compounds are regulated in different entries of the Cosmetics Regulation (EC) No 1223/2009<sup>1</sup>.

In 2013, a risk assessment issued by the Norwegian Scientific Committee for Food Safety reported that cosmetic products, and in particular antiperspirants, constitute a significantly larger contribution to the total systemic Al exposure compared to diet at least for the Norwegian population that was used in the study. As a result, SCCS was mandated to evaluate the possible risk for human health arising from the presence of Al in cosmetics. The assessment was based on products and aluminium compounds that contributed to the highest consumer's exposure, namely antiperspirants/deodorants, toothpastes and lipsticks.

In its Opinion SCCS/1525/14, the SCCS concluded that, due to the lack of adequate data on dermal penetration, the requested risk assessment could not be performed<sup>2</sup>. In 2016, industry submitted a new safety dossier to address the dermal penetration and the fate of Al (after skin application) based on a human exposure study. At its plenary meeting on 3 March 2020, the SCCS adopted its final Opinion SCCS/1613/19<sup>3</sup> and in March 2021 an addendum to this Opinion was published<sup>4</sup>.

In the addendum, the SCCS concluded that the use of aluminium compounds is safe at the following equivalent aluminium concentrations up to:

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<sup>1</sup> Annex III (entry 50 - Aluminium Zirconium Chloride Hydroxide, and entries 189, 190, 192 - hair dyes), in Annex IV (entries 117, 118, 119, 150 - colorants) and Annex VI (entry 27a – coating for UV-filter).

<sup>2</sup> “Aluminium is a known systemic toxicant at high doses. The SCCS is of the opinion 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. Therefore internal exposure to aluminium after skin application should be determined using a human exposure study under use conditions” (Opinion SCCS/1525/14).

<sup>3</sup> 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, [link](#).

<sup>4</sup> [https://ec.europa.eu/health/sites/health/files/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_248.pdf](https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_248.pdf)

- 6.25% in non-spray deodorants or non-spray antiperspirants
- 10.60% in spray deodorants or spray antiperspirants
- 2.65% in toothpaste, and
- 14% in lipstick

In addition, the SCCS stated “...*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*”.

Following the discussion at the Cosmetics Working Group held on 25 June 2020 and in light of the comments received on the use of Al compounds in a variety of products other than deodorants, antiperspirants, lipsticks and toothpastes, the Commission considered opportune to request from industry to submit additional information on the ‘other product categories’ and on the aggregate exposure not only from cosmetics.

In March 2021, industry submitted a dossier focusing on the aggregate exposure to aluminium concerning the European population when considering the use of cosmetics and personal care products, medicines (e.g. antacids) and dietary intake.

The current request is based on the dossier submission III by the applicant in order to demonstrate the safe use of aluminium in product categories other deodorants, antiperspirants, lipsticks and toothpastes, as well as concerning the aggregate exposure. The current submission includes in particular additional data and considerations on the MoS calculation and aggregate exposure from cosmetics, medicines and food intake.

## **2. Terms of reference**

- (1) *In light of the new data provided, does the SCCS consider Aluminium compounds safe when used in cosmetic products other than deodorants, antiperspirants, lipsticks and toothpastes? In the event that the estimated exposure to Aluminium from cosmetic products is found to be of concern, SCCS is asked to recommend safe concentration limits for each category.*
- (2) *Does the SCCS have any further scientific concerns regarding the use of relevant Aluminium compounds in cosmetic products taking into account the newly submitted information on aggregate exposure to Aluminium from cosmetics, medicines (e.g. antacids) and food intake?*

## **3. Deadline:** 9 months

## **4. Supporting documents:** ‘Aluminium CE dossier ‘Evaluating Aggregate Exposure to Aluminium from Food, Cosmetics and Personal Care Products and Antacids’

The SCCS approved this mandate by written procedure on 7 May 2021.