



EUROPEAN COMMISSION

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

Resources Based, Manufacturing and Consumer Goods Industries
Health Technology and Cosmetics

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY

Request for a scientific opinion: Submission II on the safety of Aluminium in cosmetic Products

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

1. Background

Aluminium and its compounds are used in cosmetics products such as antiperspirants, lipsticks and toothpastes. In particular, the most extensively used aluminium compound in cosmetic products is Aluminium Chlorohydrate in antiperspirants. While Aluminium Chlorohydrate is a cosmetic ingredient not regulated in the Cosmetic Regulation 1223/2009, other aluminium salts such as Aluminium zirconium chloride hydroxide complexes and the Aluminium zirconium chloride hydroxide glycine complexes are covered by entry 50 in Annex III of the Cosmetic Regulation for use as antiperspirants with specific conditions of use.

According to Cosmetics Europe, current conventional antiperspirants rely on a group of water soluble salts of aluminium and/or zirconium that possess similar insoluble gel-forming properties while lipstick and toothpastes generally contain water-insoluble aluminium ingredients such as aluminium colloidal colorant 'lakes' and insoluble minerals.

In 2013, the risk assessment issued by the Norwegian Scientific Committee for Food Safety showed that cosmetic products, and in particular antiperspirants, constitute a significantly larger contribution to the total systemic aluminium exposure compared to diet. As a result of this, the Commission requested the SCCS to evaluate the possible risk for human health arising from the presence of Aluminium in cosmetics, considering the exposure from other sources, such as food and food supplements. In 2014, the SCCS issued the opinion on the safety of Aluminium in cosmetic products (SCCS/1525/14) concluding that:

"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."

In October 2016, Cosmetics Europe submitted to the Commission services a new safety dossier to address the concerns expressed by the SCCS in particular by performing a clinical study on the absolute bioavailability of aluminium from dermal exposure of human volunteers to a representative antiperspirant formulation.

2. Terms of reference

- (1) *In light of the new data provided, does the SCCS consider that Aluminium compounds are safe in*
 - *antiperspirants*
 - *other cosmetic products such as lipsticks and toothpastes*
- (2) *Does the SCCS have any further scientific concerns regarding the use of Aluminium compounds in cosmetic products taking into account exposure from other sources?*
- (3) *In the event that the estimated exposure to Aluminium from specific types of cosmetic products is found to be of concern, SCCS is asked to recommend safe concentration limits for the presence of Aluminium in those cosmetic products or other risk reducing measures*

3. Deadline: June 2019

The SCCS approved this mandate at its Plenary meeting on 7 March 2017. The extension of deadline (from 10/2017 to 06/2019) was approved by the mandating DG GROW following a request to the Applicant sent by the SCCS.