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 prostaglandin analogues 'Ethyl Tafluprostamide' (DDDE) (CAS No. 1185851-52-8, EC No. 867-521-0), Methylamido-Dihydro-Noralfaprostal (MDN) (CAS No. 155206-01-2, EC No.-) and Isopropyl Cloprostenate (IPCP) (CAS No. 157283-66-4, EC No.-)

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

1. Background

In 2018, the German Federal Institute for Risk Assessment (BfR) informed the European Commission that cosmetic products intended to promote the growth of eyelashes were increasingly available on the market. These products contained substances such as prostaglandins or their analogues that may pose risks for consumers. Prostaglandins and their analogues were not listed in the Annexes to the Cosmetic Regulation (EC) No. 1223/2009 and their use was not otherwise restricted in cosmetic products.

In 2019, Member States were invited to participate in a survey on cosmetic products for eyelash growth containing prostaglandins (and analogues) and their potential undesirable health effects, which led to launching a Call for data in 2020 (from June to October 2020). During the call for data, stakeholders submitted evidence on the safety of prostaglandins and two dossiers on the safety of the analogues 'Ethyl Tafluprostamide'(DDDE) (CAS No. 1185851-52-8) and 'Isopropyl Cloprostenate' (CAS No. 157283-66-4), respectively. In 2021, the Commission services requested the SCCS to carry out a safety assessment on the safety of prostaglandins and their analogues in cosmetic products in view of the information provided.

In the Opinion SCCS/1635/21[1], the SCCS was not able to conclude on the safety of 'Isopropyl Cloprostenate' and 'Ethyl Tafluprostamide' in cosmetic products in view of the limited data provided and the available information in published literature. Nevertheless, the SCCS noted concerns about the safety prostaglandin analogues in cosmetic products intended for use in the proximity of the eye.

By January 2024, industry submitted additional evidence to support the safe use of 'Ethyl Tafluprostamide' (DDDE), 'Methylamido-Dihydro-Noralfaprostal' (MDN) and 'Isopropyl Cloprostenate' (IPCP) in eyelash and eyebrow products. The Commission requests the SCCS to carry out a safety assessment on these three substances in view of the new information provided.

[1] SCCS (Scientific Committee on Consumer Safety), Opinion on Prostaglandins and prostaglandin-analogues used in cosmetic products, preliminary version of 27 September 2021, final version of 3 February 2022, SCCS/1635/21.

2. Terms of reference

(1) *In light of the data provided and taking under consideration the concerns raised by the SCCS in Opinion SCCS/1635/21,*

(a) *does the SCCS consider Ethyl Tafluprostamide safe when used in eyelash and eyebrow products up to a maximum concentration of 0.018 %?*

(b) *does the SCCS consider Methylamido-Dihydro-Noralfaprostal safe when used in eyelash and eyebrow products up to a maximum concentration of 0.03 %?*

(c) *does the SCCS consider Isopropyl Cloprostenate safe when used in eyelash and eyebrow products up to a maximum concentration of 0.005 %?*

(2) *Alternatively, what is according to the SCCS the maximum concentration considered safe for use of Ethyl Tafluprostamide, Methylamido-Dihydro-Noralfaprostal and Isopropyl Cloprostenate, respectively, in eyelash and eyebrow products?*

(3) *Does the SCCS have any further scientific concerns regarding the use of Ethyl Tafluprostamide, Methylamido-Dihydro-Noralfaprostal and Isopropyl Cloprostenate in cosmetic products?*

Deadline

12 months.

3. Supporting documents

Safety dossier submission for ‘Ethyl Tafluprostamide’, ‘Methylamido-Dihydro-Noralfaprostal’ and Isopropyl Cloprostenate.

➔ **The SCCS approved this mandate during Plenary meeting on 27 March 2024.**