



## EUROPEAN COMMISSION

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

Resources Based, Manufacturing and Consumer Goods Industries

**Consumer Industry**

### SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

#### **Request for a scientific opinion on Prostaglandins analogues used in cosmetic products**

**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 eyelash growth treatments contain substances such as prostaglandins or their analogues.

According to the BfR's Health assessment of eyelash growth treatments, the use of prostaglandins and their analogues as components of cosmetic products may include health risks for consumers. Prostaglandin analogues are also used in drugs to reduce ocular hypertension. Increased eyelash growth has been observed as a side effect, and furthermore, other adverse effects have been found.

As a result of this communication, EU countries' competent authorities were invited in 2019 to participate in a survey on products for eyelash growth containing prostaglandins and their analogues. The information collected helped to identify an uneven situation in terms of applicable regulatory framework (e.g. cosmetic products or medicinal products). Furthermore, several cases of serious undesirable health effects were reported in many EU countries due to the use of cosmetic products containing prostaglandins analogues.

In December 2019, the sub-working group on borderline products assessed this topic and considered that an SCCS safety evaluation of such ingredients would be useful. Following this, a [call of data](#) was launched in 2020.

During the call, contributions were provided on the safety of the following substances:

- Ethyl Tafluprostamide CAS 1185851-52-8 (also known as Dechloro Dihydroxy Difluoro Ethylcloprostenolamide or DDDE) and
- Isopropyl cloprostenate CAS 157283-66-4.

The Commission database for information on cosmetic substances and ingredients (CosIng) contains 14 cosmetic ingredients, each described as '*a synthetic analogue of a prostaglandin*'; additional cosmetic ingredients relevant to the mentioned chemical family were also found using the keyword 'prost' (see Table 1 above and Paragraph 3.1.1 2018 BfR Health assessment).

In addition, the EU cosmetic products notification portal (CPNP) contains notifications of cosmetic products containing prostaglandins and their analogues placed on the EU market.

Prostaglandins and their analogues are not listed in the Annexes to the Cosmetic Regulation (EC) No. 1223/2009 and their use is not otherwise restricted in cosmetic products.

Therefore, the Commission requests the SCCS to carry out a safety assessment on Prostaglandins analogous in view of the information provided.

## **2. Terms of reference**

- (1) *In light of the data provided, does the SCCS consider Isopropyl cloprostenate (CAS 157283-66-4) and Ethyl Tafluprostamide or DDDE (CAS 1185851-52-8) safe when used up to the concentrations provided in the respective dossiers (0.006% and 0.007% for Isopropyl cloprostenate and 0.018% for Ethyl Tafluprostamide)*
- (2) *Does the SCCS have any further scientific concerns with regard to the use of Isopropyl cloprostenate (CAS 157283-66-4) and Ethyl Tafluprostamide / DDDE (CAS 1185851-52-8) in cosmetic products?*
- (3) *In light of the available data, does the SCCS consider that the use in cosmetic products of prostaglandins analogues (listed in Table 1) raises safety concerns and might pose a risk to human health?*

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

## **4. Supporting documents:**

- a. 2018 - BfR Assessment
- b. 2019 - Survey on products for eyelash growth containing prostaglandins or heir analogues
- c. 2020 - Dossiers provided by the call for data on Isopropyl cloprostenate CAS 157283-66-4 and Ethyl Tafluprostamide or DDDE CAS 1185851-52-8

The SCCS approved this mandate by written procedure on 18 January 2021.