



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 Genistein (CAS No 446-72-0, EC No 207-174-9) and Daidzein (CAS No 486-66-8, EC No 207-635-4)**

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

#### **1. Background on substances with endocrine disrupting properties**

On 7 November 2018, the Commission adopted the review<sup>1</sup> of Regulation (EC) No 1223/2009 on cosmetic products ('Cosmetics Regulation') regarding substances with endocrine disrupting (ED) properties. The review concluded that the Cosmetics Regulation provides the adequate tools to regulate the use of cosmetic substances that present a potential risk for human health, including when displaying ED properties.

The Cosmetics Regulation does not have specific provisions on EDs. However, it provides a regulatory framework with a view to ensuring a high level of protection of human health. Environmental concerns that substances used in cosmetic products may raise are considered through the application of Regulation (EC) No 1907/2006 ('REACH Regulation').

In the review, the Commission commits to establishing a priority list of potential EDs not already covered by bans or restrictions in the Cosmetics Regulation for their subsequent safety assessment. A priority list of 28 potential EDs in cosmetics was consolidated in early 2019 based on input provided through a stakeholder consultation. The Commission carried out a public call for data<sup>2</sup> in 2019 on 14<sup>3</sup> of the 28 substances (to be treated with higher priority-Group A substances) in preparation of the safety assessment of these substances. Both Genistein and Daidzein were included in the above-mentioned 14 substances for which the call for data took place.

#### **2. Background on Genistein and Daidzein**

Phytoestrogens are plant-derived compounds with structural similarity to 17 $\beta$ -estradiol, the primary female sex hormone. Among the phenolic compounds classified as phytoestrogens are isoflavones, which are typically found in legumes, including soybeans, chickpeas, fava beans, as

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<sup>1</sup><https://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-739-F1-EN-MAIN-PART-1.PDF>

<sup>2</sup>[https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products\\_en](https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en)

<sup>3</sup>Benzophenone-3, kojic acid, 4-methylbenzylidene camphor, propylparaben, triclosan, Homosalate, octocrylene, triclocarban, butylated hydroxytoluene (BHT), benzophenone, homosalate, benzyl salicylate, genistein and daidzein

well as in fruits and nuts (pistachios, peanuts, etc.). Soy and its by-products are the most used in food and dietary supplements.

Among the most common isoflavones are Genistein (CAS No 446-72-0, EC No 207-174-9) and Daidzein (CAS No 486-66-8, EC No 207-635-4) that correspond to the chemical names 'Genisteol 4',5,7-Trihydroxyisoflavone' and 'Daidzeol 7,4'- Dihydroxyisoflavone', respectively. Both substances are included in the European database for information on cosmetic substances and ingredients (CosIng) with the reported function of 'skin conditioning', however additional functions have been reported, including 'antioxidant', 'skin protecting', etc. Currently, Genistein and Daidzein are not regulated under the Cosmetic Regulation (EC) No. 1223/2009.

During the call for data, stakeholders submitted scientific evidence to demonstrate the safety of Genistein and Daidzein in cosmetic products. The Commission requests the SCCS to carry out a safety assessment on Genistein and Daidzein in view of the information provided.

### **3. Terms of reference**

- (1) *In light of the data provided and taking under consideration the concerns related to potential endocrine disrupting properties of phytoestrogens,*
  - (a) *does the SCCS consider Genistein safe when used in cosmetic products up to a maximum concentration of 0.007%?*
  - (b) *does the SCCS consider Daidzein safe when used in cosmetic products up to a maximum concentration of 0.02%?*
- (2) *Alternatively, according to the SCCS what is the maximum concentration of Genistein and Daidzein that is considered safe for individual and combined use in cosmetic products?*
- (3) *Does the SCCS have any further scientific concerns with regard to the use of Genistein and Daidzein or other related phytoestrogens in cosmetic products?*

### **4. Deadline**

9 months.

### **5. Supporting documents**

Input from the call for data on the safety of Genistein and Daidzein in Cosmetic Products.

The SCCS approved this mandate by written procedure on 8 March 2021.