



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 advice on the safety of Butylated Hydroxyanisole (BHA) (CAS No. 25013-16-5, EC No. 246-563-8) as a substance with potential endocrine disrupting properties in cosmetic products

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 a review¹ of Regulation (EC) No 1223/2009 on cosmetic products ('Cosmetics Regulation') regarding substances with endocrine disrupting 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 explicit 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 then organised a public call for data² from 16 May 2019 to 15 October 2019 on 14³ of the 28 substances (to be treated with higher priority) in order to be able to prepare the safety assessment of these substances. Triclocarban and Triclosan are among the above-mentioned 14 substances for which the call for data took place.

2. Existing information on Butylated Hydroxyanisole

The ingredient Butylated Hydroxyanisole (INCI: BHA) (CAS No. 25013-16-5, EC No. 246-563-8) with the chemical name '2-tert-butyl-4-methoxyphenol' is a monohydric phenolic antioxidant. BHA is a mixture of two isomers, 3-tertiary-butyl-4-hydroxyanisole and 2-tertiary-butyl-4-hydroxyanisole.

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

² https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en

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

BHA is currently not regulated under the Cosmetics Regulation (EC) No. 1223/2009; however, it has been used for decades in various industries, including personal care, pharma, and food industry as an antioxidant to extend the shelf life of products.

According to CosIng database, BHA is reported to have the following functions: 'antioxidant' and 'fragrance'. Cosmetic products often contain synthetic antioxidants like BHA to prevent the oxidation of fats and oils (mostly essential oils). In particular, the conjugated aromatic ring of BHA can stabilize free radicals, sequestering them acting as free radical scavenger.

BHA is closely related to BHT (butylated hydroxytoluene), which has been recently evaluated by the SCCS in view of its potential endocrine activity. In that Opinion⁴, the SCCS concluded on the safety (under certain conditions) of BHT, when used in cosmetic products. BHA is also suspected of being an endocrine disruptor.

Given the possible health risks associated with this ingredient, its safe use in cosmetic products should be evaluated by the SCCS in view of technical and scientific progress. The Commission, therefore, requests the SCCS to provide a scientific advice on the safety of BHA when used in cosmetic products.

3. Terms of reference

In light of technical and scientific progress, available scientific literature, relevant in silico tools and the SCCS' expert judgement and taking under consideration in particular the concerns related to potential endocrine disrupting properties, the SCCS is requested:

- (1) *to identify and justify whether there are specific concerns regarding the use of BHA in cosmetic products;*
- (2) *to highlight if there is a potential risk for human health from the use of BHA in cosmetic products;*

4. Deadline

15 months.

5. Supporting documents

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→ The SCCS approved this mandate by written procedure on 2 October 2024.

⁴ SCCS (Scientific Committee on Consumer Safety), scientific opinion on Butylated hydroxytoluene (BHT), preliminary version of 27 September 2021, final version of 2 December 2021, SCCS/1636/21