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 Triclocarban (CAS No. 101 20-2, EC No. 202-924-1) and Triclosan (CAS No. 3380-34-5, EC No. 222182-2) as substances 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 review[1] 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 data[2] from 16 May 2019 to 15 October 2019 on 14[3] 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.

[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

2. Existing information on Triclocarban

In cosmetic products, the ingredient Triclocarban (CAS No. 101-20-2, EC No. 202-924-1) with the chemical name '1-(4-Chlorophenyl)-3-(3,4-dichlorophenyl)urea' is regulated as a preservative (entry 23 of Annex V) at a maximum concentration of 0.2 %. Furthermore, Triclocarban is restricted to rinse-off products at a maximum concentration of 1.5 % (entry 100 of Annex III).

Triclocarban has been subject to different safety evaluations by the SCCNFP in 1999[4] and SCCP in 2004 (SCCP/0851/04). In particular, the last SCCP opinion states that '...the use of Triclocarban for non-preservative purposes in cosmetic rinse-off hand and body care products up to a maximum concentration of 1.5% does not pose a direct risk to the health of the consumer. However, the SCCP would like to draw the Commission's attention to the possible effects of triclocarban to the environment and, subsequently, on human health from such environmental contaminations'.

2.1 Existing information on Triclosan

The ingredient Triclosan (CAS No. 3380-34-5, EC No. 222-182-2) with the chemical name '5-Chloro-2-(2,4-dichlorophenoxy)phenol' is regulated as a preservative (entry 25 of Annex V) in the following product types:

a) Toothpastes; Hand soaps; Body soaps/Shower gels; Deodorants (non-spray); Face powders and blemish concealers; Nail products for cleaning the fingernails and toenails before the application of artificial nail systems - at a maximum concentration of 0.3 %; and

b) Mouthwashes - at a maximum concentration of 0.2 %.

Triclosan has been subject to different safety evaluations by the SCCNFP in 2002 (SCCNFP/0600/02)[5], by SCCP in 2006 (SCCP/1040/06)[6], 2008 (SCCP/1192/08)[7], 2009 (SCCP/1251/09)[8] and by SCCS in 2011 (SCCS/1414/11)[9]. In particular, the last SCCS opinion resulted in the existing regulatory measures that allow different concentration of Triclosan based on the product.

3. Terms of reference

In light of the information submitted via the call for data, the currently available scientific literature, relevant in silico tools and SCCS' expert judgement and taking under consideration in

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[4] https://ec.europa.eu/health/scientific committees/consumer safety/opinions/sccnfp opinions 97 04/sccp out59 en.htm

[5] https://ec.europa.eu/health/ph risk/committees/sccp/documents/out182 en.pdf

[6] https://ec.europa.eu/health/ph risk/committees/04 sccp/docs/sccp o 073.pdf

[7] https://ec.europa.eu/health/ph risk/committees/04 sccp/docs/sccp o 166.pdf

[8] https://ec.europa.eu/health/scientific committees/consumer safety/docs/sccs o 023.pdf

[9] https://ec.europa.eu/health/scientific committees/consumer safety/docs/sccs o 054.pdf

particular the concerns related to potential endocrine disrupting properties, the SCCS is requested:

1. to identify and justify specific concerns regarding the safe use of Triclocarban and Triclosan in cosmetic products

2. to highlight if a potential risk for human health from the use of Triclocarban and Triclosan in cosmetic products

4. Deadline

9 months

5. Supporting documents

Input from the call for data in 2019 on the safety of Triclocarban and Triclosan in Cosmetic Products.

The SCCS approved this mandate at plenary meeting on 24 -25 June 2021.