PUBLIC CONSULTATION ON
TRICLOSAN
IN THE FRAMEWORK OF REGULATION (EC) No 1223/2009
ON COSMETIC PRODUCTS

1. Background

Triclosan is an antimicrobial agent that has been used for more than 40 years as an antiseptic, disinfectant or preservative in clinical settings, in various consumer products including cosmetics, household cleaning products, plastic materials, toys, paints, etc.

Cosmetic uses of triclosan account for most of its total use in the EU. The substance has a long history of use as a preservative. It has been authorized as a preservative in Annex VI of the Cosmetics Directive 76/768/EEC, entry 25, with a maximum concentration of 0.3% since 1986. The functions identified in CosIng are preservative and deodorant; however, triclosan has proven to be effective in inhibiting gingivitis and plaque.

Concern regarding the widespread use of this substance and its potential to create antimicrobial resistance and cross-resistance prompted the Commission to request opinions to the successive Scientific Committees.

Between 2008 and 2011, the SCCP and SCCS have delivered three opinions on triclosan, addressing both safety for human health and the issue of antimicrobial resistance. The conclusions are summarized below.

a. The safety for human health opinions (SCCP/1192/08 and SCCS/1414/11)

- Based on the toxicological data available, the SCCP considers that the continued use of triclosan as a preservative at the current concentration limit of maximum **0.3% in all cosmetic products is not safe** for the consumer because of the magnitude of the aggregate exposure, and the SCCS confirmed this position.
- However, its use at a maximum concentration of **0.3% in toothpastes, hand soaps, body soaps/shower gels and deodorant sticks, face powders and blemish concealers, and nail products is considered safe.**
- An additional use of triclosan in **mouthwashes** at a concentration limit of **0.2 % is considered as safe** for the consumer.

b. The opinion on Antimicrobial Resistance (SCCP/1251/09)

- The six in situ studies and the one meta-analysis quoted in the opinion have **failed to demonstrate an increase in antibiotic resistance following triclosan use**. While these results are at first sight reassuring, the differences of methodologies used to measure "resistance" and to analyse the data make it **premature at this stage to conclude that triclosan exposure never leads to developing microbial resistance**.
- Based on the available scientific information including recent data from in vitro investigations, **it is not possible to quantify the risk associated with triclosan (including its use in cosmetics) in terms of development of antimicrobial resistance** (i.e. selection for less susceptible population), genetic basis for resistance and dissemination of resistance. In view of the concentrations of triclosan reported to trigger resistance in vitro, some of the environmental concentrations found in a number of geographical distinct areas are high enough to suggest that bacterial resistance could be triggered. However, no studies have been conducted on this aspect. […]

- Due to the limited number of in situ studies of resistance induced by triclosan to date, **SCCS can only recommend the prudent use of triclosan,** for example in applications where a health benefit can be demonstrated.

Triclosan is currently under evaluation in the context of both REACH and the Biocides Directive. A new mandate to the SCCS may be issued when the results of those evaluations become available.

2. Action envisaged by the Commission

Taking into account the opinions of the SCCS and the reasoning outlined above, the Commission would like to propose the following amendment to Annex V of Regulation (EC) No 1223/2009, as a first step:

	Substance Identification				Conditions			
Reference number	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	Wording of conditions of use and warnings
a	b	c	d	e	f	g	h	i
25	5-Chloro-2-(2,4-dichlorophenoxy)phenol	Triclosan	3380-34-5	222-182-2	a) Toothpastes Hand soaps Bath/shower products Deodorants Face powders and blemish concealers Nail products b) Mouthwashes	a) 0.3% b) 0.2%	Not to be used in aerosol dispensers (sprays)	

The Commission will propose the following implementation deadlines from the date of publication for the proposed Regulation:

– 6 months for placing on the market, and
– 9 months for withdrawing from the market.

3. Request

In view of the above, the Commission would like to invite any interested parties, including authorities of the Member States, manufacturers of cosmetic products, producers of those substances, relevant industry and consumers associations, to submit their comments on the considered measure and on its possible economic impact.

With relation to the economic impact the information/comments should refer, *inter alia*, to the following topics:

- competitiveness, markets and trade,
- direct and indirect costs imposed on business, including SME's,
- innovation and research,
- specific regions, sectors or workers,
- third countries and international relations,
- macroeconomic environment.

Any comments and information should be delivered with the reference: "Triclosan Public Consultation" by mail or e-mail by **19 October 2012** at the latest to:

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