Attachment 2

OPINION OF THE SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS AND NON-FOOD PRODUCTS INTENDED FOR CONSUMERS

OPINION

CONCERNING

TRICLOSAN

COLIPA n° : P32

adopted by the SCCNFP during the 21st Plenary Meeting
of 17 September 2002

1. Terms of Reference

1.1. Context of the question

Triclosan is regulated in the Cosmetic Directive 76/768/EEC, Annex VI, part 1, reference n° 25 and can therefore be used as a preservative up to a maximum concentration of 0.3% in the finished cosmetic product. Moreover, Triclosan is marked with the symbol (+) and thus may be added to cosmetic products in concentration other than those laid down in this Annex for other specific purposes apparent from the presentation of the product.

Preservatives are substances that may be added to cosmetic products for the primary purpose of inhibiting the development of micro-organisms in such products.

Recently published reports have raised the question whether Triclosan could be involved in the development of bacterial resistance.

1.2. Request to the SCCNFP

The European Commission received a request from the Swedish Medical Products Agency for a re-evaluation of the safety of use of Triclosan in cosmetic products.

The SCCNFP was asked to perform an expert review on the basis of the data provided and to answer the following questions :

1. Is the use of Triclosan as a preservative in cosmetic products safe taking into account the risk of resistance development by certain micro-organism?

2. Does the SCCNFP find it necessary in the safety assessment to take into account the fact that Triclosan is used in other consumer products?

3. Is there a need for setting a new concentration limit for the use of this substance in cosmetic products?

2. Opinion

2.1 Introduction

In the light of recent scientific papers discussing the possible impact of the use of Triclosan on the development of anti-microbial resistance and taking into account the fact that Triclosan is not only used in cosmetics but in a wide range of consumer products, e.g. household detergents, textiles, bedlinen, toys, or plastics intended for contact with food or feed, the Commission services decided to request the Scientific Steering Committee (SSC) for its opinion prior to address the issue to the SCCNFP.

The SSC was asked to answer the following question : *Is the use of Triclosan in cosmetic products safe, taking into account the risk of resistance development by certain micro-organism. Is it necessary in the safety assessment to take into account the fact that Triclosan is used in other consumer products?*

Subsequently, the SCCNFP was asked to answer the questions listed under point 1.2.

2.2 Conclusions and Recommendations

In the light of conclusions and recommendations expressed in the opinion of the Scientific Steering Committee on Triclosan resistance, adopted by the SSC at its meeting of 27-28 June 2002, and on the basis of the information provided by the Swedish Medical Products Agency, the SCCNFP is of the opinion that :

1. under current conditions of use of Triclosan as a preservative in cosmetic products, it is safe taking into account the risk of resistance by certain micro-organism.

2. there is no need for setting a new concentration limit for the use of Triclosan in cosmetic products.

Taken into account the fact that Triclosan is used in other consumer products, the SCCNFP endorses the recommendations expressed by the SSC in its above-mentioned opinion and in its opinion on microbial resistance of 28 May 1999.

3. References

1. SSC opinion on Triclosan resistance, adopted at the SSC meeting of 27-28 June 2002
2. SSC opinion on microbial resistance, adopted at the SSC meeting of 28 May 1999
3. Chanchuen R. et al. Cross-resistance between triclosan and antibiotics in *Pseudomonas aeruginosa* is mediated by multidrug efflux pumps; exposure of a susceptible mutant strain to triclosan selects nfxB mutants overexpressing MexCD-OprJ. Antimicrobial Agents and Chemotherapy 2001,45(2), 428-432
4. Heath R.J., Rock C.O., A triclosan-resistant bacterial enzyme. Nature, 2000, 406, 415
5. Hoang T.T., Schweizer H.P., Characterization of *Pseudomonas aeruginosa* enoyl-acyl carrier protein reductase (FabI) : a target for the antimicrobial triclosan and its role in acylated homoserine lactone synthesis. J. Bacteriol 1999, 181(17), 5489-97
6. Levy C.W. et al. Molecular basis of triclosan activity. Nature 1999, 398, 383-384
7. McMurry L.M., Oetinger M., Levy S.B., Triclosan targets lipid synthesis. Nature 1998, 394, 531-532
8. Ward W.H.J. et al. Kinetic and structural characteristics of the inhibition of enoyl (acyl carrier protein) reductase by triclosan. Biochemistry 1999, 38, 12514-12525