EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Directorate F- Consumer goods
ENTR F/3- Cosmetics and Medical Devices

Brussels, 03 July 2008
M/426 EN

STANDARDISATION MANDATE ASSIGNED TO CEN CONCERNING THE MICROBIOLOGICAL ANALYSIS OF COSMETIC PRODUCTS

1. MOTIVATION

This standardisation mandate relates to Council directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (hereinafter the Cosmetics Directive). The directive based on article 95 of the Treaty aims to insure free circulation of cosmetic products into the Community market. To that end it determines at Community level the regulations which must be observed as regards the composition, labelling and packaging of cosmetic products

According to article 2 of the Cosmetics Directive *"a cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the Community market".*

The scientific Committee on Consumer Products (SCCP) in its note of guidance for the testing of cosmetic ingredients and their safety evaluation[1] mentioned that *"although only a small number of cases of microbiological contamination of cosmetics, leading to microbial infections of the consumer, has been reported, microbial contamination of cosmetic products may spoil them or seriously reduce the intended quality.*
In order to ensure the quality of the product and the safety for the consumer, it is necessary to carry out routine microbiological analysis of each batch of the finished product coming on the market".

However, no methods on identification of microbiological contamination are currently defined at Community level. In order to avoid unnecessary legislation and in view of better regulation and simplifying Community legislation , creation of a standard in this area would be the best approach. Indeed the standard would allow to relate to a common reference in this technical field without creating burdensome and avoidable legislation.

2. DESCRIPTION OF THE MANDATED WORK

[1] Adopted by the SCCP during the 10th plenary meeting of 19 December 2006
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The Commission invites CEN to establish European standards giving guidance for the microbiological analysis of cosmetic products. The European standards to be produced under this mandate will cover the following areas:

- General instructions for microbiological examination,

- Detection of Candida albicans, of Escherichia coli, of Pseudomonas aeruginosa, of Staphylococcus aureus and,- Enumeration and detection of aerobic mesophylic bacteria.

For the purpose of this mandate, "Cosmetic products" shall mean "*any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition. (article 1 of the Cosmetics Directive)*".

In order to facilitate a wide acceptance of the standards, CEN will take into account, as much as possible, the work undertaken by the international standards organisations on the same subject, and, in particular the standard(s) or other standardisation deliverables under preparation or published, particularly:

- General instructions for microbiological examination; ISO 21148:2005, ISO 21148:2005/Cor 1:2006
- Detection of Candida albicans; ISO 18416:2007
- Enumeration and detection of aerobic mesophylic bacteria; ISO 21149:2006
- Detection of Escherichia coli; ISO 21150:2006
- Detection of Pseudomonas aeruginosa; ISO 22717:2006
- Detection of Staphylococcus aureus; ISO 22718:2006

CEN will avoid any unnecessary duplication of work with the international standards organisations, particularly by using the provisions for approval procedures provided for in the existing co-operation agreements ("Vienna Agreement")

3. BODIES TO BE ASSOCIATED

As appropriate, CEN will invite the representative organisations of consumers interests (ANEC), environmental protection (ECOS), workers (ETUI-REHS), small and medium-size enterprises (NORMAPME) and every relevant industrial organisation, in particular COLIPA[2], to take part in the elaboration of the standard.

4. EXECUTION OF THE MANDATED WORK

CEN will deliver the draft European standards and submit them to a public enquiry within 15 months of accepting the mandate.

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[2] The European Cosmetic Toiletry and Perfumery Association.
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CEN will publish the final European standards within two years of accepting the mandate.. By that date the standards will be available in English, French and German, and the correct title of the standard will be available in the other Community languages.

At the latest six months after the publication of the European standard by CEN, it will be implemented as a national standard by all national standards institutes in all Member States and every conflicting national standard will be withdrawn.

The acceptance of this mandate by CEN will trigger the standstill period referred to in Article 7 of Directive 98/34/EC of 22 June 1998.

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