

EUROPEAN COMMISSION ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Chemicals and construction **Chemicals**

Brussels, 28th November 2005 **M/375**

STANDARDISATION MANDATE ASSIGNED TO CEN CONCERNING GOOD MANUFACTURING PRACTICE FOR COSMETICS PRODUCTS

<u>1. MOTIVATION</u>

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 7a (1) of the Cosmetics Directive "the manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market shall for control purposes keep [inter alia] readily accessible to the competent authorities [...] the method of manufacture complying with the good manufacturing practice [...].

However, no good manufacturing practice in the cosmetic sector is 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

The Commission invites the ESO to establish a European standard giving guidance for the production, control, storage and shipment of cosmetic products.

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 standard, the ESO 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 as a result of ISO/TC 217 "Cosmetics", particularly the draft under preparation under reference ISO/CD 22716 "Cosmetics - Good manufacturing practice

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

3. BODIES TO BE ASSOCIATED

As appropriate, the ESO will ensure that 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 COLIPA¹, take part in the elaboration of the standard.

4. EXECUTION OF THE MANDATED WORK

The ESO will deliver a draft European standard and submit it to a public enquiry by 2006-02-28.

The ESO will publish a final European standard by 2007-08-31. By that date the standard 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 the ESO, 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 one of the ESO will trigger the standstill period referred to in Article 7 of Directive 98/3/EC of 22 June 1998.

¹ The European Cosmetic Toiletry and Perfumery Association.