



**EUROPEAN COMMISSION**  
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL  
Chemicals, Metals Forest-based & Textile Industries  
**Chemicals**

Brussels, 25 June 2007  
**M / 414 EN**

## **STANDARDISATION MANDATE**

**ADDRESSED TO CEN**  
**for**

**REVISION OF METHODS OF ANALYSIS TO DETECT THE RELEASE OF NICKEL FROM PRODUCTS INTENDED TO COME INTO DIRECT AND PROLONGED CONTACT WITH THE SKIN (REVISION OF THE STANDARD METHOD EN 1811:1998).**

### **1. MOTIVATION.**

This mandate falls within the scope of European legislation, in particular Directive 76/769/EEC of the Council of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, including the successive amendments and technical adoption progress.

Directive 76/769/EEC aims to ensure the free circulation of goods within the Internal Market whilst ensuring a high level of protection of human health and the environment.

Directive 94/27/EC of European Parliament and Council, amending for the twelfth time Directive 76/769/EEC, imposes restrictions on the use of nickel for piercing post assemblies and in products intended to come into direct and prolonged contact with the skin. In accordance with the recitals of Directive 94/27/EC, the Commission gave CEN a mandate (M/004) to develop a test method to permit enforcement of the limit for nickel release of 0.5 µg/cm<sup>2</sup>/week. The method, EN1811:1998, was developed and published in the Official Journal.

EN1811:1998 was adopted by CEN as the first standardisation of a test method that previously was used in research, and at the time of the publication it was also expected to require early revision in the light of further experience. It was also considered that the measured release should be multiplied by a factor of 0.1 to compensate for inter-laboratory variations and measuring inaccuracies.

Directive 94/27/EC was amended by Directive 2004/96/EC, published in the Official Journal in September 2004, in order to adapt Annex I of Council Directive 76/769/EEC to technical progress. Directive 2004/96/EC changed the limit rate for nickel release from post assemblies to less than 0.2 µg/cm<sup>2</sup>/week.

However, as the multiplication factor specified in EN1811:1998 still needs to be adjusted to the new value of the release limit recital 3 of Directive 2004/96/EC invites the Commission to request the European Committee for Standardisation (CEN) to review EN1811:1998, in particular regarding the adjustment factor and to prepare a revised standard without adjustment factor, or with a smaller adjustment factor, if appropriate.

The revised EN1811:1998 reference method would be applied for determining the rate of release of nickel from all post assemblies inserted into pierced ears and other pierced parts of the human body to ensure compliance with the limit for nickel release of less than 0.2  $\mu\text{g}/\text{cm}^2/\text{week}$ .

The establishment of standardised reference methods is of utmost importance to guarantee a uniform application and control of Community legislation in all Member States. Standardised and validated reference methods are an indispensable element in guaranteeing a high level of chemicals safety, and are the references against which other methods can be validated.

## **2. DESCRIPTION OF THE MANDATED WORK.**

The Commission mandates the CEN to review EN1811:1998 for the determination of the release of nickel from products intended to come into direct and prolonged contact with the skin. The reference to EN1811:1998 was published by Commission in the Official Journal in July 1999 and the revision of this reference method should be developed in order to ensure that compliance with the limit value of 0.2  $\mu\text{g}/\text{cm}^2/\text{week}$  required by the legislation can be reliably determined. The limit value of 0.2  $\mu\text{g}/\text{cm}^2/\text{week}$  has been adopted by Commission Directive 2004/96/EC amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of nickel for piercing post assemblies for the purpose of adapting its Annex I to technical progress.

## **3. BODIES TO BE ASSOCIATED**

As appropriate, CEN will invite the representative organisations of consumers interests (ANEC<sup>1</sup>), environmental protection (ECOS<sup>2</sup>), workers (ETUI-REHS<sup>3</sup>), small and medium-size enterprises (NORMAPME<sup>4</sup>) to take part in the elaboration of the standards.

## **4. EXECUTION OF THE REQUEST**

- 4.1 CEN will provide the Commission with a detailed work programme and a timetable for the adoption of the standards needed within three months of the acceptance of the mandate. The European standards will have to be adopted by the dates in the work programme, but in any case no longer than three years from submission of the work

---

1 European Association for the Co-ordination of Consumer Representation in Standardisation

2 European Environmental Citizens Organisations for Standardisation

3 European Trade Union Institute - Research, Education, Health and Safety

4 European Office of Crafts, Trades and Small and Medium- Sized Enterprises for Standardisation

programme. On these dates, the three linguistic versions (DE, EN, FR) must be available as well as the correct titles in the other official Community languages.

- 4.2 The CEN will keep the Commission informed at least once a year following the submission of the work programme, of the measures taken to execute this mandate and of any difficulties which arise in the process.
- 4.3 Related work within CEN in connection with nickel should be taken into account in the development of the standards under this mandate.
- 4.4 The standstill period referred to in Article 7 of Directive 98/34/EC (OJ L 217, 5.8.1998 p.18) shall commence when CEN accepts this standardisation mandate.