

Commission Directive 2004/96/EC of 27 September 2004 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 (Text with EEA relevance)

COMMISSION DIRECTIVE 2004/96/EC

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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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and

Having regard to Council Directive 76/769/EEC 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 dangerous substances and preparations⁽¹⁾, and in particular Article 2a thereof,

Whereas:

- (1) According to Directive 76/769/EEC as amended by Directive 94/27/EC of the European Parliament and the Council⁽²⁾, nickel and its compounds are not to be used in certain post assemblies for piercing and certain other products unless they conform to the requirements set out in Directive 76/769/EEC.
- (2) The risk of sensitisation of humans to nickel by piercing post assemblies has been newly assessed in a targeted risk assessment; the risk assessment concluded that a migration limit for piercing post assemblies would be more appropriate than a content limit.
- (3) The new rate of nickel release (migration limit) should be adjusted with the multiplication factor specified in EN 1811 to compensate inter-laboratory variations and measuring inaccuracies. The European Committee of Standardisation (CEN) is invited to review EN 1811 in particular regarding the adjustment factor and to prepare a revised standard without adjustment factor, or with a smaller adjustment factor, if appropriate.
- (4) The risk assessment was referred to the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) for peer review and the CSTEE has confirmed that a nickel migration limit may induce lower risks of sensitisation than a nickel content limit.
- (5) The provisions laid down by this Directive take into account the current state of knowledge, science and techniques.
- (6) This Directive should apply without prejudice to Community legislation laying down minimum requirements for the protection of workers, in particular Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage

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improvements in the safety and health of workers at work⁽³⁾, and Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)⁽⁴⁾.

- (7) The measures provided for in this Directive are in accordance with the opinion of the Committee for the adaptation to technical progress of the Directives on the removal of technical barriers to trade in dangerous substances and preparations,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 76/769/EEC is amended as set out in the Annex to this Directive.

Article 2

1 Member States shall adopt and publish, by 1 August 2005 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 September 2005.

When Member States adopt those provisions, these shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 27 September 2004.

For the Commission

Olli REHN

Member of the Commission

ANNEX

In Annex I to Directive 76/769/EEC, in point 28, Nickel, in the second column point 1 is replaced by the following:

1. in all post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than 0,2 $\mu\text{g}/\text{cm}^2/\text{week}$ (migration limit);.

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- (1) [OJ L 262, 27.9.1976, p. 201](#). Directive as last amended by Commission Directive 2004/21/EC ([OJ L 57, 25.2.2004, p. 4](#)).
- (2) [OJ L 188, 22.7.1994, p. 1](#).
- (3) [OJ L 183, 29.6.1989, p. 1](#). Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council ([OJ L 284, 31.10.2003, p. 1](#)).
- (4) [OJ L 158, 30.4.2004, p. 50](#).