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(Acts whose publication is obligatory)

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 94/27/EC

of 30 June 1994

amending for the 12th time (*) Directive 76/769/EEC 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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Acting in accordance with the procedure referred to in Article 189b of the Treaty ⁽³⁾,

Whereas Article 8a of the Treaty establishes an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas work on the internal market should gradually improve the quality of life, health protection and consumer safety; whereas the measures proposed by this Directive are in line with the Council resolution of 9 November 1989 on future priorities for relaunching consumer protection policy;

Whereas the presence of nickel in certain objects coming into direct and prolonged contact with the skin may cause sensitization of humans to nickel and may lead to allergic reactions; whereas for these reasons the use of nickel in such objects should be limited;

Whereas one Member State has already introduced a set of control measures on its territory to counteract nickel

(*) The Commission proposal was presented at the 14th amendment of Directive 76/769/EEC (OJ No C 116, 27. 4. 1993, p. 18).

⁽¹⁾ OJ No C 116, 27. 4. 1993, p. 18.

⁽²⁾ OJ No C 304, 10. 11. 1993, p. 2.

⁽³⁾ Opinion of the European Parliament of 2 December 1993 (OJ No C 342, 20. 12. 1993, p. 15), Council common position of 4 March 1994 (OJ No C 137, 19. 5. 1994, p. 60) and Decision of the European Parliament of 5 May 1994 (not yet published).

sensitization and nickel allergy and a second Member State plans to introduce on its territory a different set of control measures; whereas there is therefore a risk of barriers to trade;

Whereas the test methods to be used in demonstrating conformity with this Directive should be defined and published before the Directive is implemented; whereas these test methods should be the subject of a European standard;

Whereas limitations already adopted or planned by certain Member States on the use of nickel directly affect the completion and functioning of the internal market; whereas it is therefore necessary to approximate the laws of the Member States in this field and consequently to amend Annex I to Directive 76/769/EEC ⁽⁴⁾,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 76/769/EEC is hereby supplemented
Article 2

1. Member States shall adopt the laws, regulations and administrative provisions necessary to comply with this Directive not later than six months after publication by the Commission in the *Official Journal of the European Communities*, of the standards adopted by the European Committee for Standardization (CEN) on all the test methods used in demonstrating the conformity of the products with this Directive, or six months after the adoption of this Directive if that date is later than the former, so that:

⁽⁴⁾ OJ No L 262, 27. 9. 1976, p. 201. Directive as last amended by Directive 91/339/EEC (OJ No L 186, 12. 7. 1991, p. 64).

- six months after the expiry of one or other of those periods, whichever is applicable, no manufacturer or importer may place on the market products which fail to comply with this Directive,
- 18 months after the expiry of one or other of those periods, whichever is applicable, products which fail to comply with this Directive cannot be sold or made available to the final consumer, unless they have been placed on the market before the expiry of the period in question.

They shall forthwith inform the Commission thereof.

2. When Member States adopt the measures referred to in paragraph 1, they shall contain a reference to this

Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 30 June 1994.

*For the
European Parliament*

E. KLEPSCH

The President

For the Council

A. BALTAS

The President

ANNEX

May not be used:

28. Nickel
CAS No 7440-0-20
EINECS No 2311114
and its compounds

1. in post assemblies which are inserted into pierced ears and other pierced parts of the human body during epithelization of the wound caused by piercing, whether subsequently removed or not, unless such post assemblies are homogeneous and the concentration of nickel — expressed as mass of nickel to total mass — is less than 0,05 %;
2. in products intended to come into direct and prolonged contact with the skin such as:
 - earrings,
 - necklaces, bracelets and chains, anklets, finger rings,
 - wrist-watch cases, watch straps and tighteners,
 - rivet buttons, tighteners, rivets, zippers and metal marks, when these are used in garments
 if the rate of nickel release from the parts of these products coming into direct and prolonged contact with the skin is greater than 0,5 µg/cm²/week;
3. in products such as those listed in point 2 where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such products coming into direct and prolonged contact with the skin will not exceed 0,5 µg/cm²/week for a period of at least two years of normal use of the product.

Furthermore, products which are the subject of points 1, 2 and 3, may not be placed on the market unless they conform to the requirements set out in those points.