

COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 2 April 1993

Proposal for a

COUNCIL DIRECTIVE

amending for the fourteenth 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.

(presented by the Commission)

EXPLANATORY MEMORANDUM

I. Introduction

On 27th June 1989 Denmark adopted a law providing for a ban of the use of nickel in a wide range of jewellery and other personal items where the rate of nickel release may exceed a certain threshold value. The purpose of the law was to protect the health of consumers from the possible sensitizing effects of nickel items coming into contact with the skin.

On 21st March 1991 Germany notified the Commission and other Member States of its intention to regulate in the same field. However, unlike in the Danish case, the approach proposed was to ban the use of nickel in posts for ear-piercing and to require labelling of all nickel containing jewellery coming into contact with the skin.

The Commission having examined these divergent legislative initiatives, having received a letter expressing the concern of the Italian authorities and having consulted experts from all Member States gave notice of its intention to propose to the Council an amendment to Annex I of Council Directive 76/769 to provide for harmonized limitations on the marketing and use of certain nickel containing items which contact the skin.

The Commission considers that this proposal is consistent with the Principle of Subsidiarity and with the requirement under the Treaty to take as of base in its harmonization proposals a high level of protection concerning health, safety, environmental protection and consumer protection.

II. Background

Nickel is widely used in costume jewellery and other personal items coming into contact with the skin. Not only is it cheap but it is especially resistant to corrosion that may result from human perspiration.

Unfortunately, however, up to 10% of certain population groups are sensitized to nickel and may suffer allergic reactions in the form of skin irritation and eczema when they come into intimate and prolonged contact with nickel containing personal items. There is evidence of increase in the numbers of sensitized persons and that the phenomenon is

particularly prevalent among teenagers.

Consumers become sensitized after exposure to a particularly high concentration of nickel. This usually occurs when parts of the body such as ears and noses are pierced and a nickel containing post is inserted into the cavity during healing of the piercing wound.

Sensitized persons subsequently coming into intimate and prolonged contact with nickel containing items such as costume jewellery may suffer an allergic reaction. Irritation may not be limited to the point of contact; there may be secondary spread to flexural areas, hands and eyelids. Such allergic reactions, known as nickel dermatitis can usually be treated successfully with a skin cream (topical corticosteroids) but may recur on further contact with a nickel containing item.

Essentially there are two families of nickel containing personal goods which when used in a prolonged contact with the skin can provoke nickel dermatitis in sensitized persons. The first family uses homogeneous alloys containing nickel and the second family contains nickel but coated with a non-nickel coating. Both families include the same types of products; examples are earrings, necklaces, bracelets, wrist watch cases and straps, spectacle frames, zippers but there are many others. Typically such products are cheap fantasies and have a short life.

Given the hazards of nickel and that consumers are likely to be exposed to these hazards in every day situations it is desirable that the use of nickel be limited especially in the posts for piercing wounds but also in the case of jewellery and other personal items coming into intimate and prolonged contact with the skin.

III. Definition of Nickel

Nickel is a silvery metal placed in Group VIII of the Periodic Table together with cobalt and iron. It is identified by the following:

CAS N°: 9440-02-0

EINECS N°: 2311114

IV. Properties of Nickel

Initial sensitization to nickel as mentioned above usually occurs when parts of the body are pierced and a nickel post is inserted in the piercing wound. Sensitization takes the

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form of an irreversible reaction of the immune system which spreads from the wound and becomes generalised throughout the body.

Nickel dermatitis may occur subsequently when sensitised persons come into intimate and prolonged contact with nickel containing items such as custom jewellery. The probability of an allergic reaction has been shown to depend upon the rate of nickel release where skin contact takes place. Danish research has shown that no reaction is likely where the rate of release is less than $0.5\mu\text{g}/\text{cm}^2/\text{week}$.

V. Existence of substitutes

Substitutes for nickel are available in all the nickel applications restricted by this proposal.

In the case of posts for pierced body parts the preferred substitute is titanium though silver might also be used. The higher cost of these metals is hardly significant in view of the limited number of posts used and their small size.

The most suitable substitutes for nickel in uncoated nickel items contacting the skin are stainless steel and white gold.

The solution in the case of coated items is not to remove the nickel but rather to increase the thickness of noble metal coating on the surface (typically silver, gold or rhodium).

VI. Conclusion

It is concluded that the use of nickel in personal items coming into intimate and prolonged contact with the skin may under certain circumstances pose a danger to the health of consumers. The strategy proposed therefore is the following:

- The use of nickel in posts for pierced ears and other pierced body parts should be banned.
- The rate of nickel release from those parts of nickel containing personal items in intimate and prolonged contact with the skin should be limited to $0.5\mu\text{g}/\text{cm}^2/\text{week}$.
- The rate of nickel release from the items in (b) which have in addition a non-nickel coating should be limited to $0.5\mu\text{g}/\text{cm}^2/\text{week}$ for at least three years of normal use.

VII. Conformity with the Treaty

It is clear from the foregoing that this proposal is intended to afford a high level of protection for consumers and is therefore in conformity with Article 100A(3) of the Treaty.

The proposal does not call for any special provisions of the kind referred to in Article 8c of the Treaty.

**VIII Consultation of the European Parliament and the
Economic and Social Committee**

In compliance with Article 100A of the Treaty, the Cooperation Procedure with the European Parliament is applicable. The Economic and Social Committee has to be consulted.

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THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,¹

In cooperation with the European Parliament,²

Having regard to the opinion of the Economic and Social Committee,³

Whereas article 8A of the Treaty establishes an area without internal barriers in which the free circulation of goods, of persons, of services and capital is assured;

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;⁴

1 OJ No

2 OJ No

3 OJ No

4 OJ No C 294 of 23.11.1989 p. 1

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Whereas the presence of nickel in certain objects coming into direct and prolonged contact with the skin may cause sensitisation of man 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 sensitisation and nickel allergy, a second Member State plans to introduce on its territory a different set of control measures and that there exists therefore a risk of barriers to trade; whereas it is therefore necessary to approximate the laws of the Member States in this field and consequently amend Annex I to Directive 76/769/EEC(5) as last amended by Directive 91/339/EEC(6);

Whereas the test methods needed to check conformity with the essential requirements detailed in the annex hereto will be the subject of a European standard to be incorporated in an annex to this Directive; whereas recourse shall be made to the test methods detailed in this annex;

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 amend Annex I to Directive 76/769/EEC,⁵ as last amended by Directive 91/339/EEC;⁶

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

Article 2

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive no later than 1 year after the date of its adoption and shall forthwith inform the Commission thereof. They shall apply these provisions from (3 months after the date stated above).

5 OJ No L 262, 27.9.1976, p.201.

6 OJ No L 186 of 12.7.1991 p. 64

2. When Member States adopt the abovementioned provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by the Member States.

Article 3

This Directive is addressed to the Member States.

Done at Brussels,

For the Council

ANNEX

xx. Nickel

CAS N°7440-02-0
EINECS N°2311114
and its compounds

May not be used:

1. in post assemblies which are inserted into pierced ears and other pierced parts of the human body during epithelisation of the wound caused by piercing, whether subsequently removed or not, unless such post assemblies are homogenous and the concentration of Nickel - expressed as mass of nickel to total mass - is less than 0.05%

2. in products such as the following:

- earrings
- necklaces, bracelets and chains, anklets, finger rings, hair clips and slides
- wrist watch cases, watch straps and tighteners
- spectacle frames
- 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 $\mu\text{g}/\text{cm}^2/\text{week}$

3. In products such as those listed in paragraph 2 above 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 $\mu\text{g}/\text{cm}^2/\text{week}$ for a period of at least 3 years of normal use of

the product.

Furthermore, products which are the subject of paragraphs 1, 2 and 3 above, may not be placed on the market unless they conform to the requirements of these paragraphs

FINANCIAL STATEMENT

SECTION 1: FINANCIAL IMPLICATIONS

1. Title of operation

Proposal for a fourteenth amendment to Directive 76/769/EEC

2. Budget heading involved

Article B5-300: completing the internal market

3. Legal basis

- Article 100a of the Treaty
- Council Resolution of 7 May 1985 on a new approach to technical harmonization and standardization

4. Description of operation

4.1 Specific objective of operation

The proposed operation involves:

- restricting the marketing and use of nickel in personal goods coming into intimate and prolonged contact with the skin

4.2 Duration

This is a "one-off" operation

4.3 Target population

Industrialists and consumers

5. Classification of expenditure

- Differentiated appropriation
Non-compulsory

6. Type of expenditure

The expenditure would consist of financial support granted by the Commission to standardization organizations. As in the case of other "New Approach" directives, the Commission intends to entrust the CEN with the task of drafting harmonized standards. The necessary mandate for this task comes under the framework contract signed on 10 October 1985, which provides for just such financial support from the Commission.

7. Financial impact on appropriations for operations

7.1 Method of calculating the cost

The calculation method relating to Article B5-300 applies here. According to calculations performed by the European Committee for Standardization (CEN) on the basis of their experience of existing mandates, the average cost to the Commission of each new standard is ECU 50.000.

As two standards are to be introduced, the impact should be about ECU 100.000.

7.2 Proportion of the mini-budget

N/A

7.3 Schedule of commitment (CE) and payment (CP) appropriations
(Article 5B-300)

	CE	CP
1993	100.000	50.000
1994		50.000
TOTAL	100.000	100.000

8. What anti-fraud measures are planned?

Expenditure under the CEN contract is subject to the anti-fraud measures laid down in that contract and to any audits carried out by CEN.

SECTION 2: ADMINISTRATIVE EXPENDITURE

No new administrative expenditure is foreseen. Any meetings to be held would take place pursuant to Directive 76/769/EEC in the framework of which the "Technical Progress Committee: Dangerous Substances and Preparations" would be convoked, and would be covered by the budget for that Directive. The estimated annual budget for this Committee is made up of 174.000 ECU for meetings of experts (01/03/U/080) and 12.000 ECU for meetings of the Committee itself (01/03/T/080). However, no extra meetings are foreseen at this time.

SECTION 3: ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

1. Objective and coherence with financial programming

1. The aim of the proposed operation is to harmonize restrictions on the marketing and use of certain personal goods containing nickel so as to avoid creating obstacles to trade and, at the same time, to provide a high level of protection for consumers.

The proposal lays down essential requirements for control of nickel. These will provide a solid basis for standardization in Europe. The amount of work to be done on standards should thus be reduced and, consequently the impact on the Community budget lessened.

2. The operation is incorporated in DG III's financial programming and is included in the appropriations allocated to technical standardization and harmonization.
3. The general objective is to complete the internal market.

II. Grounds for the operation

Harmonization serves to prevent obstacles to trade and, at the same time, to provide a high level of protection for consumers. Standardization is necessary in the case of personal goods containing nickel; otherwise the various tests and conditions considered necessary before marketing the product might act as obstacles to trade.

III. Monitoring and evaluation of the operation

The Committee set up under Directive 76/769/EEC will be responsible for monitoring the application of this Directive.

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Evaluation will be carried out annually via the progress reports on the adoption of the standard drafted by the CEN.

COMPETITIVENESS AND EMPLOYMENT IMPACT ASSESSMENT

I. Nature and Rationale of the Measure

The current proposal concerns restrictions on the marketing and use of nickel and its compounds. Specifically it limits the use of nickel in certain goods of a personal nature which come into intimate and prolonged contact with the skin.

The objective of the measure is to protect consumers from sensitization to nickel and from nickel dermatitis. Sensitization usually occurs following ear piercing and is attributed to the nickel content of posts inserted in the pierced hole during the period when the wound is healing. Once so sensitized consumers may suffer from nickel dermatitis each time nickel containing objects come into intimate and prolonged contact with their skin.

The proposal would ban the use of nickel in piercing posts and stipulate that nickel release should be limited from all nickel containing objects coming into intimate and prolonged contact with the skin.

The proposal takes the form of an amendment (the 14th amendment) to Directive 76/769/EEC, the framework directive to limit the marketing and use of dangerous substances and preparations. It is not a new legislative departure, so that the question of subsidiarity does not arise. As with previous amendments Community intervention is essential to protect the Internal Market this being impossible to achieve by Member States acting alone.

II. Features of the Business in Question

The main businesses to be affected by the measure are custom jewellery and clothing. Thus companies producing piercing posts must stop using nickel and producing cheap earrings, necklaces, bracelets, watches and other fantasy type jewellery products must limit their use of nickel. So too must companies making garments e.g. jeans, brassiers etc. limit the use of nickel in buttons, rivets, zippers etc. where these come into intimate and prolonged contact with the skin.

There are at least two companies in the Community (F,

UK) making piercing posts.

Much of the cheap jewellery concerned and many of the garments are imported into the Community from third countries e.g. from South East Asia, United States and Canada. Only 50% of these industries are thought to be Community based.

III. What direct obligations does the measure impose on industry?

The Jewellery industry must:

- (a) replace nickel by another metal e.g. titanium or silver, in piercing posts.
- (b) reduce the use of nickel in homogeneous nickel alloy parts coming into intimate and prolonged contact with the skin e.g. by increasing the use of stainless steel or white gold.
- (c) increase the thickness of precious metal coatings on coated nickel containing parts coming into intimate and prolonged contact with the skin.

The obligations of the clothing industry will be mainly of the type (b).

The industry have expressed concern about the implementation of the type (b) and (c) obligations as suitable test methods are not presently available. For this reason the Commission will mandate CEN to develop suitable methods in the period preceding implementation (Preliminary work has been underway since February 1992 in CEN Technical Committee No. 283, Working Group No. 4).

IV. What indirect obligations are local authorities likely to impose on business?

None.

V. Are there any special measures in respect of SME's?

No. The Directive establishes essential requirements for nickel control that must be met by all companies, large and small so that the protection of consumer health can be assured.

VI. What is the likely effect on (a) competitiveness of industry and (b) employment?

(a) Competitiveness of industry

Companies making piercing posts will have to use more expensive materials; all will be similarly affected, however, so that relative competitiveness should not change.

If anything the competitiveness of European Jewellery and clothing industries will benefit from the measures proposed. European companies will have to compete less with imports of low quality goods.

Neither the cost of the measures nor the timing are of particular concern to the industry.

(b) Employment

The effects on employment are likely to be slight and to be felt mainly outside the Community.

VII. Consultation

The following industry and consumer associations were consulted on preparation of the proposal and participated in meetings of the Member State experts:

Interest Group	Representative Association

Industry (Metals)	European Association of Metals (Brussels)
Consumers	BEUC

Both are in broad agreement. However, the European Association of Metals maintain a reserve until such a time as adequate test methods are developed.

The European Standards organisation CEN will be mandated to develop the test methods that will be needed to check that the nickel containing personal goods covered by the Directive are in conformity with the essential requirements which the Directive sets down. Development of such test methods will be funded in part by the Commission and in part by CEN and it is intended that the European Standards incorporating the test methods will be available before the Directive enters into force.

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