EXPLANATORY MEMORANDUM TO THE

DANGEROUS SUBSTANCES AND PREPARATIONS (NICKEL) (SAFETY) REGULATIONS 2005

2005 No. 2001

1. This explanatory memorandum has been prepared by the Department of Trade and Industry and is laid before Parliament by Command of Her Majesty.

   This memorandum contains information for the House of Lords Select Committee on the Merits of Statutory Instruments.

2. DESCRIPTION

2.1. These Regulations revoke and re-enact with amendments the Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2000 [S.I. 2000 No.1668].

2.2. Council Directive 76/769/EEC (O.J. L262, 27.9.1976, p.210), on the approximation of laws in Member States, relates to restrictions on the marketing and use of certain dangerous substances and preparations. These Regulations implement this Directive insofar as it restricts the use of nickel and its compounds in products intended to come into direct and prolonged contact with the skin, and in post assemblies intended to be inserted into pierced ears and other pierced parts of the human body.

2.3. The Regulations also implement for the first time Commission Directive 2004/96/EC (O.J.L301, 28.9.2004, p.51) that amends Directive 76/769/EEC by amending the restriction on the use of nickel and its compounds in piercing post assemblies.

3. MATTERS OF SPECIAL INTEREST TO THE JOINT COMMITTEE ON STATUTORY INSTRUMENTS

3.1. The Regulations do not define the term “post assembly”. This term appears in the Directive but is not defined. It also appeared in the previous Regulations and is well understood by users. There would be a risk of failing to implement the Directive correctly or of causing confusion if we were to try and define this term. In view of this and the fact that the term appears to be well understood by users, the Department has decided not to include a definition.

4. LEGISLATIVE BACKGROUND

4.1. These Regulations are made using powers under the Consumer Protection Act 1987, section 11.

4.2. The Regulations revoke and re-enact with amendments the Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2000. The amendments, among other things, implement Commission Directive 2004/96/EC.

4.3. The Transposition Note in relation to the Regulations is attached at Annex A to this memorandum.

5. EXTENT

5.1. Consumer safety is a reserved matter and therefore the instrument will apply to all of the United Kingdom.

6. EUROPEAN CONVENTION ON HUMAN RIGHTS

6.1. As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. POLICY BACKGROUND

7.1. Directive 76/769/EEC restricts the marketing and use of certain chemicals to protect the environment, workers and consumers. The Directive lists those chemicals of concern and specifies the restrictions placed upon them. In the light of technical developments and new knowledge about the danger of chemicals, the European Commission has regularly amended this Directive by adding further chemicals or by amending existing entries.

7.2. Individuals may become sensitised to nickel when materials that contain nickel are placed in direct and prolonged contact with the skin. People so sensitised remain so for life and subsequent contact of the skin with materials that release nickel may result in nickel allergic contact dermatitis eliciting a variety of reactions ranging from mild skin irritation to severe eczema.

7.3. Directive 94/27/EC, the 12^{th} amendment to Directive 76/769/EEC, sought to prevent sensitisation to nickel by restricting the use of nickel and its compounds in items intended to come in close and direct contact with the skin. Items such as earrings and necklaces etc. were prohibited from being placed on the market if the rate of release of nickel from those parts in contact with the skin exceeded 0.5 micrograms per square centimetre per week ($0.5\mu g/cm^2$/week). Such items, having a non-nickel coating, were also prohibited from being placed on the market unless the coating was sufficient to ensure that the nickel release rate was not greater than $0.5\mu g/cm^2$/week for a period of at least two years of normal use.

7.4. Directive 94/27/EC also prohibited the use of nickel in post assemblies, which are placed into pierced ears or other pierced parts of the human body during the healing of the wound caused by piercing, unless the nickel content was less than 0.05%. The effect of this provision was that stainless steels (in particular the 316 and 316L grades of “Surgical Steel”) were prohibited for use in such post assemblies since these materials contain nickel much in

excess of the 0.05% limit. There was therefore an anomaly in that, although stainless steels were effectively prohibited for use in piercing post assemblies, certain grades could continue to be used by the medical profession for human body implants. Directive 94/27/EC was implemented in the United Kingdom by means of the Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2000.

7.5. In response to claims that the rate of nickel release from "Surgical Steel" was much less than 0.5µg/cm^2/week, LGC Ltd., supported by the European Commission, carried out a study on the "*Risk of sensitisation of humans to nickel by piercing post assemblies*". The study, published 31st March 2003, was referred to the European "Scientific Committee on Toxicity, Ecotoxicity and the Environment" (CSTEE) for peer review. CSTEE endorsed the recommendation of the study that the maximum limit of 0.05% for the *nickel content* be replaced by a maximum limit of 0.2µg/cm^2/week for the *nickel release rate*. The study also recommended that this new limit should apply to all post assemblies and not solely to those used during of the healing of the wound caused by piercing.

7.6. In the light of the LGC study and the CSTEE endorsement of its recommendations, the Commission made a proposal for a Directive to amend Directive 76/769/EEC. Subsequently, Directive 2004/96/EC was adopted by all Member States on 27th September 2004. It amended Directive 76/769/EEC by changing the requirement with which all piercing post assemblies have to conform, from one based on nickel content to a more appropriate one based on the nickel release rate.

7.7. A targeted informal consultation was held in June 2004. Subsequently a 12-week public consultation exercise on the implementation of Directive 2004/96/EC was carried out between March and June 2005 and a meeting with major stakeholders was held in June 2005. The consultation document was sent to over 100 consultees, including industry, analytical laboratories and other interested parties affected by the regulations. Of the 18 written responses to the consultations, only one had reservations about the changes made.

7.8. The change to the current regulations is not politically or legally important.

8. REGULATORY IMPACT

8.1. A Regulatory Impact Assessment has been prepared and a copy is attached at Annex B to this memorandum.

8.2. There are no identifiable costs to the public sector or to the Exchequer.

9. CONTACT

David Jenkinson at the Department of Trade and Industry, Tel: 0207 215 0366 e-mail: david.jenkinson@dti.gsi.gov.uk, can answer any queries regarding the instrument.

Regulatory Impact Assessment

1. **The Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2005**

Directive

2. 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.

Purpose and intended effect of measures

Objective

3. The primary aim of the Directive is to maintain the level of protection to the general public against the possible risk of sensitisation to nickel by the use of piercing post assemblies but replacing the limit on the nickel content of piercing post assemblies with a more appropriate limit based on the rate of nickel release.

4. It will also have the effect of removing the anomaly whereby nickel containing materials (such as stainless steels) are currently prohibited for use in post assemblies intended for use during healing of the wound caused by piercing, whereas such materials may be used by the medical profession in human body implants.

Background

5. Nickel can cause allergic contact dermatitis that, in sensitised individuals, may result in a variety of reactions ranging from a mild skin reaction to severe eczema. Individuals may become sensitised to nickel when materials that contain nickel are placed in direct and prolonged contact with the skin. Individuals, once sensitised, remain so for life and subsequent exposure to nickel ions by direct and prolonged skin contact with nickel-releasing materials may result in nickel allergic contact dermatitis. Studies have further indicated that the majority of those sensitised to nickel became so after ear piercing.

6. Directive 94/27/EC, 12th Amendment to the Marketing and Use Directive 76/769/EEC, therefore, sought to prevent sensitisation to nickel by restricting the use of nickel and its compounds in items intended to come into close and prolonged contact with the skin. Among other things, it prohibited the use of nickel and its compounds in post assemblies intended to be inserted into pierced ears and other parts of the human body during the healing of the wound caused by piercing, unless the nickel content was less than 0.05%.

7. However, in the light of the results of a recent targeted assessment of the risk of sensitisation of humans to nickel by piercing post assemblies, and its subsequent endorsement by the European "Scientific Committee on Toxicity, Ecotoxicity and the Environment" (CSTEE), the European Commission accepted that a limit on the rate of release of nickel from piercing post assemblies would be more appropriate than a limit on the nickel content of such post assemblies.

8. In consequence, Directive 2004/96/EC was adopted by all Member States on 27th September 2004 and amended Annex 1 to Directive 76/769/EEC in order to adapt it to technical progress. Nickel and its compounds may now not be used in *any* post assembly inserted into to ears and other parts of the human body unless the rate of *nickel release* from such post assemblies is less than 0.2 µg /cm^2/week.

Risk Assessment

9. The Directive will maintain the level of protection to the general public against the possible risk of sensitisation to nickel by the use of piercing post assemblies but replacing the limit on the nickel content of piercing post assemblies with a more appropriate limit based on the rate of nickel release.

Options

10. **Option (i)**: To fully implement the provisions of the Directive.

Option (ii) : To request industry to adopt voluntary measures.

Option (iii): To do nothing.

11. Option (i) The proposed Directive is consistent with UK policy and practice on this issue. Implementation of the Directive will maintain a high level of protection to individuals from sensitisation to nickel through the use of post assemblies inserted into pierced ears or other pierced parts of the human body.

    It will also remove the anomaly whereby nickel containing materials (such as stainless steels) are essentially prohibited for use in post assemblies used during healing of the wound caused by piercing, whereas such materials may be used by the medical profession in human body implants.

12. Option (ii) Under this option industry would be required to adhere to voluntary guidelines or targets. This, however, could not guarantee as high a level of consumer safety as Option (i) since it is likely that some manufacturers would adopt the code while others would not. It would also necessitate agreeing draft guidelines and the introduction of an effective monitoring system.

    Option (iii) Since Member States have a Treaty obligation to implement all agreed Directives, failure to implement this Directive would result in

infraction proceedings being initiated against the United Kingdom by the European Commission.

On balance, therefore, Option (i) is the preferred option.

Benefits

Economic

13. The Directive will permit the ear piercing industry greater choice in the materials that they are permitted to use in the manufacture of piercing post assemblies. The use of newly permitted, superior materials may result in a reduction of costs associated with complaints about quality of piercing post assemblies.

Environmental

14. No specific benefits to the environment have been identified.

Social

15. The Directive will maintain, and possibly enhance, the level of protection to the general public against the possible risk of sensitisation to nickel by the use of piercing post assemblies but will provide them with greater choice of the materials used in their construction.

Costs

16. Discussions with the relevant trade associations have indicated that the costs to industry are likely to be small. The testing procedure to demonstrate compliance with the new restrictions on piercing post assemblies is that already specified to demonstrate compliance with an existing provision of the "Nickel Directive". Although they may be some initial costs to ensure that the materials being used for post assemblies are compliant with the new provisions, once suitable materials have been identified, testing costs will be reduced.

Equity and fairness

17. The overriding consideration in the Directive is the maintenance the high level of protection afforded to the general public from the possible risks of sensitisation to nickel by the use of piercing post assemblies. The Directive will impact equally across the particular sectors of industry affected and will be implemented in all Member States.

Consultation with small business: the Small Firms Impact Test

18. Stage one of the Small Firms Impact Test was carried out by contacting small businesses, SME trade associations and other representative organisations in the small business sectors most likely to be affected by implementation of the Directive. However, we have been unable to identify any disproportionate

impact on small firms as a result of the implementation of the Directive. There was, therefore, no requirement to carry out further Small Firms Impact Test analysis. No unidentified impacts or unintended consequences of the implementation of this Directive on small firms were identified during the consultation period.

Competition Assessment

19. Stage One of the Competition Assessment was undertaken. When applying the Competition Assessment Filter, the results indicated that as the Directive will permit materials to be used in post assemblies that were previously prohibited, this will have the effect of presenting the opportunity for increased competition in the market without distorting it. The Directive will not serve as a barrier to entry for potential entrants nor impose substantially more cost on some firms than others. The Directive will set harmonised requirements to ensure that all involved in the manufacture and supply of post assemblies can compete on an equal footing.

Enforcement and Sanctions

20. The provisions of this Directive will be transposed into UK law by means of "*The Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2005*" made using powers under the Consumer Protection Act 1987 (CPA), Section 11. The Regulations will extend to Great Britain and Northern Ireland, and the sanctions applicable to breaches of safety regulations under Section 11 of the CPA, will apply.
21. In Great Britain, the Regulations will be enforced by Local Trading Standards Departments, and in Northern Ireland by Environmental Health Departments.

Monitoring and Review

22. The Regulations will be monitored and reviewed in accordance with normal procedures. A review is likely once the implementing regulations have been in force for 2-3 years.

Consultation

Within Government

23. The following Government Departments were consulted about the implementation of this Directive during this consultation exercise: Health and Safety Executive, Health and Safety Commission, Department for Environment Food and Rural Affairs and Department of Environment (Northern Ireland).

Public Consultation

24. The Consultation Document listed over 100 organisations and individuals to whom the document was sent. The consultees included,

among others, the jewellery industry, the ear piercing industry, manufacturers, the chemical industry, consumer organisations, trade associations, charities, enforcement authorities and non-Governmental organisations. The consultation ran for 12 weeks, commencing 24th March 2005.

Summary and Recommendation

25. The proposal for a Directive, in the framework of the Marketing and Use Directive 76/769/EEC, to replace the limit on the nickel content of piercing post assemblies with a more appropriate limit based on the rate of nickel release, will maintain, and possibly enhance, the level of protection to the general public against the possible risk of sensitisation to nickel by the use of piercing post assemblies. It removes the anomaly whereby nickel containing materials (such as stainless steels), are currently prohibited for use in post assemblies intended for use during healing of the wound caused by piercing, whereas such materials may be used by the medical profession in human body implants. It enhances the level of protection to the general public since the limit applies to all post assemblies and not solely to those used during the healing of the wound caused by piercing.

Declaration:

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs.

Signed by the Minister responsible

Gerry Sutcliffe

(Parliamentary Under-Secretary of State for Employment Relations and Consumer Affairs)

Date *13th July 2005*

Transposition Note for Directives 76/769/EEC and 2004/96/EC

This Transposition Note has been prepared by the Department of Trade and Industry and is intended to show how the Department has implemented the nickel restrictions contained in Directive 76/769/EEC (O.J. l262, 27.9.1976, p.201) ("the Directive") 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 as last amended by Directive 2004/96/EC (O.J. L301, 28.9.2004, p. 51).

The Directive restricts the placing on the market and use of various dangerous substances and preparations listed in the annex to the Directive. Point 28 in the Annex imposes restrictions on the marketing and use of nickel and its compounds in body piercing post assemblies and products intended to come into direct and prolonged contact with the skin. Point 28 has recently been amended by Directive 2004/96/EC.

The nickel restrictions in 76/769/EEC were inserted into the Directive by Directive 1994/27/EC which also provided for the development of standards by the European standards bodies to be used in demonstrating compliance with the requirements of the Directive. The Commission published the relevant standards under Commission Communication 1999/C 205/05 (OJ C205, 20.7.1999, p.5).

The Directive has been implemented by a variety of Regulations. The Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2000 (SI 2000/1668) ("the 2000 Regulations") implement the nickel restrictions in the Directive. The new Regulations revoke and replace the 2000 Regulations and now implement the nickel restrictions in the Directive. They also transpose Directive 2004/96/EC.

The Department of Trade and Industry has lead responsibility for implementation of Directives 76/769/EEC and 2004/96/EC. The first table below shows how the nickel restrictions in the Directive have been transposed. The table below shows how Directive 2004/96/EC has been transposed.

Directive			
Directive 76/769/EEC (O.J. L262, 27.9.1976, p.201) 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 as last amended by Directive 2004/96/EC (O.J. L301, 28.9.2004, p. 51).			
Article	**Objective**	*Transposition*	*Responsibility* (Secretary of State if not specified)
1(1)	Provides that the Directive is concerned with restricting the marketing and use in Member States of the European Union of the dangerous substances and preparations listed in the Annex.	No need to transpose	
1(2) (a) and (c)	Provides that the Directive does not apply to various matters (not relevant to nickel)	No need to transpose	
1(2)(b)	Provides that Directive does not apply to substances and preparations exported to countries which are	Regulation 3(4)(a) provides that the prohibition on the marketing and use of nickel shall not apply	

	not Member States.	to any post assembly or product intended for export to a country which is not a member of the EEA.	
1(3)	Defines substances and preparations.	No need to transpose for the purposes of the restrictions on nickel.	
2 (first sentence)	Requires Member States to take all necessary measures to ensure that the dangerous substances and preparations listed in the Annex to the Directive may only be placed on the market and used subject to the restrictions contained in that Annex. For present purposes, the relevant provisions in the Annex are found in point 28 (nickel).	Regulation 3 implements the restrictions on the marketing and use of nickel contained in point 28 of the Annex to the Directive (as explained below)	
Annex, Point 28 (paragraph 1-3)	Provides that nickel and its compounds may not be used in: 1) post assemblies inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release is less than 0.2µg/cm^2/week; 2) products intended to come into direct and prolonged contact with the skin if the rate of nickel release is greater than 0.5µg/cm^2/week (paragraph 2 contains an illustrative list of such products) 3) products intended to come into direct and prolonged contact with the skin which are covered with a non-nickel coating unless the coating is such as to ensure that the rate of nickel release does not exceed 0.5µg/cm^2/week	Regulation 3(1) provides that nickel and its compounds shall not be used in the post assemblies and other products listed in point 28 paragraphs 1-3. Regulation 3(2) defines the products restricted under point 28(2).	
[Commission	The Commission has	Regulation 4 specifies	

Communication 1999 C/205/05]	issued Communication 205/05 listing harmonised standards (test methods) to be used in demonstrating conformity with the above requirements (pursuant to the Directive and directive 94/27/EC).	the test methods to be used in demonstrating conformity with the requirements of regulations 3.	
Annex, Point 28 (final sentence)	Provides that products listed above (post assemblies and products intended to come into direct and prolonged contact with the skin) must not be placed on the market unless they meet the requirements of point 28 (i.e. satisfy the nickel release limits)	Regulation 3(3) prohibits the supply of any post assembly or product which contravenes the retractions on use contained in regulation 3(1).	
2 (second sentence)	Provides that the restrictions in the Directive shall not apply to marketing and use for Research and Development or analysis purposes.	Regulation 3(4) provides a corresponding exemption	
2a	Administrative	N/A	
3	Administrative	N/A	
4	Administrative	N/A	

Directive			
Directive 2004/96/EC (O.J. L301, 28.9.2004, p. 51) amending Council Directive 76/769/EEC as regards restrictions in the marketing and use of nickel for piercing post assemblies for the purpose of adapting its Annex 1 to technical progress			
Article	Objective	Transposition	Responsibility (Secretary of State if not specified)
1	Amends the restriction on the marketing and use of nickel in body piercing post assemblies contained in point 28 of the Annex to the Directive.	Regulation 3 restricts the marketing and use of nickel in body piercing post assemblies as provided for under the amended point 28.	
2(1) (first sentence)	Requires Member States to adopt and publish implementing legislation by 1st August 2005.	These Regulations are intended to be made before 1st August 2005.	
2(1) (second sentence)	Requires Member States to apply implementing legislation on 1st September 2005.	These Regulations will come into force on 1st September 2005.	
2(2)	Administrative	N/A	
3	Administrative	N/A	
4	Administrative	N/A	