

dti

NICKEL

Consultation on the implementation of
European Directive 2004/96/EC
concerning an amendment to the
restrictions on the marketing and use
of nickel for piercing post assemblies

CONSULTATION DOCUMENT

MARCH 2005

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dti

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We champion UK business at home and abroad. We invest heavily in world-class science and technology. We protect the rights of working people and consumers. And we stand up for fair and open markets in the UK, Europe and the world.

Introduction

Consultation on the implementation of European Commission Directive 2004/96/EC amending the restrictions on the marketing and use of nickel for piercing post assemblies

Directive 2004/96/EC amends the restrictions on the use of nickel in piercing post assemblies by changing the requirements with which such items have to conform. The *rate of nickel release (migration)* has replaced *nickel content* as the basis of conformity. Nickel will be prohibited for use in any post assembly, intended to be inserted into pierced ears and other pierced parts of the human body, unless the rate of nickel release from such a post assembly is less than 0.2 µg/cm²/week. This requirement will apply to *all* post assemblies and not only to post assemblies used during epithelization (healing) of the wound caused by piercing

This consultation document does not seek your views on the Directive itself, but on our proposed implementation of it in the United Kingdom.


It seeks your views on the likely impact the new regulations will have on industry and consumers. Responses to this consultation will help in the preparation of a full Regulatory Impact Assessment.

We also request your views on a draft of the Guidance Notes to the new regulations.

Document issued on: 24th March 2005

Responses to be received by: 16th June 2005

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1 **Executive Summary**

Purpose of this consultation

1.1 This consultation document seeks your views on how the United Kingdom proposes to implement Commission Directive 2004/96/EC¹ which was adopted by all Member States on 27th September 2004. This Directive amends the Marketing and Use Directive 76/769/EEC² by making changes to Point 28 of Annex 1 to that Directive, concerning restrictions on the marketing and use of nickel and its compounds.

1.2 The first paragraph of the second column of Point 28, which requires that

“Nickel and its compounds may not be used in post assemblies which are inserted into 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%”

has been deleted and replaced by

“Nickel and its compounds may not be used in all post assemblies which are inserted into ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than 0.2 µg/cm²/week (migration limit)”

1.3 This consultation document seeks your views on how we intend to implement Directive 2004/96/EC in the United Kingdom and the likely impact the new regulations will have on industry and consumers. Responses to this consultation will help in the preparation of a full Regulatory Impact Assessment. It also asks for your views on a draft of the Guidance Notes to the new Regulations.

1.4 Commission Directive 2004/96/EC is attached at Annex A and drafts of the new Regulations and Guidance Notes at Annexes B and C respectively.

Why these measures have been adopted

1.5 They have been taken in the light of the conclusions reached in a targeted assessment of the risk of sensitisation of humans to nickel by piercing post assemblies. The conclusion of this Risk Assessment Report³ was that the

1 OJ L301, 28.9.2004, p.51.

2 OJ L262, 27.9.76, p.201.

3 “Risk of sensitisation of humans to nickel by piercing post assemblies” LGC Ltd. Final Report 31st March 2003.

requirement with which piercing post assemblies must conform should be based on a nickel migration limit, which was considered more appropriate than the existing one based on a limit on the nickel content.

Views on the implementation of Directive 2004/96/EC in the UK

1.6 Your views are invited on the; -

- draft of The Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2005, by which means we intend to implement this Directive in the United Kingdom.
- impact, both economic and otherwise, the new Regulations will have on industry, business and consumers. A number of specific questions are set out in paragraph 1.16.
- draft of the Guidance Notes to the new Regulations.

How to respond

1.7 When responding please state whether you are responding as an individual or representing the views of an organisation. If responding on behalf of an organisation, please make it clear who or what the organisation represents and, where applicable, how the views of its members were assembled.

1.8 Please submit your response to this consultation by post, fax or (preferably) email to:

David Jenkinson
428
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1 Victoria Street

david.jenkinson@dti.gsi.gov.uk

Fax 0207 215 0339


Closing Date

1.9 Responses must be received by 16th June 2005. However, earlier responses would be appreciated.

Additional copies

- 1.10 Additional copies of this consultation document may be made without seeking permission.
- 1.11 Further printed copies of this consultation document may be obtained by post from:

DTI Publications Orderline
ADMAIL 528
London SW1 W8YT

 0845 015 0010
Fax 0845 015 0020
Email www.dti.gov.uk/publications

- 1.12 Electronic versions may be viewed on the DTI website at:

<http://www.dti.gov.uk/ccp/consultations.htm> , or
<http://www.dti.gov.uk/consultations/>

Help with Queries

- 1.13 If you have any questions about the issues discussed in this consultation document, please contact David Jenkinson.

 020 7215 0366
Email david.jenkinson@dti.gsi.gov.uk

Complaints

- 1.14 The Code of Practice on Consultation can be found at Annex E to this document.
- 1.15 If you wish to make a complaint about, or comment on, the way in which this consultation has been conducted, please contact:

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Consultation questions

1.16 The following are general questions that you may wish to consider.

- i. What additional costs, if any, will the new Regulations impose on your business?*
- ii. Will the requirement for piercing post assemblies to meet a maximum nickel release rate rather than a maximum nickel content cause you any compliance difficulties?*
- iii. The new Regulations will come into force on 1st September 2005. Does this date present you with any problems?*

1.17 All comments in relation to the Partial Regulatory Impact Assessment are welcome.

2 Draft Regulations – ‘The Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2005’

2.1 Background to the existing Regulations

2.1.1 The Marketing and Use Directive 76/769/EEC⁴

This Directive was adopted in 1976 to restrict or prohibit the use and marketing of certain chemicals in order to protect the environment, workers, consumers and public health in Member States. Annex 1 to that Directive lists those chemicals of concern and specifies the restrictions on marketing and use placed upon them. In the light of technical developments and new knowledge about the danger of chemicals, the European Commission has regularly updated this Annex by adding further chemicals to the list or by amending existing entries.

2.1.2 Nickel Allergic Contact Dermatitis

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. In Europe, between 5 and 15% of females and up to 2% of males have reportedly been sensitised by non-occupational contact with nickel.

Individuals may become sensitised to nickel when materials that contain nickel are placed in direct and prolonged contact with the skin. Dissolution of nickel and nickel salts, primarily by sweat, may occur and the nickel ions so released may then penetrate the skin. If sufficient quantities are present, they may then interact with the body's immune system to induce nickel allergy. 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.

Nickel-plated jewellery, nickel-releasing piercing post assemblies and nickel-plated items used in garments, such as zippers and rivets etc., are now accepted to be amongst those items responsible for the prevalence of nickel sensitivity. Studies have further indicated that the majority of those sensitised to nickel became so after ear piercing.

⁴ OJ L262, 27.9.76, p.201.

2.1.3 Directive 94/27/EC⁵ (the “Nickel Directive”) of 30th June 1994

This Directive 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.

It was adopted by all Member States on 30th June 1994, forming the 12th Amendment to the Marketing and Use Directive and inserting a new Point 28 into Annex 1 of that Directive.

28 Nickel CAS No 7440-0-20 EINECS No 2311114 and its compounds	<p>May not be used:</p> <ol style="list-style-type: none">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:<ul style="list-style-type: none">- 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<p style="margin-left: 40px;">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;</p> 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. <p>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.</p>
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⁵ OJ L188, 22.7.94, p.1.

http://europa.eu.int/smartapi/cgi/sqa_doc?smartapi!celexapi!prod!CELEXnumdoc&lq=EN&numdoc=31994L0027&model=guichett

2.1.4 Commission Communication 1999/C 205/5⁶ of 20th July 1999

The European Standards to be used in demonstrating compliance with the provisions of Directive 94/27/EC were set out in this Commission Communication: -

Reference	Title of the harmonised standards	Year of the ratification
EN 1810:1998	Body-piercing post assemblies – Reference test method for determination of nickel content by flame atomic absorption spectrometry	1998
EN 1811:1998	Reference test method for release of nickel from products intended to come into direct and prolonged contact with the skin	1998
EN 12472:1998	Method for the simulation of wear and corrosion for the detection of nickel release from coated items	1998

2.1.5 The Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2000

Directive 94/27/EC was implemented in the United Kingdom by means of the SI 2000/1668 – “*The Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2000*”

These Regulations may be viewed on the HMSO website at: -
<http://www.hmso.gov.uk/si/si2000/20001668.htm>

2.2 Background to the new Regulations

2.2.1 The provisions of Directive 94/27/EC recognised that it is the rate of nickel ion release from items in direct and prolonged contact with the skin, rather than the nickel content of such items, that may result in sensitisation of individuals to nickel. In the case of ear and body piercing, however, additional safeguards were provided to consumers during epithelisation by prohibiting the use of nickel in excess of 0.05% in post assemblies intended for use in this period.

- 2.2.2 The effect of this provision was that stainless steels (in particular the 316 and 316L grades of “Surgical Steel”) were prohibited for use in piercing post assemblies intended for use after an initial piercing and worn during the healing process, since these materials contain nickel much in excess of the prescribed limit of 0.05%. There is 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. There were claims that the rate of nickel release from 316 and 316L grade “Surgical Steel” is much less than 0.5 µg/cm²/week and should therefore be permitted for use in piercing post assemblies during epithelisation and in healed piercings. In the light of these claims, LGC Ltd., supported by the European Commission, carried out a study on the risks of sensitisation of humans to nickel by the use of stainless steel piercing post assemblies.
- 2.2.3 The LGC study - “Risk of sensitisation of humans to nickel by piercing post assemblies” - evaluated the scientific knowledge on stainless steels used in body piercing with respect to nickel release and the ability of such steels to cause nickel allergic contact dermatitis. Nickel release was measured from a number of different stainless steels, and from similar stainless steels with different surface finishes, using the body fluids (artificial sweat, blood plasma and urine) likely to be in contact with a post assembly during the period of epithelisation.
- 2.2.4 In order to limit the risks of sensitisation of humans to nickel by piercing post assemblies, the Report proposed specifying a maximum value, determined under controlled conditions, for the rate of nickel release from such items. This approach obviated the need for consideration of the composition, metallurgical structure and surface finish of the materials used. The Report, therefore, recommended that the existing requirement of a maximum nickel content of 0.05% by mass in post assemblies, set out in Directive 94/27/EC, be replaced by a nickel migration limit of 0.2 µg/cm²/week, applicable to *all* post assemblies and determined using the methodology specified in the European Standardised method EN 1811:1998 (“Reference test method for release of nickel from products intended to come into direct and prolonged contact with the skin”). A copy of the LGC Report of 31st March 2003, may be viewed at:
- <http://europa.eu.int/comm/enterprise/chemicals/legislation/markrestr/studies/nickel.pdf>
- 2.2.5 The European Commission referred this risk assessment to the European “Scientific Committee on Toxicity, Ecotoxicity and the Environment” (CSTEE) for peer review. The Committee was requested to assess the overall scientific quality of the report and comment on its findings, conclusions and recommendations. In its Opinion⁷, adopted in

⁷ Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on the LGC’s Report on “Risk of sensitisation of humans to nickel by piercing post assemblies” Final report 31 march 2003 – Contract No. EDT/FIF.2001592

November 2003, the Committee agreed with the recommendation in the report that the maximum nickel content of 0.05% in post assemblies, required by Directive 94/27/EC (the “Nickel Directive”), be replaced by a nickel migration limit of 0.2 µg/cm²/week.

A copy of the CSTEE Opinion may be viewed at:

http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out211_en.pdf

2.2.6 Directive 2004/96/EC of 27th September 2004

In the light of the LGC Risk Assessment Report and the CSTEE endorsement of its recommendations, Directive 2004/96/EC was adopted by all Member States on 27th September 2004. The Directive amended Directive 76/769/EEC as regards restrictions on the marketing and use of nickel for piercing post assemblies. The provisions laid down by Directive 2004/96/EC took account of the current state of knowledge by amending Point 28 of the Annex to Directive 76/769/EEC. The first paragraph of the second column of Point 28, which requires that

“Nickel and its compounds may not be used in post assemblies which are inserted into 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%”

has been deleted and replaced by

“Nickel and its compounds may not be used in all post assemblies which are inserted into ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than 0.2 µg/cm²/week (migration limit)”

A full copy of the Directive is attached at Annex A to this Consultation Document.

2.2.7 The rate of nickel release from piercing post assemblies is to be determined by the method set out in Commission Communication 1999/C 205/5. The relevant method is EN1811:1998 and the multiplication factor specified in this method is to be applied to compensate for inter-laboratory variations and inaccuracies in measurements.

The Commission has, however, invited the European Committee of Standardisation (CEN) to review EN 1811:1998, particularly in regard to the adjustment factor. CEN is to prepare a revised standard without an adjustment factor or with a smaller adjustment factor.

2.3 *The new Regulations: The Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2005*

Directive 2004/96/EC will be implemented in Great Britain and Northern Ireland by means of “*The Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2005*”. These Regulations will revoke “*The Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2000*” [SI 2000/1668] and re-enact them with amendments.

A draft of the 2005 Regulations is attached at Annex B.

3 Partial Regulatory Impact Assessment

Directive

1. 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

2. 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.
3. 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

4. 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.
5. 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%.

6. 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.
7. 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/cm²/week.

Risk Assessment

8. 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

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

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

Option (iii): To do nothing.

10. **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.

11. 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.

Benefits

Economic

12. 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 due to complaints about quality.

Environmental

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

Social

14. 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 will provide them with greater choice of the materials used in their construction.

Costs

15. 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 there 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

16. 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

17. 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. No disproportionate impact on small firms as a result of this Directive has been identified. However, should any as yet unidentified impacts or unintended consequences of the implementation of this Directive on small firms be identified during the consultation period, further work to assess this impact will be carried out and the position reviewed. The Small Business Service is content with this approach.

Competition Assessment

18. Stage One of the Competition Assessment was undertaken. When applying the Competition Assessment Filter, the results indicate 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

19. 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.

20. In Great Britain, the Regulations will be enforced by Local Trading Standards Departments, and in Northern Ireland by Environmental Health Departments.

Monitoring and Review

21. 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

22. The following Government Departments are being 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

23. The Consultation Document lists those organisations and individuals to whom the document has been sent. The consultees include, 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 will run for 12 weeks.

Summary and Recommendation

24. 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 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.

Declaration

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

Signed by the Minister responsible

.....

Date

4 What happens next?

- 4.1 The results of this consultation exercise, including a summary of views expressed, will be published on the DTI website and may be viewed at

<http://www.dti.gov.uk/ccp/consultations.htm>

We aim to publish these results no later than three months after the close of the consultation exercise. Paper copies of the results will also be made available, on request, from DTI from the source provided at paragraph 1.5 above

- 4.2 The Regulations will be published no later than 1st August 2005 and will come into force on 1st September 2005.

Annex A

Commission Directive 2004/96/EC

of 27th 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 1 to technical progress

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)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

that a nickel migration limit may induce lower risks of sensitisation than a nickel content limit.

Having regard to the Treaty establishing the European Community, and

(5) The provisions laid down by this Directive take into account the current state of knowledge, science and techniques.

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,(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 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⁾.

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.

(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,

(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.

HAS ADOPTED THIS DIRECTIVE:

Article 1

(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.

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

Article 2

(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

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.

⁽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).⁽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).⁽²⁾ OJ L 188, 22.7.1994, p. 1.⁽⁴⁾ OJ L 158, 30.4.2004, p. 50.

They shall apply those provisions from 1 September 2005.

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*.

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.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 27 September 2004.

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.

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 µg/cm²/week (migration limit);'

D R A F T S T A T U T O R Y I N S T R U M E N T S

2005 No. ---

CONSUMER PROTECTION

**Dangerous Substances and Preparations (Nickel) (Safety)
Regulations 2005**

Made - - - - - ---

Laid before Parliament ---

Coming into force - - - *1st September 2005*

Whereas the Secretary of State has, in accordance with section 11(5) of the Consumer Protection Act 1987(a), consulted such organisations as appear to her to be representative of interests substantially affected by these Regulations, such other persons as she considers appropriate and the Health and Safety Commission;

Now, therefore, the Secretary of State in exercise of the powers conferred upon her by section 11 of the said Act hereby makes the following Regulations—

Citation, commencement and revocation

1.—(1) These Regulations may be cited as the Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2005 and shall come into force on 1st August 2005.

(2) The Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2000(b) are hereby revoked.

Interpretation

2.—(1) In these Regulations—

“BS EN 1811:1999” means the British Standard Specification for the Reference test method for release of nickel from products intended to come into direct and prolonged contact with the skin published by the British Standards Institution on 15th April 1999(c);

“BS EN 12472:1999” means the British Standard Specification for the test method for the simulation of wear and corrosion for the detection of nickel release from coated items published by the British Standards Institution on 15th April 1999(d);

“EN 1811:1998” means the European Standard specifying a reference test method for release of nickel from products intended to come into direct and prolonged contact with skin which was approved by the European Committee for Standardisation on 10th October 1998;

(a) 1987 c.43.
(b) S.I. 2000/1668
(c) ISBN 0580308472
(d) ISBN 0580308480

“EN 12472:1998” means the European Standard specifying a method for the simulation of wear and corrosion for the detection of nickel release of coated items which was approved by the European Committee for Standardisation on 14th October 1998;

“Member State” means a state which is a member of the European Economic Area which was established by the Agreement on the European Economic Area signed at Oporto on 2nd May 1992;

“supply” includes offering to supply, agreeing to supply, exposing for supply and possessing for supply.

Prohibition on marketing and use

3.—(1) No person shall use nickel or its compounds in—

- (a) any post assembly intended to be inserted into a pierced part of the human body unless the rate of nickel release from any such post assembly is less than $0.2\mu\text{g}/\text{cm}^2/\text{week}$;
- (b) any product to which paragraph (2) below applies if the rate of nickel release from those parts of the product which come into direct and prolonged contact with the skin is greater than $0.5\mu\text{g}/\text{cm}^2/\text{week}$; and
- (c) any product to which paragraph (2) below applies and which has a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of the product which come into direct and prolonged contact with the skin does not exceed $0.5\mu\text{g}/\text{cm}^2/\text{week}$ for a period of at least two years of normal use of the product.

(2) This paragraph applies to any product intended to come into direct and prolonged contact with the skin including—

- (a) earrings;
- (b) necklaces, bracelets, chains, anklets and finger rings;
- (c) wrist-watch cases, watch straps and tighteners; and
- (d) rivet buttons, tighteners, rivets, zippers and metal marks contained in or intended to be used in garments.

(3) No person shall supply any post assembly or product which contravenes a requirement of paragraph (1) above provided that it shall not be unlawful to supply any post assembly which it was permitted to supply under the Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2000 and which was first placed on the market in a Member State before these Regulations came into force.

(4) The prohibitions in paragraphs (1) and (3) above do not apply to any post assembly or product which—

- (a) is intended for export to a country which is not Member State;
- (b) was first placed on the market in a Member State before 20th January 2000.

Assessment Procedures

4.—(1) Conformity of a post assembly or product with the requirements of regulations 3(1)(a) and 3(1)(b) above shall be demonstrated using the procedure specified in—

- (a) EN 1811:1998;
- (b) BS EN 1811:1999; or
- (c) any other standard or specification recognised for use in a Member State which corresponds to EN 1811:1998.

(2) Conformity of a product with the requirements of regulations 3(1)(c) above shall be demonstrated using the procedure specified in—

- (a) EN 12472:1998;
- (b) BS EN 12472:1998; or

- (c) any other standard or specification recognised for use in a Member State which corresponds to EN 12472:1998.

Proceedings

5. In England, Wales and Northern Ireland a magistrates' court may try an information (in the case of England and Wales) or a complaint (in the case of Northern Ireland) in respect of an offence under section 12 of the Consumer Protection Act 1987 arising from a contravention of these Regulations if (in the case of England and Wales) the information is laid or (in the case of Northern Ireland) the complaint is made twelve months from the time when the offence was committed and in Scotland summary proceedings for such an offence may be brought at any time within twelve months from the time when the offence was committed.

Gerry Sutcliffe
Parliamentary Under Secretary of State for
Employment Relations, Postal Services and Consumers
Department of Trade and Industry

Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke and re-enact with amendments the Dangerous Substances and Preparations (Nickel Safety) Regulations 2000.

The Regulations implement Council Directive 76/769/EEC (O.J. L262, 27.9.1976, p.201) on the approximation of laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous products and preparations insofar as that Directive restricts the use of nickel and its compounds and the marketing of products containing those substances. They also implement for the first time Directive 2004/96/EC which amends Directive 76/769/EEC by amending the restriction on the use of nickel and its compounds in post assemblies.

The Regulations restrict the use of nickel and its compounds in post assemblies and products intended to come into direct and prolonged contact with skin including products which have been coated with a non-nickel coating. The Regulations amend the previous restriction on the supply of post assemblies containing nickel. However, it will remain lawful to supply post assemblies which were lawful under the previous Regulations provided that they were first placed on the market in a Member State before these Regulations came into force.

However, the restrictions do not apply to any product first placed on the market in a Member State before 20th January 2000 or to products intended for export to a country which is not a Member State.

EN 1811:1998 and EN 12472:1998 are required to be used to demonstrate compliance with the requirements relating to nickel content. However, the Regulations also permit the use of national standards which correspond to EN 1811:1998 and EN 1272:1998 including BS EN 1811:1999 and BS EN 12472:1999. The latter may be obtained from any of the sales outlets operated by the British Standards Institution (BSI) or by post from 389 Chiswick High Road, London, W4.

A full regulatory impact assessment of the effect that these Regulations will have on costs to business is available from the Consumer and Competition Policy Directorate of the Department of Trade and Industry, 1 Victoria Street, London SW1H 0ET. Copies of a transposition note relating to these Regulations have been placed in the libraries of both Houses of Parliament. Copies are

also available to the public from the Consumer and Competition Policy Directorate of the Department of Trade and Industry, 1 Victoria Street, London SW1H 0ET.

Annex C

DRAFT

*A Guide to “The Dangerous Substances and Preparations (Nickel)
(Safety) Regulations 2005”*

A GUIDE TO THE DANGEROUS SUBSTANCES AND PREPARATIONS (NICKEL) (SAFETY) REGULATIONS 2005

Introduction

The main objective of the Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2005⁸ is to seek to prevent people becoming sensitised to nickel, which can lead to skin dermatitis (see Questions and Answers section for further information).

The Regulations come into force on 1st September 2005. Until that time, the Dangerous Substances and Preparations (Nickel) (Safety) Regulations 2000⁹ continue to apply.

This guide has been prepared in consultation with the Local Authorities Coordinators of Regulatory Services (LACORS), Trading Standards and the Institute of Trading Standards Administration. It is intended to help consumers and suppliers of Nickel-based products understand how the Regulations affect them.

This guide is not an authoritative interpretation of the Regulations, which is a matter for the courts. It explains the requirements in general terms, but does not cover all the details. You should refer to the Regulations themselves for a full statement of the requirements.

Background to Legislation

To deal with the problem of nickel sensitisation, the European Commission issued Directive 94/27/EC¹⁰ in 1994 – a 'Nickel Amendment' to the 'Marketing and Use' Directive 76/769/EEC. A further Nickel Amendment was issued in 2004¹¹ which these Regulations implement.

Products covered

The Regulations prohibit the supply of any products intended to come into direct and prolonged contact with the skin, which contain nickel or a nickel compound, including:

⁸ Statutory Instrument 2005/No. xxxx, available from the Stationary Office Ltd and online at:

⁹ Statutory Instrument 2000/No. 1668, available from the Stationary Office Ltd and online at: www.legislation.hmso.gov.uk/si/2000/20001668.htm

¹⁰ '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' (known as 'The Marketing and Use' Directive).

¹¹ '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 1 to technical progress'.

- earrings
- necklaces, bracelets, chains, anklets and finger rings
- wrist-watch cases, watch straps and tighteners
- rivet buttons, tighteners, rivets and zippers, contained in or intended to be used in garments

unless such products possess a non-nickel coating sufficient to ensure that the permitted nickel release rate (see 'Nickel Release Rate' section) is not exceeded.

Products manufactured for export to countries outside the European Union are not affected by these Regulations.

Post Assembly

A post assembly is a post or stud (generally made of metal) which is used to keep open newly created holes in the body after piercing, together with any accompanying metal or plastic butterfly clasps.

Nickel Release Rate

The Regulations prohibit the supply of all types of post assemblies (whether they are used during or after the period of healing of the wound caused by piercing) with a nickel release rate of 0.2 micrograms per square centimetre per week, or more¹². This restriction applies to the ear-posts of ordinary ear-rings, whether or not they are plated with a non-nickel coating.

The Regulations also prohibit the supply of any other products that come into direct and prolonged contact with the skin that have a nickel release greater than 0.5 micrograms per square centimetre per week.

It is the supplier's responsibility to decide which parts of a piece will be in direct and prolonged contact with the skin. Advice can be sought from your Local Authority Trading Standards Department (in Great Britain) or the District Council (in Northern Ireland).

Testing

It is advisable that an appropriately accredited test house carries out tests. Some organisations may prefer to use their own testing facilities; however, it is advisable that an accredited testing house periodically checks in-house measurements. The UK Accreditation Service can provide details of suitable testing houses – Tel: 020 8917 8400, website: www.ukas.com.

¹² Until 1st September 2005, the nickel content of post assemblies intended for use during the period of epithelization (healing) of the wound caused by piercing must be less than 0.05% by mass. The British Standard Specification reference test method for the measurement of nickel content is BS EN 1810:1998.

Stock

Within the European Community, only compliant products can be placed on the market. You can hold stock which does not comply – for sale outside the EU only – but it is essential to ensure that such stock is clearly identified.

Other Descriptions

Descriptions such as 'nickel free', 'hypo-allergenic', 'nickel safe' etc are **not covered by the Regulations** and will continue to be covered by the Trade Descriptions Act 1968. If you wish to use such descriptions, it is your responsibility to ensure that they are accurate regarding your product and that you have sufficient evidence to substantiate their use.

You should bear in mind that the obvious message to the consumer in using the term 'nickel free', for example, is that your product contains no nickel and therefore will not promote a nickel allergic reaction. Use of 'nickel free', under the Trade Descriptions Act, is only possible if nickel is present at concentrations that will not be material. What constitutes 'material' is a matter for the Courts to decide. However, evidence suggests that a nickel sensitive reaction is unlikely to occur at concentrations below 100 parts per million or 0.01%.

Test Methods used in the Regulations

BS EN 1811:1999 is the reference test method for nickel release.

BS EN 12472:1999 is the method for the simulation of wear and corrosion of coated items.

Due Diligence

Suppliers have a duty to ensure their products comply with the relevant legislation, which is known as showing 'due diligence'. If you wish to use the defence of due diligence, you will need to prove that you took all reasonable steps to avoid an offence being committed. What constitutes 'reasonable steps' depends on your circumstances, e.g. the size of your operation. In general, however, taking reasonable steps is likely to involve you setting up a control system that takes regard of the risks involved and covers all regulatory requirements. Such a system should be operated properly, kept under review and amended as necessary.

Further Information

If you have any further queries, the Jewellery Distributors' Association and the British Jewellers' Association give advice to members free of charge. Otherwise, you can contact the Department of Trade and Industry (DTI) or your local Trading Standards office (see below for details).

The Nickel Development Institute can provide advice on the release of nickel from nickel-containing alloys – Tel: 01527 584777.

The DTI will publish any revisions to the Regulations or supporting Test Standards as they occur.

The Jewellery Distributors' Association

Federation House
10, Vyse Street,
Hockley
Birmingham, B16 6LT
Tel: 0121 237 1107
Fax: 0121 236 3921
Website: www.jda.org.uk

The British Jewellers' Association

Federation House
10 Vyse Street,
Hockley
Birmingham, B16 6LT
Tel: 0121 237 1112
Fax: 0121 237 1113
Website: www.bja.org.uk

Department of Trade and Industry

Room 428
1 Victoria Street,
London, SW1 0ET
Tel: 0207 215 0366
Fax: 0207 215 0399
Website: www.dti.gov.uk

British Standards Institute

389 Chiswick High Road
London, W4 4AL
Tel: 0208 996 9001
Fax: 0208 996 7001
Website: www.bsi-global.com

Acknowledgements

DTI thanks the Jewellery Distributors' Association and the British Jewellers' Association, along with members of the Nickel Working Group, whose efforts have resulted in this Guide. Thanks also to LACORS for the use of their 'nickel free' and 'due diligence' guidance notes, and to LGC Ltd for their technical input.

Questions and Answers

1. Why is nickel a problem?

Nickel can cause allergic contact dermatitis (ACD). Signs of ACD range from dryness, chapping and inflammation of the skin to eczema and blisters.

Nickel sensitivity affects approximately 10% of women and 1% of men in western countries. It is not an inherited condition but is related to direct and prolonged skin contact with the substance. Nickel ACD was first noticed in industries where soluble forms of nickel came into contact with workers' skin, e.g. electroplating and battery manufacture.

Nickel sensitivity outside of occupational industries was first noticed in people who had skin contact with clothing buckles, zips and clasps that had been nickel-plated. ACD has increased with the use of nickel-plated jewellery and particularly with the practice of body-piercing.

2. How does nickel sensitisation happen?

When an item containing nickel comes into direct and prolonged contact with the skin, sweat can act on it to release nickel ions. Sensitisation can take between one and three weeks of such contact. The quantity of nickel ions required to induce it varies with individuals. Skin condition, other allergies, gender and age can all be factors. Some nickel-sensitised people may develop ACD with further exposure.

3. How long does nickel sensitisation last?

Nickel sensitisation lasts for life. However, some nickel-sensitised people display no symptoms (such as allergic skin rashes), either because they are minimally exposed or because relatively high amounts of nickel ions are required in them to cause ACD.

Short-term contact with nickel-releasing items such as keys, coins and tools is unlikely to lead to nickel allergy in non-sensitised people or cause ACD in those who are nickel sensitised.

4. How is nickel ACD treated?

Simply, avoiding exposure to nickel-releasing materials is often a sufficient remedy. ACD may also be treated with anti-inflammatory topical skin creams or ointments, e.g. cortisone-based skin moisturisers.

5. Why has a maximum nickel content limit been replaced by a restriction on nickel release?

It is not known precisely what concentration of nickel can cause sensitisation. Therefore a maximum nickel content was originally set at the lowest possible level to ensure protection from the risk of sensitisation. However, studies since have shown that certain types of stainless steel with a high nickel content do not elicit an allergic response in the majority of people who are already sensitised to nickel. When tests for migration (see Question 6) were performed on these stainless steels, very low levels of migrated nickel were detected, or could not be

detected at all. Therefore, while the requirement of a maximum nickel content would remove any possibility of sensitisation, it was decided that this was not proportionate to the risk of sensitisation from products containing nickel that migrate little or none of the substance.

6. What is migration and how is it measured?

Migration is the measure of release of a substance from the surface of an object, usually into a liquid, over a period of time. For the purposes of testing under EN 1811, the media used is an artificial sweat solution which simulates human sweat. This standard requires a post assembly of known surface area to be immersed into a known volume of artificial sweat solution for a period of 1 week.

7. Does the 0.2 micrograms per square centimetre per week limit only apply to piercing post assemblies used during the period of healing of the wound caused by piercing?

No, the limit applies to all piercing post assemblies, whether they are used during or after the period of healing of the wound caused by piercing.

8. Will the 0.2 and 0.5 micrograms per square centimetre per week limits prevent nickel sensitisation?

These limits are confidently expected to reduce new incidences of nickel sensitisation, as experience in Denmark has shown.

9. Will these limits prevent elicitation of nickel ACD in sensitised individuals?

Unfortunately, even these extremely low levels of nickel release will not prevent all cases of elicitation of nickel allergy in people already sensitised to nickel.

10. Is it permissible for piercing post assemblies to be plated with a non-nickel coating?

Yes, but as well as complying with the 0.2 micrograms per square centimetre per week nickel release requirement, such piercing post assemblies should also comply with the requirement not to release nickel in excess of 0.5 micrograms per square centimetre per week for a period of 2 years' normal use.

11. What testing is applicable to non-nickel plated piercing post assemblies?

EN 1811 is the reference test method to assess nickel release. To assess non-nickel plated piercing post assemblies for compliance with these Regulations, separate identical items should be tested for nickel release before and after undergoing the procedure for wear and corrosion as described in EN 12472.

Annex D

Consultees

This consultation document has been sent to the following interested parties:-

Allders Department Stores Limited	National Association of Goldsmiths
AMTAC Laboratories	National Association of Local Councils
Arcadia Group plc.	National Consumer Council
Association of Public Analysts	National Consumer Federation
Baby Products Association	National Council of Women of Great Britain
Birmingham Assay Office	National Federation of Women's Institutes
Body Shock Ltd.	Nickel Institute
Boots Product Quality and Development Centre	Northern Ireland Chamber of Commerce and Industry
British Association for Chemical Specialities	Northern Ireland Local Government Association
British Chambers of Commerce	Northern Ireland Office
British Chemical Distributors & Traders Association	OXFAM
British Coatings Federation Ltd.	Penetrate Body Piercing
British Home Stores	Radford Jewellery
British Importers Association	SATRA Quality Assurance Limited
British Medical Association	Scotland Office
British Red Cross	Scottish Consumer Council
British Retail Consortium	Scottish Executive Environment & Rural Affairs Dept.
British School of Body Piercing	Sheffield Assay Office
British Shops & Store Association Ltd.	Shirley Technologies Ltd.
British Stainless Steel Association	Signet Group plc
BSI Group Headquarters	Society of Chemical Industry
BSI Product Services	Society of Local Authority Chief Executives and Senior Managers
Caflon Ltd.	Studex
Chemical Industries Association	Sue Ryder Care
CMS Cameron McKenna	TDi Ltd
Confederation of British Industry	Technicare Services Ltd.
Convention of Scottish Local Authorities	Trades Union Congress
Cooksons Precious Metals	Trading Standards Institute
Debenhams Retail plc	Wales Office
Department for the Environment, Food and Rural Affairs	Welsh Consumer Council
Department of Health	Welsh Local Government Association
Department of the Environment (Northern Ireland)	Which?
Direct Marketing Association	Women's Environmental Network
Direct Selling Association	World Wildlife Fund
Ear Piercing Manufacturers of Europe Ltd.	
Federation of Small Businesses	
Friends of the Earth	
General Consumer Council for Northern Ireland	
Health & Safety Commission	
Health & Safety Executive	
House of Fraser	
Intertek Testing Services (Leicester) Ltd.	
Jewellery Distributors Association	
John Lewis Partnership	
LACORS	
Laytons	
LGC Limited	
Local Government Association	
Mail Order Traders Association	
Marks & Spencer Group plc	
Medical Research Council	
Morton International Ltd.	
Mr Frank Moore	
National Association of Citizens Advice Bureaux	
	Academia:
	Prof Geoffrey Woodroffe - Brunel University
	Prof David Oughton - De Montfort University
	Mr Chris Willet – De Montfort University
	Mr Simon Whittaker – St John's College, Oxford
	Prof Hugh Beale - Law Commission
	Prof Hugh Collins - LSE
	Mr Colin Scott - LSE
	Mr Richard Bragg - Manchester University
	Mr Cowan Ervine - University of Dundee
	Ms Deborah Parry - University of Hull
	Mr Peter Cartwright - University of Nottingham
	Prof Stephen Weatherill - University of Oxford
	Mr Christian Twigg-Flesner - University of Sheffield
	Mr Robert Bradgate – University of Sheffield
	Prof Geraint Howells - University of Sheffield
	Christopher JS Hodges - CMS Cameron McKenna

Annex E

The Consultation Code of Practice

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.
3. Ensure that your consultation is clear, concise and widely accessible.
4. Give feedback regarding the responses received and how the consultation process influenced the policy.
5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation coordinator.
6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

The complete code may be viewed on the Cabinet Office website at:-

<http://www.cabinet-office.gov.uk/regulation/consultation/index.asp>