EXPLANATORY MEMORANDUM

The Dangerous Substance and Preparations (Safety) (Consolidation) (Amendment) Regulations 2004 No. 1417

1. PURPOSE OF INSTRUMENT

These Regulations implement European Parliament and Council Directives 2003/34/EC (O.J. No. L156, 25.6.03, p. 14) and 2003/36/EC (O.J. No. L156, 25.6.03, p. 26) which amend for the 23rd and 25th times respectively Council Directive 76/769/EEC (O.J. No. L262, 27.9.76, 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 substances and preparations.

Directive 76/769/EEC seeks to protect human health and the environment in the Member States by restricting the use of the dangerous substances and preparations listed in Annex I to that Directive. Member States are required to take all necessary measures to ensure that the dangerous substances and preparations listed in Annex I may only be placed on the market or used subject to the conditions specified in the Directive.

Directives 2003/34/EC and 2003/36/EC amend Directive 76/769/EEC by adding further substances, newly classified as carcinogenic (inducing cancer), mutagenic (inducing hereditary genetic defects) or substances toxic to reproduction (inducing non-hereditary congenital malformations), to the list of substances in Annex I. They prohibit these substances from being placed on the market for sale to consumers.

Directive 76/769/EEC has been implemented by the Dangerous Substances and Preparations (Safety) (Consolidation) Regulations 1994 (S.I. 1994/2844) ("the Principal Regulations"). The proposed Regulations implement the above directives by amending the Principal Regulations.

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

Directive 2003/34/EC requires Member States to publish and adopt laws implementing the Directive by 15th July 2004. However, the Directive does not require Member States to apply such laws until 15th January 2005. Accordingly, Regulation 2(3), which implements Directive 2003/34/EC will not come into force until 15th January 2005.

Directive 2003/36/EC requires Member States to publish and adopt laws implementing the Directive by 25th June 2004. However, the Directive does not require Member States to apply such laws until 25th December 2004. Accordingly, those parts of the Regulations, which implement Directive 2003/36/EC will not come into force until 25th December 2004.

3. LEGISLATIVE BACKGROUND

These Regulations are made under section 11 of the Consumer Protection Act 1987.

Parliamentary Scrutiny of Directive 2003/34/EC
The Department submitted an explanatory memorandum (9037/01) relating to this Directive on 20th June 2001. The House of Commons European Scrutiny Committee considered it politically important, cleared it and requested further information (Report 7, Item 22433, Session 01/02). The House of Lords European Communities Select Committee did not report on it (Progress of Scrutiny, 9th July 2001, Session 01/02).

Parliamentary Scrutiny of Directive 2003/36/EC
The Department submitted an explanatory memorandum (6353/02) relating to this Directive on 9th April 2002. The House of Commons European Scrutiny Committee did not scrutinise it preferring to wait for a full Regulatory Impact Assessment. The House of Lords European Communities Select Committee did not report on it (Progress of Scrutiny, 28th October 2002, Session 01/02). A supplementary explanatory memorandum (6353/02) was submitted on 18th October 2002. The House of Commons European Scrutiny Committee considered it not legally or politically important and cleared it (Report 39, Item 23266, Session 01/02). The House of Lords European Communities Select Committee did not report on it (Progress of Scrutiny, 21st October 2002, Session 01/02).

A Transposition Note is attached to this Memorandum.

4. EXTENT

Consumer safety is a reserved matter and therefore the instrument will apply to Wales as it applies to the whole of the United Kingdom.

5. EUROPEAN CONVENTION OF HUMAN RIGHTS

In the Department's view, these Regulations are compatible with the European Convention on Human Rights.

6. POLICY BACKGROUND

An initial consultation exercise for the 23rd Amendment was conducted in November 2002 prior to adoption of the Directive. This involved in excess of 170 manufacturers, trade associations, consumer groups and other interested parties and the results indicated that the Directive would not have any major impact on manufacturers, importers, wholesalers and retailers of these chemicals and/or products containing these chemicals. Ten responses were received, all of which supported the proposal. An initial consultation exercise for the 25th Amendment was conducted in January 2002 prior to the directive's adoption and the results indicated a similar view.

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A further consultation exercise was carried out in relation to both directives in December 2003 after adoption. This involved in excess of 120 manufacturers, trade associations, consumer groups and other interested parties. Five responses were received and none suggested any changes to the proposed regulations.

7. REGULATORY IMPACT

The Regulations will ensure that these carcinogenic substances, mutagenic substances and substances toxic to reproduction are not placed on the market for consumer use and will, thus protect the health of consumers. The costs have been estimated to be negligible due to the very limited use of these substances in consumer products.

A Regulatory Impact Assessment (RIA) and Transposition Note have been prepared and are attached to this memorandum.

8. COSTS TO THE PUBLIC

There will be no additional costs imposed on the public.

9. COSTS TO THE EXCHEQUER

No additional costs will fall to the Exchequer.

10. CONTACT

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DEPARTMENT OF TRADE AND INDUSTRY

25th May 2004

REGULATORY IMPACT ASSESSMENT

1. The Dangerous Substances and Preparations (Safety) (Consolidation) (Amendment) Regulations 2004

2. Issue and Objective

2.1 Directive 76/769/EEC seeks to protect human health and the environment in the Member States by restricting the use of dangerous substances and preparations listed in Annex I to that Directive. Member States are required to take all necessary measures to ensure that the dangerous substances and preparations listed in Annex I may only be placed on the market or used subject to the conditions specified therein.

2.2 Directives 2003/34/EC and 2003/36/EC amend Directive 76/769/EEC for the 23rd and 25th times respectively. Additional substances, or classes of substance, newly classified as category 1 or category 2 cmrs (carcinogens, mutagens and substances toxic to reproduction) have been added to points 29, 30 and 31 of the Annex to Directive 76/769/EEC.

3. Risk Assessment

Within the framework for action in the field of public health, the European Parliament and the Council have adopted an action plan to combat cancer. Due to the fact that the use of chemicals by consumers cannot be controlled, safety can only be insured by prohibiting the use, by consumers, of cmrs and preparations containing them.

The European Commission sought advice on the preparation of these Directives through two meetings involving experts from Member States and industry. Industry was represented by the European Chemical Industries Council (CEFIC) and Eurometaux (the European Association of Metals).

4. Options

4.1 Option 1: To fully implement the two Directives.

4.2 Option 2: To do nothing.

4.3 Option 1 is the recommended option. The Directives are consistent with the current UK policy and practice on this issue and implementation of the Directives will produce harmonised rules for the circulation of substances and mixture classified as cmrs. It will also guarantee a high level of protection of the health and safety of consumers.

4.4 Failure to implement the Directives under Option 2 will result in infraction proceedings being initiated against the United Kingdom since Member States have a Treaty obligation to implement all agreed Directives. Further, Option 2 does not guarantee the level of protection of the health and safety of consumers afforded by Option 1.

Issues of Equity or Fairness

The overriding factor in the Directives is consumer safety. The Directives will impact equally across industry.

5. Benefits

The two Directives will ensure that consumers are safeguarded from the possible health risks of exposure to carcinogens, mutagens or substances toxic to reproduction (cmrs). The Directives will be implemented by all Member States, thus applying to all sectors of industry in the European Union.

Quantifying and Valuing the Benefits

Feedback from the consultation indicates there will be negligible costs.

The benefits will be a reduction in exposure to cmr substances and a consequent reduction in the risk to the health of consumers from them.

6. Costs

Compliance Costs for Business, Charities and Voluntary Organisations

The Directives will not affect charities or voluntary organisations. The prohibition will relate to the manufacturers of these substances and to those industries using them in their production processes. No costs to these sectors have been identified.

Recurring Compliance Costs

No recurring compliance costs have been identified.

Non-recurring Compliance Costs

As it is known from what date the ban on the use of these substances will come into force, the firms involved have had sufficient notice to begin running down stocks and so costs due to loss of stocks will be negligible.

Other costs

No other costs were identified from the extensive consultation carried out.

Total Compliance Costs

The Directives are not contentious and merely involve alterations to the list of prohibited substances which would be controlled in the same manner as previous similar substances. Therefore there will be no compliance costs.

7. The Small Firms Impact Test

Stage one of the Small Firms Impact test was undertaken. Small businesses and relevant trade associations were contacted in order to evaluate the effect of implementation of these Directives in the UK. No responses were received.

8. Competition Assessment

Stage one of the Competition Assessment was undertaken and this concluded that as these Directives place restrictions on the marketing and use of particular chemicals it is unlikely to have the effect of distorting or removing competition in the market. The Directives will not serve as a barrier to entry for potential entrants nor impose substantially more cost on some firms than others. The structure of the market is fragmented and competitive and this is unlikely to be changed by the introduction of the new Directives.

9. Result of the Consultation

Initial Consultation

Feedback from the initial consultation exercise for the 23rd Amendment indicated that the Directive would not have any major impact on manufacturers, importers, wholesalers and retailers of these chemicals and/or products containing these chemicals. A total of 176 organisations, which included industry, relevant trade associations, LACORS and other Government bodies, were approached. Ten responses were received, all of which supported the proposal.

Feedback from the initial consultation exercise for the 25th Amendment indicated a similar view to that referred to above. 16 chemical speciality organisations and over 130 trade associations, manufacturers and other interested parties were consulted. No responses were received.

Consultation

Over 120 manufacturers, trade associations and other interested parties were identified and consulted. Five responses were received, four to register they had no comment to make and one to suggest a minor amendment to the wording of this document.

10 Enforcement, Sanctions, Monitoring and Review

These Directives will be enforced in Great Britain by the Local Authority Trading Standards Departments. The Regulations are made under the Consumer Protection Act 1987 section 11; therefore the sanctions applicable to breaches of safety regulations under Part II of the 1987 Act apply. 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. In Northern Ireland these Directives will be enforced by the Environmental Health Departments.

11 Summary and recommendation

The 23rd and 25th Amendments to Directive 76/769/EEC were the options chosen at European level by the EU Member States and the European Commission as offering the highest level of protection for consumers. They provide a regulatory framework which will ensure a level playing field throughout the UK and the other EU Member States. They remove potentially hazardous chemicals from the consumer market thereby reduce the potential for ill health and possible deaths caused by exposure through the use of these cmrs.

It is recommended that the option chosen offers the best level of consumer protection because it should reduce the risk of ill health and death in the UK associated with chemicals which are carcinogenic, mutagenic or toxic to reproduction.

12. Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that the balance between cost and benefit is the right one in the circumstances.

Signed by the Minister responsible: *Gerry Sutcliffe*

(Parliamentary Under-Secretary of State for Employment Relations, Competition and Consumers)

Date: 24 May 2004

TRANSPOSITION NOTE RELATING TO DIRECTIVES 2003/34/EC AND 2003/36/EC

Directives 2003/34/EC and 2003/36/EC

The purpose of Directives 2003/34/EC and 2003/36/EC is to amend European Parliament and Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.

Directive 76/769/EEC is implemented in part by the Dangerous Substances and Preparations (Safety) (Consolidation) Regulations 1994 ("the Principal Regulations"). Directive 76/769/EEC contains an Annex listing substances considered to be Carcinogenic, Mutagenic or Toxic to Reproduction. This Annex is reproduced in Schedule 2 to the Principal Regulations.

The Department Of Trade and Industry has lead responsibility for implementation of Directives 2003/34/EC and 2003/36/EC.

Directive			
Council Directive 2003/34/EC (O.J. No. L156, 25.6.03, p.14) of the European Parliament and Council of 26 May 2003 which amends European Parliament and Council Directive 76/769/EEC (O.J. No. L262, 27.9.76, p.201) on the approximation of the laws, regulations and administrative provisions of Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.			
Articles	**Objectives**	**Implementation**	**Responsibility**
Article 1	Inserts the substances listed in the Annex to Directive 2003/34/EC in the Appendix to Annex I to Directive 76/769/EEC.	Schedule 2 to these Regulations sets out the substances listed in the Annex to Directive 2003/34/EC. Regulation 2(3) amends Schedule 2 to the Principal Regulations by inserting those substances.	Secretary of State
Directive			
Council Directive 2003/36/EC (O.J. No. L156, 25.6.03, p. 26) of the European Council and Parliament of 26 May 2003 which amends European Parliament and Council Directive 76/769/EEC (O.J. No. L262, 27.9.76, p.201) on the approximation of the laws, regulations and administrative provisions of Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.			
Article	**Objective**	**Implementation**	**Responsibility**
Article 1 first	Inserts the substances	Schedule 1, Part I to	Secretary of State

sentence	listed in the Annex to Directive 2003/36/EC (with the exception of those listed under section 1 c)) in the Appendix to Annex I to Directive 76/769/EEC.	these Regulations sets out the substances listed in the Annex to Directive 2003/36/EC (with the exception of the substances listed in section 1 c) of that Annex). Regulation 2(1) amends Schedule 2 to the Principal Regulations by inserting those substances.	
Article 1 second sentence	Deletes the substances listed in section 1 c) of the Annex to Directive 2003/36/EC from the Appendix to Annex I to Directive 76/769/EEC.	Schedule 1, Part II to these Regulations sets out the substances listed in section 1 c) of the Annex to Directive 2003/36/EC. Regulation 2(2) amends Schedule 2 to the Principal Regulations by deleting those substances.	Secretary of State

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25 May 2004