

# 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 23<sup>rd</sup> and 25<sup>th</sup> 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 23<sup>rd</sup> 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 25<sup>th</sup> 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 23<sup>rd</sup> and 25<sup>th</sup> 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 .....

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

Date .....