

EXPLANATORY MEMORANDUM TO
THE DANGEROUS SUBSTANCES AND PREPARATIONS (SAFETY)
(AMENDMENT) REGULATIONS 2007

2007 No. 386

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

2. **Description**

2.1 The Dangerous Substances and Preparations (Safety) Regulations 2006 (SI 2006/2916) (“the principal Regulations”) revoked the Dangerous Substances and Preparations (Safety) (Consolidation) Regulations 1994 (SI 1994/2844) and its six amending Regulations and consolidated them, making amendments necessary to implement three further Directives. An explanatory memorandum in relation to the principal Regulations was submitted by the Department.

2.2 The Dangerous Substances and Preparations (Safety) (Amendment) Regulations 2007 correct two errors in the principal Regulations and also make consequential amendments to the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2002.

2.3 Regulation 1(2) of the principal Regulations provided that regulation 12, which implemented Directive 2005/59/EC so far as it relates to toluene, should come into force on 24th August 2007. The 2007 Regulations correct that date to 15th June 2007.

2.4 In Regulation 8(4) of the principal Regulations (Fuel for decorative lamps), the words “which this” appear twice. The 2007 Regulations correct this error by omitting these words where they occur for the second time.

2.5 Regulation 1(4) of the principal Regulations amends the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (SI 2002/1689) which do not extend to Northern Ireland. The principal Regulations, however, extend to the whole of the United Kingdom and amendments to the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2002 (SR 2002/301) are therefore also required. The necessary amendments are made by means of regulation 3 of the Dangerous Substances and Preparations (Safety) (Amendment) Regulations 2007.

3. **Matters of special interest to the Joint Committee on Statutory Instruments**

3.1 The 4th Report of the JCSI for the 2006-7 Session reported the principal Regulations for defective drafting on two counts.

3.2 The first was that the coming into force date of 24th August 2007 for regulation 12, given in regulation 1(2), was incorrect. In its memorandum to the Committee the Department admitted and apologised for this error. This instrument corrects the coming into force date for regulation 12 to 15th June 2007.

3.3 The second point on which the Committee reported the instrument was for the drafting of regulation 8(4) which says:

"Paragraphs (2) and (3) do not prohibit the supply of a liquid substance or preparation to which this regulation applies in a single package containing more than 15 litres."

The Committee considered that this formulation failed unambiguously to exempt the supply of a single package containing a quantity of more than 15 litres of a liquid substance or preparation to which the regulation applies. The Department has given careful consideration to the Committee's reasoning. However, the Department considers that regulation 8(4) correctly exempts a supply in more than 15 litres of a relevant substance or preparation in a single package, notwithstanding the possibility of also interpreting the exemption in the way favoured by the Committee. This being the case we have decided against reverting to the previous wording of the exemption.

3.4 The opportunity has been taken to remove the repeated words "which this" in regulation 8(4).

4. Legislative Background

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

5. Extent

5.1 Consumer safety in relation to goods is a reserved matter and therefore the Regulations will apply to the whole 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 No consultation on the 2007 Regulations was carried. However, a 12-week consultation exercise in relation to the draft of the principal Regulations was conducted between 10 April and 3 July 2006. The consultation document was published on the DTI website and hard copies were sent to in excess of 130 interested parties including manufacturers, the chemical industry, the DIY sector, consumer organisations, trade associations, enforcement authorities and Government Departments. Thirty responses to the consultation were received,

the majority (19) of the substantive comments relating to the regulation implementing the Directive concerning phthalates.

8. Impact

8.1 A Regulatory Impact Assessment (RIA) was prepared in relation to the principal Regulations and a copy is attached to this memorandum. As no impact on the private or voluntary sectors is foreseen no further RIA for the 2007 Regulations has been prepared.

9. Contact

9.1 David Jenkinson at the Department of Trade and Industry (Tel: 0207 215 0366 or email: david.jenkinson@dti.gsi.gov.uk), can answer any queries regarding the instrument.

Regulatory Impact Assessment

1. The Dangerous Substances and Preparations (Safety) Regulations 2006

A.

Directive

2. Directive 2005/84/EC prohibits the placing on the market for sale to the general public phthalates in toys and childcare articles and forms the 22nd amendment to the "Marketing and Use" Directive (76/769/EEC).

Purpose and intended effect of measures

Proposal

3. To transpose the European Directive 2005/84/EC into UK Law, following its publication in the Official Journal (OJ 27.12.2005 L344, p 40).

Objective

4. The primary aim of the Directive (OJ 27.12.2005 L344, p 40) is to protect public health by banning the use of three phthalates (chemical plasticizers DEHP, DBP, BBP) from use in toys and childcare articles and restricting the use of three other phthalates (DINP, DIDP, DNOP) in toys and childcare articles, which can be placed in the mouth.

Risk Assessment

5. Three phthalates (chemical plasticizers DEHP, DBP, BBP) have been shown to damage the testes and reduce fertility and have been classified as reprotoxic Category 2. Scientific evidence on three other phthalates (DINP, DIDP, DNOP) is either lacking or conflicting, but they may have similar effects. As all these substances work in a similar way, their effects are expected to add up. Testicular toxicity is a very serious effect, especially in infants as this is a very sensitive life-stage. Also exposure during this period may cause effects which are not manifested until later in life.

6. Children may be exposed to phthalates from a variety of sources and they can be taken in through the mouth, through the skin or by breathing. However, there is particular concern that many soft plastic toys and teethingers are composed of PVC plastic and can contain a high concentration of phthalates. Teethingers commonly used as child-care products or as toys for babies are manufactured especially for chewing/biting by babies at the time when their teeth start erupting. The physical "chewing" and at the same time provision of fresh saliva around the article can be a rather effective extraction procedure for phthalates.

7. The uncertainties in the evaluation of exposure to phthalates, such as mouthing times and exposure to emissions from other sources, require that precautionary provisions are taken into account. Therefore to minimize the risk, their use in toys intended to be mouthed by children 0-36 months has been banned on a temporary basis for a number of years.

8. This ban is now to be made permanent and the ban is extended to the use of phthalates in all toys and childcare articles or parts of toys and childcare articles which can be placed in the mouth. The European Commission is drafting guidelines on what items or parts of items can be placed in the mouth.

Options

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

(ii) To request industry to adopt voluntary measures.

(iii) To do nothing.

Option (i)

10. This is the recommended option. The Directive makes permanent a ban that had previously been implemented on a temporary and voluntary basis. It guarantees a high level of consumer safety, restricting the use of ingredients identified as potentially repro-toxic to small children.

Option (ii)

11. UK industry has voluntarily applied a partial ban on the use of phthalates in toys. However, the Directive significantly extends the restriction of the use of phthalates in toys and childcare articles and voluntary measures do not guarantee knowledge of the restrictions on use of the ingredients in these products. This option would expose the UK to the likelihood of infraction proceedings by the European Commission for failing to implement the Directive as required.

Option (iii)

12. This option would not legally enforce the restrictions. It could possibly mislead manufacturers and consumers as to the safety of particular products containing these substances. This option would also expose the UK to the likelihood of infraction proceedings for failing to implement the Directive as required.

Benefits

Economic & Social

13. Children as developing organisms are particularly vulnerable to reprotoxic substances. Therefore, the exposure of children to all practically avoidable sources of emissions of these substances, especially from articles, which are put into the mouth by children, should be reduced as far as possible.

14. The Directive widens the restriction on the use of phthalates to all toys and childcare articles which can be placed in the mouth. The restriction on ingredients will remove the use of phthalates in products on the market in the interests of improving consumer safety, phthalates having been identified as being reprotoxic and potentially harmful to the physical development of children.

15. The toy industry and retailers are assessing the full impact of the Directive in the context of the European Commission's guidelines on what is considered to be able to be placed in the mouth but it expects that most of these costs will be absorbed by the industry and not passed onto the consumer.

Environmental

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

Costs

17. There are about 160 toy companies operating in the UK and approximately 60% of them market products that contain plastic. The UK toy market is worth £1.1bn at manufacturers prices. The top 12 companies account for about 75% of this turnover. Although most of the major toy companies have UK based operations, there is very little toy manufacture based in the UK. In fact 70% of all toys sold in the EU are imported from China. Much of the manufacture is done by subsidiary companies or contracted and licensed out. Therefore it is likely that most of the increase in production costs is likely to be passed on by the manufacturers to the toy companies.

18. In the manufacture of toys and childcare articles, the substitution of other plasticizers for phthalates will increase costs. According to industry contacts, the substitute ingredients will cost on average 40% more than phthalates. Depending on how much PVC is used, the higher cost of substitute ingredients will translate to an average increase in manufacturing costs of between 2%, and 23% increases in the manufacturing cost of toys according to the toy industry responses to the consultation. The figures vary since a PVC toy with the equivalent properties of the DINP version might require more citrate (which is about twice as expensive as DINP).

19. The main increase in costs will affect products with high PVC content, primarily inflatables – paddling pools, inflatable toys, buoyancy aids such as armbands and baby seats – where costs will increase by a much higher proportion of 40%. This sector of the toy industry is currently worth £10m at manufacturers prices, suggesting that the costs to companies in this portion of the market will increase by approximately £4m. Given the large increase in production costs for these items, at least some of the increase will be passed on to the consumer.

20. However, on the rest of the market for toys containing plastics, consultation responses suggest that the Directive could increase manufacturing costs by the lower end of the 2-23% range, the most likely increase being 3% overall. The toys & games market is valued at £1.1 bn at manufacturers prices. However, toys aimed at children aged 0-36 months already exclude phthalates. It is not clear what percentage of the

market this accounts for, but infant/pre-school toys accounted for 17% of the market in 2004 (Source: Keynote). Making the simplifying assumption, therefore, that toys for 0-36 months account for 13% of the market, an upper bound indication for policy costs imposed by implementing the Directive on toy companies due to changing production materials is £30m per year.

21. In practice this policy cost will be much lower as a minority of toys do not contain plastic, for example many soft toys, wooden jigsaws and others. Furthermore, the above estimate is made on the basis that companies will remove phthalates from *all* toys containing plastics. Potentially large categories of toys have been covered such as play figures, dolls (including dolls' hands of course), baby and pre-school toys, inflatables, water and outdoor play toys, plastic kits and sets and activity centres, dinosaurs, animals and radio-controlled products with PVC antennae, cars with soft PVC tyres and robots with PVC tubing. These will all have to be assessed against the Commission's guidelines.

22. In practice, the Commission's guidelines accompanying the Directive specifying what is to be considered as a toy that 'can be placed in the mouth' should mean that fewer toy product ranges are affected. This document has yet to be finalised, with the Commission publishing draft guidelines that are subject to review, amendment or elaboration. However the current version states that:

'Articles which exceed a size of 5 cm in all three dimensions cannot be placed in the mouth by children. If an article or a part of an article in one dimension is smaller than 5 cm, it can be taken into the mouth.' (*With proper consideration being given to detachable parts*).

- And that:

'Inaccessible parts of articles can also not be taken into the month. Articles or parts of articles should be considered inaccessible if, during proper use or reasonably foreseeable improper use by children, they can not be reached.'

23. The toy market is highly competitive and is dominated by a few key retailers – Argos, Woolworths, Toys R Us and, increasingly, the supermarket chains. Therefore, except for products that have a high PVC content, such as inflatables, it is expected that the impact of much of the increased costs resulting from the Directive will be absorbed have to by toy companies through price competition in the industry. In addition to the change in restriction on the use of phthalates, toy industry margins and profitability are being squeezed by a number of other factors, including: an overall increase in manufacturing costs, price competition and growing retailer power. Oil price increases have lead to a sharp increase in the cost of plastic (up to 30% is estimated). Industry contacts suggest that the change in the restriction on the use of phthalates is of less significance than these other factors.

24. Respondents to the consultation also highlighted the likely increase in costs for re-evaluating and testing toys that use a changed plasticizer. One leading company calculates that the new Regulation will affect 600 of its 1800 items currently in production and additional testing costs are likely to be approximately £60,000. This would be a one-off cost to test that re-formulated products comply with the new Regulation. *However* there is no statutory obligation for companies to undertake this retesting.

25. The consultation asked for suggestions for possible ways the impact of the new Regulation could be offset. There is little scope for direct offsetting. This is a very specific restriction that affects only one industry. The toy industry is truly international, with the same products sold into many different markets. Toy companies are gearing up to comply with the implementation the Directive across the EU. Even if the Directive wasn't implemented in the UK, industry would be incurring increased costs to comply with the Directive elsewhere. The broader better regulation will deliver significant savings up to 2010 and DTI will be working with the EU to reduce burdens on business arising from EU legislation.

26. The one issue raised by *all* respondents to the consultation was that of 'placing on the market' and the sell through of product that did not comply with the new Regulation after 16th January 2007. The expression 'placing on the market' does not exist in UK law and the draft Regulation uses the word 'supply'. For the purposes of legislation and enforcement we view 'supply' as meaning the same as the European Commission's definition in the "Guide to the implementation of directives based on the New Approach and the Global Approach", known as 'the Blue Book' that:

"A product is placed on the Community market when it is made available for the first time. This is considered to take place when a product is transferred from the stage of manufacture with the intention of distribution or use on the Community market".

27. The Commission has issued a recommendation paper, clarifying the matter for both toys companies and enforcement authorities in the EU. This means that products to do not meet the new requirements of the Regulation, but have been imported into the EU before the 16th January 2007 implementation date can continue to be sold to consumers after that date. It is proposed that there be a 12-month transition period for the sell through for these products.

28. The Regulation does not create any additional administrative obligations on companies to prove that they are in compliance with Standards for toys and childcare articles.

Equity & Fairness

29. The overriding consideration of the Directive is the safety of consumers. 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

30. On the advice of the Small Business Service, stage one of the Small Firms Impact Test was carried out by contacting small businesses and the industry trade association. We were unable to identify any disproportionate impact on small firms as a result of the implementation of this Directive.

Competition Assessment

31. Stage One of the Competition Assessment was undertaken. When applying the Competition Assessment filter, the results indicated that, while the proposed Directive

introduces new restrictions, it is unlikely to have the effect of distorting or removing competition in the market. The Directive will not serve as a barrier to entry for potential entrants nor impose substantially more cost on some firms than others.

Enforcement & Sanctions

32. Regulations to implement the Directive will be enforced in Great Britain by local authorities' Trading Standards departments and in Northern Ireland by Environmental Health Departments Trading Standards officers will periodically test purchase products to see if they comply with the Regulations. A breach of the Regulations will lead to an order to withdraw a product from the market. Serious and persistent breaches of the Regulations may lead to prosecution, at the discretion of Trading Standards.

33. The temporary ban on the use of phthalates in toys and childcare articles, which can be placed in the mouth for children 0-36 months has been implemented in the UK on a voluntary basis. The DTI regularly conducted market surveys to check that the relevant products on the market do not contain phthalates. It is anticipated that the DTI will continue to periodically conduct further surveys to ensure the effectiveness of the permanent ban.

Monitoring and Review

34. 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

35. As the relevant interested department, the Department of Health was consulted about these proposals during the consultation exercise.

Public Consultation

36. The consultees include, amongst others: manufacturers, the chemical industry, the DIY sector, consumer organisations, trade associations, charities, enforcement authorities, Government Departments and non-Governmental organisations. The consultation ran for 12 weeks from 10 April to 3 July 2006.

37. For the phthalates Regulation, we received 19 responses, 6 from toy companies and 7 from retailers – mainly from the main players in this sector.

Summary & Recommendation

38. Our recommendation is that the option chosen offers the best level of public health protection. Extending the restrictions on use of specific substances in toys and childcare articles addresses an identified potential health risk to young children.

39. Implementation of the Directive into UK law is in line with our obligations under the Treaty of Rome.

B.

Proposal

1. To transpose the European Directive 2005/90/EC into UK Law, following its publication in the Official Journal (OJ 4.2.2006 L33, p28).

Purpose and intended effect of measures

Objective

2. *The primary aim of Directive 2005/90/EC is to reduce the risks of ill health to the general public as a consequence of exposure to substances that have been classified as carcinogens, mutagens and substances toxic to reproduction (cmrs). Such substances are capable of inducing, or increasing the incidence of, cancer, hereditary genetic defects and non-hereditary congenital malformations. Since the use by consumers of substances classified as cmrs cannot be effectively controlled, safety can be ensured only by prohibitions on the marketing of these substances to the general public.*

Risk Assessment

Background

3. *The Dangerous Substances Directive (67/548/EEC) concerns the classification, packaging and labelling of dangerous substances. Annex 1 to this Directive contains a list of dangerous substances, together with particulars of the harmonised classification and labelling for each substance. The list is regularly updated to include further notified new substances and existing substances, as well as adapting the current entries to take account of technical developments and new knowledge about the dangers of chemicals.*
4. *Directive 2004/73/EC (29th Adaptation to Technical Progress of Directive 67/548/EEC) was adopted on 29th April 2004 and, among other things, classified 42 substances as Category 1 or 2 cmrs for the first time.*
5. Directive 2005/90/EC has the effect of adding these substances to the Appendices concerning points 29 to 31 of Annex 1 to the Marketing and Use Directive 76/769/EEC. These points specify that the substances so listed, and preparations containing them, may not be placed on the market for sale to the general public.

Options

6. (i) To fully implement the provisions of the Directive.
- (ii) To request industry to adopt voluntary measures.
- (iii) To do nothing.
7. Option (i)

This is the recommended option. The Directive is consistent with UK policy and practice on these issues. Implementation of the Directive will provide a high level of protection from the risks to human health from possible exposure to these hazardous chemicals. It will also provide harmonised rules for the circulation of these substances.

Option (ii)

This option would require UK industry adherence to voluntary guidelines or targets. However, this would 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)

This option does not guarantee the level of protection of human health and the environment afforded by Option (i). 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.

Benefits

Economic

8. In the event that these dangerous substances are being used in products currently on the market, the prohibition on marketing for sale to the general public will serve to foster the development of safer alternatives.

Environmental

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

Social

10. The Directive affords an increased level of protection to the general public from the risks of ill health as a consequence of possible exposure to cmrs.

Costs

11. We have been unable to identify any products, currently on the market for sale to the general public that contain any of these 42 chemicals. Major trade organisations have stated that none of their members use any of the substances in consumer products.
12. The majority of the substances subject to prohibition are used as raw materials, or are intermediates, in chemical processes to synthesise other chemicals. Others are used for very specific professional or worker applications.
13. The remaining substances, which have in the past been used in consumer products, or as constituents of consumer products, are prohibited from being placed on the market for sale to the general public by legislation or other controls.
14. On the basis of this information, no costs to industry are anticipated.

Equity and fairness

15. The overriding consideration of the Directive is the safety of the consumer. 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

16. On the advice of the Small Business Service (SBS), 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 the Directive. However, we have been unable to identify any disproportionate impact on small firms as a result of the implementation of this Directive. During the initial stages of the RIA process, we consulted the SBS on a number of occasions for advice on gauging impact of the proposals on small firms, and they agreed that there is no requirement to carry out further Small Firms Impact Test analysis.

Competition Assessment

17. Stage One of the Competition Assessment was undertaken. When applying the Competition Assessment Filter, the results indicated that, as the Directive will 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 Directive will not serve as a barrier to entry for potential entrants nor impose substantially more cost on some firms than others. Indeed, the Directive will set harmonised requirements to ensure that all involved in the manufacture and supply of products that might possibly contain the substances in question can compete on an equal footing.

Enforcement and Sanctions

18. In Great Britain, the Regulations will be enforced by local authorities' Trading Standards Departments, and in Northern Ireland by Environmental Health Departments.

Monitoring and Review

19. 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

20. The following Government Departments and Agencies were consulted: Health and Safety Executive, Health and Safety Commission, Department for Environment Food and Rural Affairs, Pesticides Safety Directorate, Medicines and Healthcare Products Regulatory Agency, and Department of the Environment (Northern Ireland).

Public Consultation

21. This Consultation Document listed those organisations and individuals to whom the document was sent. The consultees included, among others: manufacturers, the chemical industry, the DIY sector, consumer organisations, trade associations, charities, enforcement authorities, Government Departments and non-Governmental organisations. The consultation ran for 12 weeks.

Summary and Recommendation

22. *We recommend that to place restrictions on the marketing and use of 42 substances newly classified as Category 1 or 2 carcinogens, mutagens or substances toxic to reproduction, is the most effective means of reducing the risks to human health from possible exposure to these hazardous chemicals.*
23. Our legal obligations under the Treaty of Rome compel us to implement this Directive into UK law.

C.

Proposal

1. To transpose European Directive 2005/59/EC into UK Law, following its publication in the Official Journal (OJ 25.11.2005 L309, p13).

Purpose and intended effect of measures

Objective

2. The primary aim of Directive 2005/59/EC with regard to toluene is to reduce the risks of ill-health to consumers as a consequence of exposure to toluene, when using toluene or adhesives and spray paints containing toluene. The Directive prohibits toluene, or adhesives and spray paints containing in excess of 0.1% toluene, from being placed on the market for sale to the general public.

Risk Assessment

Background

3. Risk Assessment Reports for toluene carried out in the framework of the Existing Substances Regulation (EEC 793/93), concluded that further risk reduction measures were needed in addition to those already being applied. These additional measures were considered necessary to provide improved protection from the risks to human health (of both workers and consumers) from this substance
4. The European Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) considered the Risk Assessment Reports. In its Opinions of June and July 2001 it confirmed the conclusions of the assessments and the need to reduce risks to health. In-depth risk reduction strategies for toluene were prepared by the Danish Environmental Protection Agency.
5. In light of the risk assessments and risk reduction strategies, the European Commission issued a Commission Recommendation on 29th April 2004, which was adopted by all Member States. In this document the Commission made recommendations for strategies for limiting risks. Amongst other things, it recommended that a reduction in risks to consumers due to exposure to toluene should be effected by restrictions under the framework of the Marketing and Use Directive 76/769/EEC.

Options

6. (i) To fully implement the provisions of the Directive
- (ii) To request industry to adopt voluntary measures.
- (iii) To do nothing.

7. Option(i)

This is the recommended option. The Directive is consistent with UK policy and practice on these issues. Implementation of the Directive will provide a high level of protection from the risks to human health from exposure to this hazardous chemical. It will also produce harmonised rules for the circulation of this substance.

Option(ii)

This option would require UK industry adherence to voluntary guidelines or targets. However, this would 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)

This option does not guarantee the level of protection of human health and the environment afforded by Option (i). 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.

Benefits

Economic

8. The proposed restrictions on the marketing and use of toluene will serve to foster the development of safer alternatives to this substance.
9. A reduction in the damage to human health will reduce the costs associated with the adverse effects of such damage.

Environmental

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

Social

11. The Directive will reduce the risks of ill-health to consumers as a consequence of exposure to toluene, when using toluene or adhesives and spray paints containing toluene.

Costs

12. We have been unable to identify any disproportionate impact on industry caused by the implementation of this Directive.
13. The Directive will have little impact on the spray paint sector but that there were some concerns in the sector manufacturing adhesives. However, feedback from our consultations and face-to-face contact with key stakeholders has indicated that because manufacturers were made aware of these restrictions at an early stage, the majority have already taken steps to put suitable alternatives in place.
14. The Regulations implementing the provisions of the Directive will be enforced by nominated Enforcement Authorities. There may be small additional costs placed on these organisations.

Equity and fairness

15. The overriding consideration of the Directive is the safety of consumers. 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

16. On the advice of the Small Business Service (SBS), 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 the Directive. However, we have been unable to identify any disproportionate impact on small firms as a result of the implementation of this Directive. During the initial stages of the RIA process, we consulted the SBS on a number of occasions for advice on gauging impact of the proposals on small firms, and they agreed that there is no requirement to carry out further Small Firms Impact Test analysis.

Competition Assessment

17. Stage One of the Competition Assessment was undertaken. When applying the Competition Assessment Filter, the results indicated that, as the Directive will 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 Directive will not serve as a barrier to entry for potential entrants nor impose substantially more cost on some firms than others. Indeed, the Directive will set harmonised requirements to ensure that all involved in the manufacture and supply of products that might possibly contain the substance in question can compete on an equal footing.

Enforcement and Sanctions

18. *In Great Britain, the Regulations will be enforced by local authorities' Trading Standards Departments, and in Northern Ireland by Environmental Health Departments.*

Monitoring and Review

19. 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

20. The following Government Departments and Agencies were consulted: Health and Safety Executive, Health and Safety Commission, Department for Environment Food and Rural Affairs, Pesticides Safety Directorate, Medicines and Healthcare Products Regulatory Agency, and Department of the Environment (Northern Ireland).

Public Consultation

21. This Consultation Document listed those organisations and individuals to whom the document was sent. The consultees included, amongst others: manufacturers, the chemical industry, the DIY sector, consumer organisations, trade associations, charities, enforcement authorities, Government Departments and non-Governmental organisations. The consultation ran for 12 weeks.

Summary and Recommendation

22. We consider that placing certain restrictions on the marketing and use of toluene is the most effective means of reducing the risks to human health from exposure to this potentially hazardous chemical.
23. Our legal obligations under the Treaty of Rome compel us to implement this Directive into UK law.

Declaration:

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

Date: 12th February 2007

Signed by the Minister responsible: Ian McCartney

**Minister for Trade, Investment and Foreign Affairs
Department of Trade and Industry**