EXPLANATORY MEMORANDUM TO

THE DANGEROUS SUBSTANCES AND PREPARATIONS (SAFETY) REGULATIONS 2006

2006 No. 2916

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 revoke the Dangerous Substances and Preparations (Safety) (Consolidation) Regulations 1994 (S.I. 1994/2844) and the six amending Regulations to the extent and on the dates specified in the list in Schedule 1. They consolidate those Regulations making amendments necessary to implement three further Directives and update cross-references to other legislation.

2.2 The Regulations implement 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 certain dangerous substances and preparations (O.J. L262, 27.9.1976, p.201) as amended and so far as the amended Directive concerns substances and preparations prohibited for supply to consumers.

2.3 The three newly implemented Directives are: -

Directive 2005/59/EC of the European Parliament and of the Council of 26 October 2005 (O.J. L309, 25.11.2005, p.13) so far as it relates to toluene and adhesives and spray paints containing toluene. The provisions of Directive 2005/59/EC relating to restrictions on the marketing and use of trichlorobenzene will be implemented separately by Defra (The Department for Environment, Food and Rural Affairs).

Directive 2005/84/EC of the European Parliament and of the Council of 14 December 2005 (O.J. L344, 27.12.2005, p.40) relating to phthalates in toys and childcare articles, and

Directive 2005/90/EC of the European Parliament and of the Council of 18 January 2006 (O.J. L33, 4.2.2006, p.28) relating to amendments to the list of substances classified as carcinogenic, mutagenic or toxic to reproduction.

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

None.

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4. Legislative Background

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

4.2 Parliamentary Scrutiny of Directive 2005/90/EC. The Department submitted an explanatory memorandum (EM 13774/04) on 5 November 2004 concerning a proposal for a Directive of the European Parliament and of the Council amending for the 29th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (substances classified as carcinogens, mutagens of substances toxic to reproduction – cmr). The House of Commons European Scrutiny Committee considered it not legally or politically important and cleared it 17 November 2004 (Report 37, Session 2003-4). The House of Lords Select Committee on the European Union considered the EM on 17 November 2004 when the document was retained under scrutiny pending submission of a full Regulatory Impact Assessment (RIA). The EM was cleared by a letter of 8 July 2005 to the Minister after submission of a full RIA on 9 June 2005.

4.3 Parliamentary Scrutiny of Directive 2005/84/EC. The Department submitted an explanatory memorandum (EM 13308/99) on 14 January 2000 concerning a proposal for a Directive of the European Parliament and of the Council amending for the 22nd time Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates) and amending Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys. The House of Commons European Scrutiny Committee considered a Ministers' letter of 20 September 2004 to be politically important and cleared it (Report 33, Item 20750, Session 2003-4). The House of Lords Select Committee on the European Union did not report on it (Progress of Scrutiny, 21/1/2000, Session 1999-2000).

4.4 Parliamentary Scrutiny of Directive 2005/59/EC. The Department for Environment, Food and Rural Affairs submitted an explanatory memorandum (EM 9123/04) on 18 May 2004 concerning a proposal for a Directive of the European Parliament and of the Council amending for the 28th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of toluene and trichlorobenzene. A supplementary EM was submitted on 21 February 2005. The House of Commons European Scrutiny Committee considered it not legally or politically important and cleared it (Report 12, Session 2004-5). The House of Lords Select Committee on the European Union cleared it by letter of 17 March 2005 to the Minister.

5. Extent

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

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

7. Policy Background

7.1 The Marketing and Use Directive 76/769/EEC seeks to protect human health and the environment in Member States by restricting the marketing and use of certain dangerous substances and preparations. Annex 1 to the Directive lists those chemicals of concern and specifies the restrictions on marketing and use placed upon them. The Annex is regularly updated by the European Commission by adding further chemicals or by amending existing entries.

7.2 Directive 2005/90/EC, which amended Directive 76/769/EEC for the 29th time, aims to reduce the risk of ill health to the general public as a consequence of exposure to substances, which have been classified as carcinogens, mutagens, or 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. Directive 2005/90/EC, among other things, added a further 42 substances, newly classified as cmrs, to the list of those substances prohibited from being placed on the market for sale to the general public.

7.3 Directive 2005/84/EC, which amended Directive 76/769/EEC for the 22nd time, aims to protect the health of the general public by banning the use of three phthalates (the plasticizers DEHP, DBP and BBP) from being used in toys and childcare articles and restricting the use of three other phthalates (DINP, DIDP and DNOP) in toys and childcare articles which can be placed in the mouth. Phthalates have been identified as reprotoxic (damaging to unformed reproductive organs) and their use in toys intended to be mouthed by children up to 36 months has been banned on a temporary basis for a number of years. Directive 2005/84/EC makes this temporary ban permanent and extends the ban to the use of phthalates in all toys and childcare articles, or parts of toys and childcare articles, that can be placed in the mouth.

7.4 Directive 2005/59/EC, which amended Directive 76/769/EEC for the 28th time, aims 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. Toluene may cause eye irritation and acute toxicity as a consequence of dermal exposure or inhalation. Toluene, or adhesives or spray paints containing toluene, may not be placed on the market for sale to the general public if the concentration of toluene is equal to or greater than 0.1% by mass.

The Directive also aims to reduce the adverse effects on the environment by its exposure to trichlorobenzene. Since provisions of the Directive relating to trichlorobenzene concern the environment, rather than consumer safety, they will be implemented separately by Defra.

7.5 A 12-week consultation exercise on the draft Regulations implementing the three Directives 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.

7.6 Comments about the regulation concerning phthalates were submitted by toy companies and retailers and they all commented on the meaning of the phrase "placing on the market" and the sale, after 16 January 2007, of products not complying with the new regulation which comes into force on this date. The European Commission has issued a recommendation paper, which clarifies the matter for both toy companies and enforcement authorities. This means that products, which do not meet the requirements of the new regulation, but have been imported into the EU before the 16 January coming into force date, may continue to be sold to consumers after this date. The consultation document asked also for suggestions for possible ways of offsetting the impact of the new regulation. There is, however, little scope for direct offsetting because the regulation imposes a very specific restriction that affects a single industry.

7.7 No substantive comments were received about the regulations concerning the restrictions on toluene and carcinogens etc. Manufacturers have been aware for some time of the proposed restrictions on toluene in adhesives and spray paints and have already taken steps to have suitable alternatives in place and consequently no further substantive comments were forthcoming. Similarly, the restrictions on the use of further carcinogens etc. prompted no further substantive comments since there is no evidence that the newly restricted chemicals are currently used in preparations sold to the general public.

8. Impact

A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

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 teethers are composed of PVC plastic and can contain a high concentration of phthalates. Teethers 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. *<u>Option (i)</u>*

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.

<u>Option (ii)</u>

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

<u>Within Government</u>

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.

Signed by the Minister responsible

Ian McCartney

(Minister for Trade, Investment and Foreign Affairs)

November 2006

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TRANSPOSITION NOTE

RELATING TO THE DANGEROUS SUBSTANCES AND PREPARATIONS (SAFETY) REGULATIONS 2006

This Transposition Note has been prepared by the Department of Trade and Industry and is intended to show how the Department has implemented Directives which amend, or adapt to technical progress, the Marketing and Use Directive 76/769/EEC (O.J. L.262, 27.9.1976, p.201). This Directive restricts the placing on the market and use of certain dangerous substances and preparations. It is implemented in the United Kingdom by the Dangerous Substances and Preparations (Safety) Regulations 2006 in so far as it concerns substances and preparations prohibited for supply to consumers.

The Regulations revoke the Dangerous Substances and Preparations (Safety) (Consolidation) Regulations 1994 (S.I. 1994/2844) and its six amending Regulations. They consolidate those Regulations making the amendments necessary to implement three further Directives. There is no gold plating in respect of the implementation of these new Directives. Where gold plating is present in the implementation of the other Directives, these areas have been identified in the third column of the table below, which lists those Directives implemented by the Regulations and for which the Department has responsibility.

Directive		
Council Directive 79/663/EEC (O.J. L197, 3.8.79, p. 37) of 24 July 1979 supplementing the Annex to Council Directive 76/769/EEC as regards restrictions on the marketing and use of certain dangerous substances and preparations.		
Article	Objective	Transposition
Article 1a amends Annex I to Directive 76/769/EEC by adding point 4.	Point 4 prohibits the use of tris (2,3-dibromopropyl) phosphate in textile articles, such as garments, undergarments and linen intended to come into contact with the skin.	Regulation 6(2)(a), 6(2)(b) and 6(2)(c). This regulation does more than is necessary to implement the Directive in that it inserts, in addition, a reference to "child's dressing-gown" and provides that the ban shall apply to such dressing-gowns, whether or not they come in contact with the skin.

Directive		
Council Directive 82/806/EEC (O.J. L 339, 1.12.82, p. 55) of 22 November 1982 amending for the 2nd time Council Directive 76/769/EEC as regards restrictions on the marketing and use of certain dangerous substances and preparations (benzene).		
Article	Objective	Transposition
Article 1 amends Annex I to Directive 76/769/EEC by adding point 5.	The first sentence of point 5 to Directive 76/769/EEC prohibits, with exceptions, the use of benzene in toys or parts of toys where the concentration of benzene is in excess of 5mg/kg.	Regulation 4(3). This regulation does more than is necessary to implement the Directive in that it inserts, in addition, the words "including a kit for making balloons ……or a substance which is intended for making balloons …"

Directive		
Council Directive 89/677/EEC (O.J. L 398, 30.12.89, p. 19) of 21 December 1989 amending for the 8th time Council Directive 76/769/EEC as regards restrictions on the marketing and use of certain dangerous substances and preparations (benzene).		
Article	Objective	Transposition
Article1.3 amends Annex I to Directive 76/769/EEC by amending point 5.	The second sentence of point 5 provides that benzene may not be used in concentrations greater than 0.1% by mass in substances and preparations placed on the market.	Regulation 4(1).
Article 1.3(a), 1.3(b) and 1.3(c) amends Annex I to Directive 76/769/EEC by amending point 5.	Points 5(a), 5(b) and 5(c) lists exceptions to the prohibition on benzene in the second sentence of point 5.	Regulations 4(2)(a), 4(2)(b), and 4(2)(c)

Directive		
Commission Directive 97/10/EC (O.J. L68, 8.3.97, p.24) of 26 February 1997 adapting to technical progress for the 3rd time Annex I to Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (carcinogens, mutagens and substances toxic to reproduction - cmrs)		
Article	Objective	Transposition
Article 1 adapts Annex I to Directive 76/769/EEC to technical progress by replacing points 29, 30 and 31.	Points 29, 30 and 31 prohibit , with exceptions, the use of substances and preparations classified as carcinogenic, mutagenic and toxic to reproduction respectively, in substances and preparations placed on the market for sale to the general public.	Regulation 5.
	The carcinogenic, mutagenic and substances toxic to reproduction subject to the prohibition are listed in the Appendix to Annex I to Directive 76/769/EEC.	Schedule 2 to the Regulations lists the substances which are carcinogenic, mutagenic or toxic to reproduction.

Directive		
Directive 97/56/EC of the European Parliament and of the Council (O.J. L333, 4.12.97, p.1) of 20 October 1997 amending for the 16th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (carcinogens, mutagens and substances toxic to reproduction - cmr)		
Article	Objective	Transposition
Article 1(2) amends Annex I to Directive 76/769/EEC by replacing the Appendix to Directive 76/769/EEC by the text contained in the Annex to the Directive.	Further carcinogenic, mutagenic and substances toxic to reproduction are added to the Appendix to Directive 76/769/EEC and the Appendix is consolidated.	Schedule 2 to the Regulations amended by the insertion of the substances.

Directive		
Directive 1999/43/EC of the European Parliament and of the Council (O.J. L166, 1.7.1999, p.87) of 25 May 1999 amending for the 17th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (carcinogens, mutagens and substances toxic to reproduction - cmr)		
Article	Objective	Transposition
Article 1 amends the Appendix to Annex I to Directive 76/769/EEC.	The cmr substances, listed at Annex I to the Directive, are added to the Appendix concerning points 29, 30 and 31 of the Annex to Directive 76/769/EEC.	Schedule 2 to the Regulations amended by the insertion of these entries.
Article 2 amends the Appendix to Annex I to Directive 76/769/EEC.	The cmr substances listed at Annex II to the Directive are deleted from the list of those substances in the Appendix concerning point 29 of the Annex to Directive 76/769/EEC.	Schedule 2 to the Regulations amended by the deletion of these entries.

Directive		
Directive 2001/41/EC of the European Parliament and of the Council (O.J. L194, 18.7.2001, p.36) of 19 June 2001 amending for the 21st time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (carcinogens, mutagens and substances toxic to reproduction - cmr)		
Article	Objective	Transposition
Article 1(2) amends the Appendix to Annex I to Directive 76/769/EEC.	The cmr substances, listed at the Annex to the Directive, are added to the Appendix concerning points 29 and 31 of the Annex to Directive 76/769/EEC.	Schedule 2 to the Regulations amended by the insertion of these entries.

Directive		
Directive 2003/34/EC of the European Parliament and of the Council (O.J. L156, 25.6.2003, p.14) of 26 May 2003 amending for the 23rd time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (carcinogens, mutagens and substances toxic to reproduction - cmr)		
Article	Objective	Transposition
Article 1 amends the Appendix to Annex I to Directive 76/769/EEC.	The cmr substances, listed at the Annex to the Directive, are added to the Appendix concerning points 29, 30 and 31 of the Annex to Directive 76/769/EEC.	Schedule 2 to the Regulations amended by the insertion of these entries.

Directive		
Directive 2003/36/EC of the European Parliament and of the Council (O.J. L156, 25.6.2003, p. 26) of 26 May 2003 amending for the 25th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (carcinogens, mutagens and substances toxic to reproduction - cmr).		
Article	Objective	Transposition
Article 1 amends the Appendix to Annex I to Directive 76/769/EEC.	The cmr substances, listed at the Annex to this Directive are added to or deleted from the Appendix concerning points 29, 30 and 30 of the Annex to Directive 76/769/EEC.	Schedule 2 to the Regulations amended by the insertion or deletion of these entries, as appropriate.

Directive		
Directive 2005/90/EC of the European Parliament and of the Council (O.J. L33, 4.2.2006, p.28) of 18 January 2006 amending for the 29th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (carcinogens, mutagens and substances toxic to reproduction)		
Article	Objective	Transposition
Article 1 amends the Appendix to Annex I to Directive 76/769/EEC.	The cmr substances, listed at the Annex to this Directive are added to, deleted from or amended in the Appendix concerning points 29, 30 and 30 of the Annex to Directive 76/769/EEC.	Schedule 2 to the Regulations amended by the insertion, deletion or amendment of these entries, as appropriate.

Directive		
Council Directive 83/264/EEC (O.J. L147, 6.6.1983, p.9) of 16 May 1983 amending for the 4th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations.		
Article	Objective	Transposition
Article 1 amends Annex I to Directive 76/769/EEC by adding point 8 and 9.	Point 8 prohibits the use of tris-aziridinyl)-phosphinoxide in textile articles, such as garments, undergarments and linen intended to come into contact with the skin. Point 9 prohibits the use of polybrominated biphenyls (PBB) textile articles, such as garments, undergarments and linen intended to come into contact with the skin.	Regulation 6(2)d, 6(2)e and 6(2)f. This regulation does more than is necessary to implement the Directive in that it inserts, in addition, a reference to "child's dressing-gown" and provides that the ban shall apply to such dressing-gowns, whether or not they come in contact with the skin.

Directive		
Commission Directive 96/55/EC (O.J. L231, 12.9.96, p.20) of 4 September 1996 adapting to technical progress for the 2nd time Annex I to Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (chlorinated solvents).		
Article	Objective	Transposition
Article1 amends Annex I to Directive 76/769/EEC by replacing the existing Points 33 to 40 (inclusive) by new Points 33 to 40.	Points 33 to 40 prohibit the use of eight chlorinated solvents in concentrations greater than 0.1% by weight in substances or preparations placed on the market for sale to the general public.	Regulations 7(1)(a) to 7(1)(h).
	These provisions do not apply to medicinal, veterinary or cosmetic products.	Regulations 7(2)(a) to 7(2)(c).

Directive		
Commission Directive 97/64/EC (O.J. L315, 19.11.97, p. 13) 10 November 1997 adapting to technical progress for the 4th time Annex I to Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (lamp oils).		
Article	Objective	Transposition
Article 1 amends Annex I to Directive 76/769/EEC by replacing the existing Point 3 by a new Point 3.	Point 3(2) provides that, with exceptions, substances and preparations classified by Directive 67/548/EEC as dangerous, that are required to be labelled with the risk phrase R65 (harmful: may cause lung damage if swallowed) and which can be used as fuel in decorative lamps, may not contain a colouring agent, unless required for fiscal reasons, or perfume or both.	Regulations 8(1)(a)-(c), 8(2)and 8(4)
	The last paragraph in the right-hand column of Point 3 provides that such substances and preparations must be labelled "Keep lamps filled with this liquid out of the reach of children"	Regulation 8(3)
	Point 3(1) provides that such substances or preparations may not be used in certain ornamental objects, tricks and jokes, and certain games.	Regulations 9(1) and 9(2)
Directive		
Council Directive 83/264/EEC (O.J. L147, 6.6.1983, p.9) of 16 May 1983 amending for the 4th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations		
Article	Objective	Transposition
Article 1 amends Annex I to Directive 76/769/EEC by adding Points 10, 11 and 12.	The substances listed in Points 10, 11 and 12 may not be used in jokes and hoaxes or in objects intended to be used as such.	Regulation 10.

Directive		
Directive 2005/84/EC (O.J. L309, 25.11.2005, p. 13) of the European Parliament and of the Council of 14 December 2005 amending for the 22nd time Council Directive 76/769/EEC as regards restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles).		
Article	Objective	Transposition
Article 1(1) amends Article 1(3) of Directive 76/769/EEC.	A new paragraph 3(c), which gives the definition of a "childcare article" is added to Article 1 of Directive 76/769/EEC.	Regulation 11(1).
Article 1(2) amends Annex I to Directive 76/769/EEC by adding point 51.	Point 51 of Annex I to Directive 76/769/EEC prohibits the supply of toys or childcare articles containing in excess of 0.1% by mass of the plasticized material of any of the phthalates DEHP, DBP and BBP.	Regulation 11(2).
Article 1(2) amends Annex I to Directive 76/769/EEC by adding point 51A.	Point 51A of Annex I to Directive 76/769/EEC prohibits the supply of toys or childcare articles which can be placed in the mouth by children containing in excess of 0.1% by mass of the plasticized material of the phthalates DINP, DIDP and DNOP.	Regulation 11(3).

Directive
Directive 2005/59/EC (O.J. L309, 25.11.2005, p. 13) of the European Parliament and of the Council of 26 October 2005 amending for the 28th time Council Directive 76/769/EEC as regards restrictions on

the marketing and use of certain dangerous substances and preparations (toluene and trichlorobenzene).		
Article	Objective	Transposition
Article 1 amends Annex I to Directive 76/769/EEC by adding points 48 and 49.	Point 48 of Annex I to Directive 76/769/EEC provides that toluene may not be placed on the market or used as a substance or constituent of preparations in a concentration equal to or higher than 0.1% by mass in adhesives and spray paints intended for sale to the general public.	Regulation 12 implements the provisions relating to toluene (Point 48). The provisions relating to trichlorobenzene (Point 49), will be implemented by the Department for Environment Food and Rural Affairs (Defra).