

**EXPLANATORY MEMORANDUM TO
THE CONTROLS ON DANGEROUS SUBSTANCES AND PREPARATIONS
REGULATIONS 2006**

2006 No. 3311

1. This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. **Description**

- 2.1 This statutory instrument places restrictions on the marketing and use of trichlorobenzene and certain polycyclic aromatic hydrocarbons in extender oils and tyres.

It also revokes and replaces without any change in regulatory burden, 17 instruments that implement previous amendments to the Marketing and Use Directive (76/769/EC) in respect of substances and preparations for which DEFRA has responsibility. These instruments are:

UK:

S.I. 1987/783;

England and Wales and Scotland:

S.I. 1992/31; S.I. 1992/1583; S.I. 1993/1; S.I. 1993/1643; S.I. 2001/3141; S.I. 2003/3274; S.I. 2004/1816 and S.I. 2004/3278;

Northern Ireland:

S.R. 1994 No.223; S.R. 1994 No.224; S.R. 2003 No.105; S.R. 2003 No.106; S.R. 2003 No.165; S.R. 2003 No.548; S.R. 2004 No.302 and S.R. 2004 No.509;

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

- 3.1 None

4. **Legislative Background**

- 4.1 This instrument implements EU Directive 2005/69/EC and EU Directive 2005/59/EC which adapts for the 27th and 28th time respectively Council Directive 76/769/EC relating to the restrictions on the marketing and use of certain dangerous substances and preparations.

Both Commons and Lords gave scrutiny clearance in March 2005 to Directive 2005/59/EC on TCB. Scrutiny Clearance for the Directive 2005/56/EC on PAHs was given March 2004 by the Commons and April 2004 by the Lords.

A transposition note is attached at Annex A

5. Territorial Extent and Application

5.1 This instrument applies to all 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 Under the Existing Substances Regulation (793/93/EC), TCB was a priority substance for risk assessment and, where necessary, risk management, at the European Union level. The Danish rapporteur undertook this work and TCB was found to be toxic and a risk to the aquatic and terrestrial environment as a consequence of exposure as a dye carrier and other uses. For consumers, TCB can cause eye and respiratory tract irritation as a consequence of repeated inhalation and dermal exposure to this substance.

7.2 On this basis of the evidence put forward the UK supported both proposals for restrictions on the marketing and use of TCB and of PAHs in extender oils and tyres. However on the proposals relating to TCB the UK lobbied for a derogation for an essential UK manufacturing use from the restrictions permitting the use of TCB in the manufacture of TATB, a substance used in the manufacture of sensitive munitions. This was successful. As a result it was concluded that EU wide marketing and use restrictions of these substances with derogations would provide the most appropriate means for controlling the risk associated with the substances. This took the form of the 27th and 28th amendments (2005/69/EC and 2005/59/EC) to Council Directive 76/769/EEC.

7.3 The revocation and consolidation of 17 statutory instruments into a single SI is as result of a review of the current arrangements, which we believe are cumbersome and impractical for businesses. This is why Defra in agreement with the Devolved Administrations have adopted this new approach. Overall the effect will be to simplify the regulatory regime in this area in line with Defra's commitment to better regulation. As this is a consolidation exercise and does not change any current burdens nor put in place any new or additional regulatory burdens there is no change in impact and therefore an impact assessment is not needed.

7.4 Consultation.

During the negotiation stage for these proposals several meetings were held with the UK industry that uses TCB. This helped inform the UK negotiating position. A twelve public consultation was also ran in the UK on both draft Directives, they was also placed on the Defra website, a summary of responses is held in the Defra library.

This SI was consulted for the statutory twelve week period. From the 300 copies sent out to key stakeholders, relevant industries, NGOs and other interested parties 10 responses were received all of which supported the proposals in the SI. A summary of these response has been lodged in the DEFRA library.

A Cabinet Committee write round letter was also sent for the consolidation element of this SI seeking Ministerial agreement from the Devolved Administrations. This was given.

Guidance

No additional guidance is needed to accompany this SI. The existing guidance for compliance on the marketing and use amendments that are to be consolidated in this SI does not change and remains current. For the new provisions on PAHs no guidance is needed as the rubber and tyre manufacturing industry which helped develop the proposals at the EU level fully expect to meet the requirements set out in the Directive. For TCB only there is only one industry in the UK that uses this substance for the manufacture of TATB, a substance crucial for the manufacture of insensitive munitions. This use has been given a permanent derogation to permit continued use.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum in relation to the new restriction on TCB and PAHs.

8.2 There is no impact on the public sector.

9. Contact

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TRANSPOSITION OF DIRECTIVE 2005/59/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL – RESTRICTIONS ON THE MARKETING & USE OF TOLUENE AND TRICHLOROBENZENE: AND

DIRECTIVE 2005/69/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL – RESTRICTIONS ON THE MARKETING AND USE OF CERTAIN POLYCYCLIC AROMATIC HYDROCARBONS IN EXTENDER OILS AND TYRES

These Directives have been transposed in the UK by the following measure:

Environmental Protection – The Controls on Dangerous Substances and Preparations Regulations 2006. SI No [...]

EC Directive 2005/59/EC (Official Journal No. L309, 25 November 2005, page 13/14) amends for the 28th time Council Directive 76/769/EEC restricting the marketing and use of toluene¹ and trichlorobenzene (TCB).

EC Directive 2005/69/EC (Official Journal No. L323, 9 December 2005, page 51- 54) amends for the 27th time Council Directive 76/769/EC restricting the marketing and use of polycyclic aromatic hydrocarbons (PAHs) in extender oils and tyres.

Statutory Instrument 2006 No. [...] Environmental Protection - The Controls on Dangerous Substances and Preparations Regulations 2006. Regulation 3 and Schedule 1 (at point numbers 49 and 50) transpose into UK law Directives 2005/59 EC and 2005/69/EC to:

- Prohibit on or after 15 June 2007 the placing on the market or use as a substance or constituent of substances or of preparations in concentrations higher than 0.1 % by mass of TCB for all uses except
 - as an intermediate in synthesis
 - as a process solvent in closed chemical applications for chlorination reactions, or
 - in the manufacture of 1,3,5-trinitro-2,4,6-triaminobenzene
- Prohibit on or after 1 January 2010 the placing on the market or use for the production of tyres or parts of tyres, extender oils if they contain²:
 - more than 1mg/kg Benzo(a)Pyrene, or
 - more than 10mg/kg of the sum of all listed PAHs
- Tyres and treads for re-treading manufactured on or after 1 January 2010 may not be placed on the market if they contain extender oils exceeding the limits above, this does not apply to already re-treaded tyres if their tread does not contain extender oils exceeding this limit³.

¹ It should be noted that the provisions in this Directive relating to the restriction on the marketing and use of toluene have been implemented using powers under the Consumer Protection Act and can be found in SI 2006/2916

² The limits of more than 1mg/kg Benzo(a)Pyrene, or more than 10mg/kg of the sum of all listed PAHs are regarded as kept if the polycyclic aromatics (PCA) extract is less than 3% by mass, as measured by the Institute of Petroleum Standard IP346:1998, provided that compliance with the limit values of BaP and of the listed PAHs, as well as the correlation of the measured values with the PCA extract, is controlled by the manufacturer or importer every six months or after each major operational change, whichever is earlier.

³ These limits are regarded as kept if the vulcanised rubber compounds do not exceed the limit of 0,35% Bay protons as measured and calculated by ISO 21461

Background

On 26 October 2005 the European Commission issued Directive 2005/59/EC, the 28th amendment of Commission Directive 76/769/EC. This places restrictions on the marketing and use of toluene and TCB (CAS no 120-82-1) . On the 16 November 2005 the European Commission issued Directive 2005/69/EC, the 27th amendment of Commission Directive 76/769/EC. This places restrictions on the marketing and use of PAHs in extender oils and tyres.

Under the Existing Substances Regulation (793/93/EC) framework, Risk Assessment Reports for both toluene and TCB carried out and 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 (both workers and consumers) and the environment from these substances. TCB is toxic and a risk to the aquatic and terrestrial environment as a consequence of exposure as a dye carrier and other uses. For consumers, TCB can cause eye and respiratory tract irritation as a consequence of repeated inhalation and dermal exposure to this substance.

The European Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) was consulted and considered the Risk Assessment Reports. In their opinions of June and July 2001 they confirmed the conclusions of the Assessments of the need to reduce risks to health. In-depth risk reduction strategies for both toluene and TCB were prepared by the Danish Environmental Protection Agency.

For PAHs the proposals are largely based on research carried out by Sweden for their own proposed national ban and then taken up by the Commission for a EU wide restriction. This Directive has been adopted to provide a high level of protection to human health and the environment by further reducing polycyclic aromatic hydrocarbons. Certain polycyclic aromatic hydrocarbons are classified as carcinogenic, mutagenic and reprotoxic substances. Furthermore, polycyclic aromatic hydrocarbons are regarded as Persistent Organic Pollutants under the UN ECE Protocol on Persistent Organic Pollutants (the 1998 Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants) and are subject to obligation to reduce total annual emissions.

The PAHs covered by the restrictions are:

Benzo(a)pyrene (BaP) CAS No 50-32-8
Benzo(e)pyren (BeP) CAS No 192-97-2
Benzo(a)anthracene (BaA) CAS No 56-55-3
Chrysen (CHR) CAS No 218-01-9
Benzo(b)fluoranthene (BbFA) CAS No 205-99-2
Benzo(j)fluoranthene (BjFA) CAS No 207-08-9
Benzo(k)fluoranthene (BkFA) CAS No 207-08-9
Dibenzo(a, h)anthracene (DBAhA) CAS No 53-70-3

Regulatory Impact Assessment - Transposition of Directive 2005/59/EC on Polycyclic aromatic hydrocarbons in extender oils and tyres and Directive 2005/69/EC on toluene and trichlorobenzene.

Issue

1. Transposition into UK law of Directives 2005/69/EC and 2005/59/EC which amend for the 27th and 28th time respectively Council Directive 76/769/EEC. Directive 2005/69/EC relates to restrictions on the marketing and use of certain polycyclic aromatic hydrocarbons in extender oils and tyres whilst Directive 2005/59/EC relates to the restrictions on the marketing and use of toluene and trichlorobenzene.

Objective

2. The objective for this RIA is to determine the most appropriate option for implementing the Commission Directives into UK law.

Background

3. On 26 October 2005 the European Commission issued Directive 2005/59/EC, the 28th amendment of Commission Directive 76/769/EC. This places restrictions on the marketing and use of toluene and trichlorobenzene. On the 16 November 2005 the European Commission issued Directive 2005/69/EC, the 27th amendment of Commission Directive 76/769/EC. This places restrictions on the marketing and use of PAHs in extender oils and tyres.

4. This RIA does not cover the provisions in Directive 2005/59/EC relating to toluene. These have been implemented by the DTi using consumer safety legislation and the provisions can be found in SI 2006/2916.

4. Under the Existing Substances Regulation (793/93/EC) framework, Risk Assessment Reports for both toluene and TCB carried out and 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 (both workers and consumers) and the environment from these substances. TCB is toxic and a risk to the aquatic and terrestrial environment as a consequence of exposure as a dye carrier and other uses. For consumers, TCB can cause eye and respiratory tract irritation as a consequence of repeated inhalation and dermal exposure to this substance

5. The European Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) was consulted and considered the Risk Assessment Reports. In their opinions of June and July 2001 they confirmed the conclusions of the Assessments of the need to reduce risks to health. In-depth risk reduction strategies for both toluene and TCB were prepared by the Danish Environmental Protection Agency.

6. For PAHs the proposals are largely based on research carried out by Sweden for their own proposed national ban and then taken up by the Commission for a EU wide restriction. This Directive has been adopted to provide a high level of protection to human health and the environment by further reducing polycyclic aromatic hydrocarbons. Certain polycyclic aromatic hydrocarbons are classified as carcinogenic, mutagenic and reprotoxic substances. Furthermore, polycyclic aromatic hydrocarbons

are regarded as Persistent Organic Pollutants under the UN ECE Protocol on Persistent Organic Pollutants (the 1998 Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants) and are subject to obligation to reduce total annual emissions

6. On this basis of the evidence put forward the UK supported both proposals for restrictions the marketing and use of TCB, toluene and PAHs in extender oils and tyres. It was concluded that EU wide marketing and use restrictions of these substances would provide the most appropriate means for controlling the risk associated with the substances. These took the form of the 27th and 28th amendments to Council Directive 76/769/EEC.

Options

7. To enact the requirements of the Directives two options were considered.

- Do nothing.

European law has precedence over Member State law, and Member States have an obligation to implement European legislation properly. Consequently, the United Kingdom would be in breach of its EU obligations if it does not implement the Directive. In such circumstances, the UK would be subject to infraction proceedings, and the UK Government could be subject to large fines. This is therefore not an option

- Proper implementation of the derogation.

This is the preferred option. The proposed Directives are 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 and the environment from exposure to these hazardous chemicals. It will also provide harmonised rules for the circulation of these substances.

COSTS

8. Cost associated with conforming to the requirements of the marketing and use restrictions are detailed in the regulatory impact assessment prepared on the original, European legislation (annex A &B) but in summary:

8.1 PAHs

This proposal is supported by industry and imposes no additional regulatory costs on business beyond those, which the industry will bear through its existing commitment to phase out the use of polycyclic aromatic hydrocarbon-rich extender oils. Some oil producers have already developed polycyclic aromatic hydrocarbon-low extender oils and the production of polycyclic aromatic hydrocarbon-rich extender oils is declining. Certain tyres have also been developed without resorting to the use of polycyclic aromatic hydrocarbons-rich extender oils.

8.2 TCB

TCB is no longer manufactured in the UK and there is only a low level of usage. It is no longer used in the manufacture of herbicides/pesticides or as a dye carrier, where, in the UK, other chemicals have substituted it. In the past it has been used as a dielectric fluid, solvent or heat transfer medium in electrical equipment and may therefore be found in existing electrical equipment. Other uses have included a constituent of metal working fluids and corrosion inhibitor sprays. A reduction in the damage to the environment from these historical uses and to human health will reduce the costs associated with these adverse effects.

There is a small usage of TCB in the UK in the manufacture of high performance insulation in wire and cable products. During the public consultation those industries were asked to indicate whether there would be any economic consequences to them as a result of this Directive and none were put forward.

Benefits

9. Full benefits are outlined in the regulatory impact assessment prepared for the European legislation (Annex A & B). However in summary the restrictions will mean a high level of protection to human health and the environment. The proposed restriction will ensure that polycyclic aromatic hydrocarbon-rich extender oils and tyres produced with these oils are phased out. The production of high-grade polycyclic aromatic hydrocarbons-low extender oil would increase the competitiveness of the European Industries concerned

The Directive, if adopted, would reduce the risks to the environment from TCB and products containing TCB. Additionally, it would reduce the risks to human health as a consequence of exposure to TCB from the environment, especially via drinking water.

Securing Compliance

10. See regulatory impact assessment at annex A & B

Impact on Small Business

11. See regulatory impact assessment at annex A & B

Monitoring and Evaluation

12. See regulatory impact assessment at annex A & B

Consultation

13. During development of the regulatory impact assessments at Annex A & B, two extensive public consultation were undertaken with industry, downstream users, trade associations and other key stakeholders with an interest in these substances.

Declaration

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

Signed by the Minister responsible

.....Jeff Rooker.....11th December 2006.....

Annex A - Polycyclic Aromatic Hydrocarbons - Final Regulatory Impact Assessment

Proposal

1. A European Directive which seeks to place restrictions on the marketing and use of polycyclic aromatic hydrocarbons and which forms the 27th amendment to the Marketing and Use Directive 76/769/EEC.

Purpose and intended effect of measures

Objective

2. The purpose of this Directive is to provide a high level of protection to human health and the environment by further reducing polycyclic aromatic hydrocarbons contained in tyre debris from entering the environment. This will contribute to the reduction of total annual emissions of polycyclic aromatic hydrocarbons as required in the 1998 Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants. The proposals within this Directive will contribute to the decline of polycyclic aromatic hydrocarbons entering the environment. Major sources of polycyclic aromatic hydrocarbons are being addressed through the Air Quality Framework Directive 96/62/EC and a daughter Directive specifically addressing the need to reduce polycyclic aromatic hydrocarbons. Support of this current proposal follows the precedent set by these two preceding instruments.

Background

3. Certain polycyclic aromatic hydrocarbons are classified as carcinogenic, mutagenic and reprotoxic substances. The substance Benzo(a)pyrene (BaP) can be a qualitative and quantitative marker for the presence of polycyclic aromatic hydrocarbons. Benzo(a)pyrene is classified as carcinogenic, mutagenic and reprotoxic category 2 in the framework of Directive 67/548/EEC, and it can pose unacceptable risks to human health or the environment. Furthermore, polycyclic aromatic hydrocarbons are regarded as Persistent Organic Pollutants under the United Nations Economic Commission for Europe's (UN ECE) Protocol on Persistent Organic Pollutants (the 1998 Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants) and are subject to obligation to reduce total annual emissions.

4. Polycyclic aromatic hydrocarbons can be constituents in oils. Some of these oils are used as extender oils in the production of tyres. The extender oil is incorporated into the rubber matrix and remains there locked in the rubber of the final tyre. Consequently, the extender oil can also be present in the tyre debris. Technical processes allow the content of certain polycyclic aromatic hydrocarbons in extender oils to be reduced to low limits. Tyre producers have been willing to work towards a high level of protection of health and the environment by phasing out high aromatic extender oils.

5. The Commission's proposal is in line with the opinion of its Scientific Committee and the United Nations Convention on persistent organic pollutants (POPs). It is

intended that this Directive cover passenger car tyres¹, light and heavy truck tyres², agricultural tyres³ and motorcycle tyres⁴ for the polycyclic aromatic hydrocarbons listed in Annex I.

The proposal is not applicable to aircraft tyres as defined in paragraph 3 of Annex I.

The following point [50] is added to Annex I of Directive 76/769/EEC:

<p>[50]. Polycyclic-aromatic hydrocarbons (PAH) 1. Benzo(a)pyrene (BaP) CAS No. 50-32-8 2. Benzo(e)pyren (BeP) CAS No. 192-97-2 3. Benzo(a)anthracene (BaA) CAS No. 56-55-3 4. Chrysen (CHR) CAS No. 218-01-9 5. Benzo(b)fluoranthene (BbFA) CAS No. 205-99-2 6. Benzo(j)fluoranthene (BjFA) CAS No. 205-82-3 7. Benzo(k)fluoranthene (BkFA) CAS No. 207-08-9 8. Dibenzo(a,h)anthracene (DBAhA) CAS No. 53-70-3</p>	<p>(1) Extender oils may not be placed on the market and used for the production of tyres, if they contain more than 1 mg/kg BaP, or more than 10 mg/kg of the sum of all listed PAHs. (2) Furthermore, the tyres may not be placed on the market if they contain extender oils exceeding the limits indicated in paragraph 1. (3) By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in air craft tyres. However, the date from which this Directive shall apply to air craft tyres can be set in accordance with Article 2a of Directive 76/769/EEC.</p>
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Financial Implications

6. This proposal is supported by industry and imposes no additional regulatory costs on business beyond those which the industry will bear through its existing commitment to phase out the use of polycyclic aromatic hydrocarbon-rich extender oils. Some oil producers have already developed polycyclic aromatic hydrocarbon-low extender oils and the production of polycyclic aromatic hydrocarbon-rich extender oils is declining. Certain tyres have also been developed without resorting to the use of polycyclic aromatic hydrocarbons-rich extender oils.

Benefits

7. The benefits of the proposal are to establish an Internal Market as well as to provide a high level of protection to human health and the environment. The proposed restriction will ensure that polycyclic aromatic hydrocarbon-rich extender oils and tyres produced with these oils are phased out. The production of high-grade polycyclic

¹ Council Directive 92/23/EEC, OJ L 129, 15.5.1992, p. 95 as amended.

² Council Directive 92/23/EEC, OJ L 129, 15.5.1992, p. 95 as amended.

³ UN/ECE Regulation 106

⁴ Directive 97/24/EC of the European Parliament and the Council, OJ L 226, 18.8.1997, p. 1 as amended.

aromatic hydrocarbons-low extender oil would increase the competitiveness of the European Industries concerned.

Options

8. (i) To fully implement the provisions of the proposed Directive, by all Member States.

(ii) To request industry to adopt voluntary measures.

(iii) To do nothing

9. Option (i). 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 and the environment from exposure to these hazardous chemicals. It will also provide harmonised rules for the circulation of these substances.

10. Option (ii). This would require industry adherence to voluntary guidelines or targets. Initial contacts with industry have shown that it supports the proposal; indeed, the industry has offered to go somewhat further through a voluntary commitment. However, this would not guarantee as high a level of consumer safety as Option (i). It is likely that some manufacturers would adopt the code while others would not which would necessitate agreeing draft guidelines and the introduction of an effective monitoring system.

11. Option (iii). Failure to implement the Directive, will result in infraction proceedings being initiated against the United Kingdom by the European Commission, since Member States have a Treaty obligation to implement all agreed Directives. Further, this option does not guarantee the level of protection of human health and the environment afforded by Option (i).

Competition Assessment

12. We intend to undertake Stage One of the Competition Assessment but Risk Assessments suggest that as the proposed Directive would 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 would set harmonised requirements to ensure that all involved in the manufacture and supply of products containing the substances in question can compete on an equal footing.

Enforcement and Sanctions

13. If the proposal will be transposed into English law using powers under section 2(2) of the European Communities Act 1972. The Government and the Devolved Administrations agreed to extend this to UK.

Monitoring and Review

14. 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

Consultations performed in preparing the Draft Directive

15. Advice on the preparation of the proposal was sought through meetings involving experts from Member States, the European Association of the Rubber Industry (BLIC), the Oil Companies' European Organisation (CONCAWE), and the European Car Industry. The European Consumers' Organisation BEUC has also been invited to give comments.

Within Government

16. Other Government Departments were consulted about these proposals during the consultation.

Public Consultation

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

Summary and Recommendation

18. The proposal for a Directive, in the framework of the Marketing and Use Directive 76/769/EEC, to place certain restrictions on the marketing and use of polycyclic aromatic hydrocarbons, is considered the most effective means of reducing the risks to human health and the environment from exposure to this potentially hazardous chemical. The Directive, will remove this chemical from the consumer market and thereby reduce the potential for human ill-health and damage to the environment caused by exposure through its use.

Annex B - Trichlorobenzene- Regulatory Impact Assessment

Proposal

1. A European Directive which seeks to place certain restrictions on the marketing and use of toluene and trichlorobenzene (TCB) and which forms the 28th amendment to the Marketing and Use Directive 76/769/EEC.

Purpose and intended effect of measures

Objective

2. The primary aim of the proposed Directive 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. It also aims to reduce the risks to the environment from TCB and products containing TCB. Additionally, it aims to reduce the risks to human health as a consequence of exposure to trichlorobenzene from the environment, especially via drinking water.

Background

3. Risk Assessment Reports for both toluene and TCB 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 (both workers and consumers) and the environment from these substances.
4. The European Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) was consulted and considered the Risk Assessment Reports. In their Opinions of June and July 2001 they confirmed the conclusions of the Assessments of the need to reduce risks to health. In-depth risk reduction strategies for both toluene and TCB were prepared by the Danish Environmental Protection Agency.
5. In the 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 as to the strategies for limiting risks. Amongst other things, this document 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. Similarly, a reduction of risks to consumers and the environment due to TCB should also be effected by restrictions under this Directive.
6. The proposal was presented by the European Commission on 28th April 2004 and forms the 28th amendment to the Marketing and Use Directive. Two further points will be added to Annex 1 of the Directive – one dealing with restrictions on toluene, the other dealing with TCB.

The following points [48] to [49] are added to Annex I of Directive 76/769/EEC:

“[48].	May not be placed on the market or used as a
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Toluene CAS No. 108-88-3	substance or constituent of preparations in a concentration equal or higher than 0.1 % by mass in adhesives and spray paints intended for sale to the general public.
[49]. Trichlorobenzene CAS No. 120-82-1	May not be placed on the market or used as a substance or constituent of preparations in a concentration equal or higher than 0.1 % by mass for all uses except - as an intermediate of synthesis, or - as a process solvent in closed chemical applications for chlorination reactions, or - in the manufacture of 1,3,5-trinitro-2,4,6-triaminobenzene (TATB)

7. Toluene, or adhesives and spray paints containing in excess of 0.1% toluene, will be prohibited from being placed on the market for sale to the general public. TCB, and preparations containing in excess of 0.1% TCB, will be prohibited from being placed on the market for any use except as an intermediate.

Risk Assessment

8. The primary aim of the proposed Directive 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. It also aims to reduce the risks to the environment from TCB and products containing TCB. Additionally, it aims to reduce the risks to human health as a consequence of exposure to TCB from the environment, especially via drinking water. If the provisions of the proposed Directive, were not implemented, consumers and the environment would still be at risk from these chemicals.

9. The proposals for TCB are likely to have little adverse impact on industry – the use of this substance in the UK has virtually ceased except for its use in the manufacture of explosives where it is used as an intermediate.

10. Preliminary indications are that the toluene proposals will have little impact on the spray paint sector but that there is some concern in the sector manufacturing adhesives.

Options

11. (i) To fully implement the provisions of the proposed Directive, by all member States.

(ii) To request industry to adopt voluntary measures.

(iii) To do nothing

12. Option (i). 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 and the environment from exposure to these hazardous chemicals. It will also provide harmonised rules for the circulation of these substances.

13. Option (ii). This would require industry adherence to voluntary guidelines or targets. However, this would not guarantee as high a level of consumer safety as Option (i). It is likely that some manufacturers would adopt the code while others would not which would necessitate agreeing draft guidelines and the introduction of an effective monitoring system.

14. Option (iii). Failure to implement the Directive, will result in infraction proceedings being initiated against the United Kingdom by the European Commission, since Member States have a Treaty obligation to implement all agreed Directives. Further, this option does not guarantee the level of protection of human health and the environment afforded by Option (i).

Benefits

Economic

15. The proposed restrictions on the marketing and use of toluene and TCB will serve to foster the development of safer alternatives to these substances.

16. A reduction in the damage to the environment and to human health will reduce the costs associated with these adverse effects.

Environmental

17. The Directive will reduce the risks to the environment from TCB and products containing TCB. Additionally, it will reduce the risks to human health as a consequence of exposure to TCB from the environment, especially via drinking water.

Social

18. 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. It will also reduce the risks to human health as a consequence of exposure to TCB from the environment, especially via drinking water.

Costs

19. Quantification of these costs was sought through a consultation and by meetings with the relevant industries. No figures or further data were provided in any returns made to the consultation exercise.

20. The Regulations implementing the provisions of the Directive, will be enforced by nominated Enforcement Authorities. There may be small additional costs, yet to be determined, placed on these organisations.

Equity and fairness

21. The overriding factor in the Directive is consumer safety and protection of the environment. 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

Toluene.

22. As part of our initial soundings we contacted the main trade associations in the sector to identify potential costs to their members as a result of the proposals. These were: the British Coatings Federation, The British Adhesives and Sealants Association, British Aerosol Manufacturers Association, British Chemical Distributors and Trades Association and Chemicals Industry Association.

23. Responses suggested that the impact on the industry would be minimal. This view corresponds with the risk assessment and risk reduction strategy reports for both chemicals which states that the proposed Directive will pose only minor problems to industry, including small business, as the use of the chemicals is declining and companies have already developed, and continue to develop, water-based product alternatives to toluene.

24. The Small Business Service also considers that small firms are unlikely to suffer any significant impact. However, if as a result of formal consultation we identify any as yet unidentified or unintended impacts for small firms, we will further consult with the Small Business Service. As no additional impacts were notified through the consultation or elsewhere this did not happen.

TCB

25. As part of our initial soundings we contacted the CIA, British Cable Makers Confederation, AWE, BAE Systems, Other Government Departments and the Environment Agency to identify potential costs and further meetings with key stakeholders are being held.

26. Responses from industry were minimal and for those sectors that had a view indicated that the proposals will have, in line with the findings of the risk reduction strategy, minimal impact.

Competition Assessment

27. We intend to undertake Stage One of the Competition Assessment but Risk Assessments suggest that as the proposed Directive would 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, if adopted, will not serve as a barrier to entry for potential entrants nor impose substantially more cost on some firms than others. Indeed, the Directive would set harmonised requirements to ensure that all involved in the manufacture and supply of products containing the substances in question can compete on an equal footing.

Enforcement and Sanctions

28. In the Directive those provisions relating to toluene will be transposed into UK law by means of Regulations made using powers under the Consumer Protection Act 1987 (CPA), Section 11. The Regulations will extend to Great Britain and Northern Ireland and the sanctions applicable to breaches of safety regulations under Section 11 of CPA

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

29. Those provisions relating to TCB will be transposed into English law using powers under Section 2(2) of the European Communities Act 1972, and the enforcement arrangements will be set out at this stage. The Government and the Devolved Administrations agreed jointly to extend this the UK.

Monitoring and Review

30. 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

31. Other Government Departments were consulted about these proposals during the consultation.

Public Consultation

32. The Consultation Document lists those organisations and individuals to whom the document has been sent. 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.

Summary and Recommendation

33. The proposal for a Directive, in the framework of the Marketing and Use Directive 76/769/EEC, to place certain restrictions on the marketing and use of toluene and TCB, is considered the most effective means of reducing the risks to human health and the environment from exposure to these potentially hazardous chemicals. The Directive, if adopted, will remove these chemicals from the consumer market and thereby reduce the potential for human ill-health and damage to the environment caused by exposure through use of them.