EXPLANATORY MEMORANDUM TO

THE CONTROLS ON PENTABROMODIPHENYL ETHER AND OCTABROMODIPHENYL ETHER (NO.2) REGULATIONS 2004

2004 No.3278

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.

2. Description

2.1 This SI prohibits revokes and replaces with minor amendments SI 2004/371 relating to the marketing and use restrictions on penta and octabromodiphenyl ether by way derogation. The adaptation allows the use of pentabromodiphenyl ether in aircraft emergency evacuation systems until 31 March 2006.

3. Matters of interest to the JCSI/ SCSI

3..1 None.

4. Legislative Background

4.1 This instrument implements EU Directive 2004/98/EC which adapts for the 14th time Council Directive 76/769/EC relating to the restrictions on the marketing and use of certain dangerous substances and preparations.

4.2 A transposition note is attached.

4.3 Scrutiny clearance was given in November 2003, by both Commons and Lords to the original Directive 2003/11/EC which this adapts.

5. Extent.

5.1 The SI extends to Great Britain. The Northern Ireland Office intends to lay regulations in January 2005.

6. European Convention on Human Rights

6. Not appilicable

7. Policy Background

7.1 Under Regulation 793/93/EC, pentabromodiphenyl ether was a priority substance for risk assessment and, where necessary, risk management, at the European Union level. Risks were identified in both the human health and environmental compartments and a regulatory impact

assessment was prepared on behalf of Defra by Risk and Policy Analyst ltd. This helped to inform the UK negotiating position in determining the most appropriate option for controlling the risks associated with penta and octabromodiphenyl ether.

7.2 On this basis UK supported a ban on the marketing and use of pentabromodiphenyl ether and this was agreed by the Council and European Parliament. It was concluded that EU wide marketing and use restrictions on pentabromodiphenyl ether, in the form of a ban, would provide the most appropriate means for controlling the risk associated with the substances. This took the form of the 24th amendment (2003/11/EC) to Council Directive 76/769/EEC.

7.3 As a result of this ban the manufacturer of airline evacuation slides (Goodrich) discovered at a late stage that they use pentabromodiphenyl ether as a flame retardant in their slides at levels above those permitted in Directive 2003/11/EC. These slides are fitted in the majority of commercial Boeing and Airbus aircraft and the marketing and use restrictions in 2003/11/EC would effectively ground most European Commercial airlines on safety grounds as the evacuation slides could not be serviced or replaced.

7.4 A proposal by the airline industry and Goodrich asking for a derogation to Directive 2003/11/EC to permit the use of pentabromodiphenyl ether in aircraft evacuation systems until 31 March 2006 was put to the Commission and Member States in August 2004 and agreed. This proposal has taken the form of the 14th adaptation to technical progress.

8. Impact

8.1 See the attached RIA

9. Contact

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Transposition of Directive 2004/98/EC Pentabromodiphenyl use in aircraft evacuation systems: Regulatory Impact Assessment

Issue

1. Transposition of Directive 2004/98/EC which adapts for the 14th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (pentabromodiphenyl ether) into UK law.

Objective

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

Background

3. On 30 September 2004 the European Commission issued the 14th adaptation to technical progress of Commission Directive 76/769/EC (Marketing and Use) which related to releases of Pentabromodiphenyl ether. This took the form of Directive 2004/98/EC

4. Under Regulation 793/93/EC, pentabromodiphenyl ether was a priority substance for risk assessment and, where necessary, risk management, at the European Union level. Risks were identified in both the human health and environmental compartments and a regulatory impact assessment was prepared on behalf of Defra by Risk and Policy Analyst ltd. This helped to inform the UK negotiating position in determining the most appropriate option for controlling the risks associated with penta and octabromodiphenyl ether.

5. On this basis UK supported a ban on the marketing and use of pentabromodiphenyl ether and this was agreed by the Council and European Parliament. It was concluded that EU wide marketing and use restrictions on pentabromodiphenyl ether, in the form of a ban, would provide the most appropriate means for controlling the risk associated with the substances. This took the form of the 24th amendment (2003/11/EC) to Council Directive 76/769/EEC.

6. As a result of this ban the manufacturer of airline evacuation slides (Goodrich) discovered at a late stage that they use pentabromodiphenyl ether as a flame retardant in their slides at levels above those permitted in Directive 2003/11/EC. These slides are fitted in the majority of commercial Boeing and Airbus aircraft and the marketing and use restrictions in 2003/11/EC would effectively ground most European Commercial airlines on safety grounds as the evacuation slides could not be serviced or replaced.

7. A proposal by the airline industry and Goodrich asking for a derogation to Directive 2003/11/EC to permit the use of pentabromodiphenyl ether in aircraft evacuation systems until 31 March 2006 was put to the Commission and Member States in August 2004 and agreed. This proposal has taken the form of the 14th adaptation to technical progress.

Options

8. To enact the requirements of the Directive 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. Such a measure would permit the use of pentabromodiphenyl ether in aircraft emergency evacuation systems until March 2006. This would allow Goodrich the time needed to test the appropriate substitute and carry out the 9000 or so tests that are required for approval by the European Aviation Safety Agency and its U.S counterpart Federal Aviation Authority when changes are made to safety equipment.

COSTS

9. 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 at Annex A but in summary:

9.2 Pentabromodiphenyl ether

The total estimated maximum costs for UK industry is estimated to be around £0.9 million over the period to two years following implementation and £1.2 million for five years. However, these should be viewed as maximum costs since substitution is not problematic and also because the annual costs are likely to decrease over time.

9.3 The possible substitutes identified in the risk reduction strategy are those that could be used to retain the same level of fire protection as that afforded by use of pentabromodiphenyl ether. Thus, there should not be any increase in deaths or injuries associated with use of these alternatives. However, if the level of fire safety is reduced, there could be costs to society associated with an increase in the incidence of fires.

Overall, the costs are not believed to be prohibitive given that suitable substitutes generally exist in terms of environmental hazard and technical suitability (including fire safety).

Benefits

10. Full benefits are outlined in the regulatory impact assessment at annex A. However in summary the restrictions will mean a reduction over time of pentabromodiphenyl ether in the environment, will remove the risk to workers through workplace exposure and the substitute available for fire retardancy are such

that there is unlikely to be any increase in the incidence of fires and associated injuries.

Securing Compliance

11. See regulatory impact assessment at annex A

Impact on Small Business

12. See regulatory impact assessment at annex A

MONITORING AND EVALUATION

13. See regulatory impact assessment at annex A

CONSULTATION

14. During development of the regulatory impact assessment at Annex A, an extensive public consultation was undertaken with industry, downstream users, trade associations and other key stakeholders with an interest in penta and octabromodiphenyl ether.

Annex A

Pentabromodiphenyl Ether: Regulatory Impact Assessment

1. PURPOSE AND INTENDED EFFECT

1.1 Issue

Pentabromodiphenyl ether (Penta-BDPE) is a brominated flame retardant, used almost exclusively in flexible polyurethane (PUR) foam products. These PUR products are mainly used in automotive and domestic furniture applications, with a minor use in small-run and prototype components, such as (non-foamed) PUR instrument casings.

Penta-BDPE is not produced in the European Union (EU) but was imported for sale by two companies until recently[1]. The European market is relatively small, with a demand of 210 tonnes per annum (tpa) in 1999, as compared to demand in the Americas of 8,290 tpa. Imports into the EU were expected to be around 125 tpa for the year 2000. In the UK, use is estimated to be between around 20 tpa and 40 tpa, representing a probable value of £50,000 to £100,000 per year. This amounts to just under 0.1% of the quantity and just over 0.1% of the value of all flame retardants used in the UK.

A risk assessment for Penta-BDPE carried out under Council Regulation (EEC) 793/93 has been published by the European Commission[2]. This assessment has identified unacceptable risks to the environment and a concern regarding exposure of breast-fed children to Penta-BDPE.

On 15 January 2001, the European Commission proposed a ban on the marketing and use of Penta-BDPE, including a ban upon articles that contain the substance (COM (2001) 12 final).

1.2 Objective

The objective of this Regulatory Impact Assessment is to determine the most appropriate option for controlling the risks associated with Penta-BDPE in the UK, taking into account a risk reduction strategy prepared for the EU level. The most appropriate option is determined mainly through appraisal of the risks, benefits, costs and compliance issues of various options for action.

Flame retardants, including Penta-BDPE, have contributed to an improvement in consumer safety through the prevention of fire-related casualties. Any measure taken to reduce risks for human health and the environment should also take into account the implications for fire safety.

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1 One of these companies has recently ceased selling Penta-BDPE in the EU.

2 Risk assessments for the two other commercial polybrominated diphenyl ethers (Octa-BDPE and Deca-BDPE) are also currently underway but are not yet complete.

2. RISK ASSESSMENT

2.1 Background

Under Council Regulation (EEC) 793/93, the UK is rapporteur responsible for undertaking an assessment of the human health and environmental risks associated with Penta-BDPE. The Health and Safety Executive (HSE) is responsible for the former, with DETR, working in partnership with the Environment Agency, responsible for the latter. The final risk assessment report for Penta-BDPE was published by the European Commission in August 2000[3].

It should be noted that the risk assessment does not quantify the consequences associated with exposure to Penta-BDPE in terms of the resultant harm to human health and the environment. Instead, for the human health risk assessment, the margin of safety between the predicted exposure and the level of exposure having no effect for workers, consumers and for indirect exposure via the environment (as well as other relevant endpoints) is used as a basis for risk assessment. In the case of environmental risk assessment, the predicted concentrations in various environmental 'compartments' are compared to the concentrations at which no adverse effects are predicted to occur.

2.2 Risks for Human Health

No need for risk reduction was identified in relation to consumer exposure or from the physicochemical properties of Penta-BDPE.

However, a need for further information/testing was identified for occupational exposure due to uncertainties in exposure data, applicability of effects in rodents for human health and the potential for Penta-BDPE to accumulate in human tissue. Similar uncertainties apply for indirect exposure via the environment (though not for development of a 'chloracne-like' response).

In relation to exposure via human breast milk, the assessment also identified a need for further information/testing because "uncertainties are such that it is currently not possible to say whether or not [the margins of safety] provide reassurance of little or no risk to the breast feeding infant either at the present time or in the future." Furthermore, the European Commission's Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) confirmed concerns about exposure of breast fed children to Penta-BDPE and concluded that the increasing levels of Penta-BDPE in breast milk might be the result of a use not yet identified.

2.3 Risks for the Environment

The risk assessment identified a risk for both the aquatic and terrestrial food chains associated with high levels of Penta-BDPE both predicted and measured near to sources of release (a localised risk related to PUR production sites).

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[3] The report is available at http://ecb.ei.jrc.it/existing-chemicals.

Furthermore, a possible risk for the terrestrial food chain has been identified at the regional level and linked to diffuse releases arising from use of the PUR foam. The widespread environmental occurrence and bioaccumulative nature of Penta-BDPE also lend support to the overall concern for this end-point. Risks were also identified for the sediment and terrestrial compartment from local exposure sources (i.e. PUR foam production).

Thus, the environmental risks associated with Penta-BDPE are associated not only with emissions from the production of PUR foams that contain the product, but also from diffuse releases during the use of PUR foam products.

Taking into account the risk assessment, the risk reduction strategy and the Precautionary Principle, the Commission proposal seeks to ban all marketing and use of Penta-BDPE and of articles containing Penta-BDPE.

3. BENEFITS OF RISK REDUCTION OPTIONS

3.1 Introduction to Options

Following identification of unacceptable risks under the risk assessment, a risk reduction strategy was prepared on behalf of DETR by Risk & Policy Analysts Limited, for discussion at the EU level. This strategy was based upon an analysis of the advantages and drawbacks of various options for reducing the risks. The strategy concluded that marketing and use restrictions on Penta-BDPE, in the form of a ban, would provide the most appropriate means for controlling the risks associated with Penta-BDPE. The strategy comprises an annex to this Regulatory Impact Assessment.

The following options for reduction of the risks associated with Penta-BDPE are considered herein:

- a ban on the marketing and use of Penta-BDPE through amendment to Directive 76/769/EEC;
- introduction of environmental quality standards/emission limit values for Penta-BDPE emissions to water;
- control of emissions from industrial sources under the Integrated Pollution Prevention and Control (IPPC) regime; and
- controls on emissions from finished products, either voluntarily or through restrictions on the marketing and use of Penta-BDPE.

3.2 Ban on the Marketing and Use of Penta-BDPE

Assuming compliance with legislation, a ban upon the marketing and use of Penta-BDPE would eliminate any further inputs to the environment. However, due to its low rate of biodegradation and bioaccumulative nature, it is possible that exposure to Penta-BDPE would continue for several years. Nonetheless, this option would lead to a reduction over time in exposure, in body tissue concentrations and in the associated risks.

A number of substitutes for Penta-BDPE were identified as part of the environmental risk reduction strategy. Reduction in the risks associated with Penta-BDPE would, to some extent, be offset by the risks associated with those substitutes. Suitable substitutes (generally other halogenated products) are believed to be available for all applications in which Penta-BDPE is used. A range of these substitutes can allow finished products to meet the requirements of the relevant fire safety standards and would be expected to lead to a net decrease in risks to the environment.

3.3 Environmental Quality Standards and Emission Limit Values

In theory, concentration limits could be set (for effluent and/or for the receiving waters) that would eliminate the risks associated with Penta-BDPE. However, the current system for introduction of such limits is being revised, in the light of Directive 2000/60/EC (the 'Water Framework Directive'). It is currently uncertain as to how measures will be developed and cost estimates for these controls have not yet been developed by the European Commission. There would, therefore, be a considerable delay in addressing the risks using this measure.

This option would apply mainly to the industrial sources of Penta-BDPE in the environment (i.e. PUR production facilities). Risks associated with Penta-BDPE also relate to diffuse releases from finished products. Although Directive 2000/60/EC makes reference to "controls on the principal sources" of substances, it is even less certain how controls on such releases could be implemented, except through a ban upon use[4]. Thus, the benefits of this option would be essentially limited to a reduction in the risks associated with production of PUR foams and not those associated with their use.

3.4 Integrated Pollution Prevention and Control

As with the previous option, controls on emissions under IPPC would only apply to emissions from production of PUR foams and not to diffuse releases from products. The benefits in terms of reduced risk would likewise not include those associated with such diffuse emissions.

However, since IPPC is concerned with emissions to (and via) all environmental compartments, and not just water, there is the *potential* for a greater reduction in risk since risks for the terrestrial food chain would also be targeted. However, as with the previous option, the mechanisms by which emission controls may be introduced on a substance-specific basis under IPPC have not yet been determined. The benefits cannot, therefore, be quantified. Thus, as with the previous option, there would be a significant delay in implementation of emissions controls under this measure.

3.5 Controlling Emissions from Finished Products

As stated above, risks to the environment associated with Penta-BDPE occur not only through emissions during PUR foam production but also through

[4] Since no technically and economically feasible means of controlling releases during use has been identified (see later).

releases during the use of finished products. To adequately control the risks, such releases must also be targeted.

In undertaking the risk reduction strategy (see annex), the potential for reducing emissions from finished products was investigated. This could be implemented either voluntarily by the industry, through the introduction of standards or could be enforced via legislative means.

In technical terms (theoretically), emissions from finished products could be reduced by reducing the concentration of Penta-BDPE within the foam or reformulating so as to achieve this effect. In relation to the former option, concentrations of Penta-BDPE are already optimised by manufacturers due to the high cost of the substance, and so could not be reduced further without compromising fire safety. In relation to the latter, no technologies to better encapsulate Penta-BDPE within foam products have been identified.

4. COSTS OF RISK REDUCTION OPTIONS

4.1 Business Sectors Affected

Sectors affected by the possible options include suppliers of Penta-BDPE and alternative flame retardants, producers of PUR containing Penta-BDPE and companies using PUR in finished products (e.g. furniture manufacturers). The general public will also be affected in terms of the cost of flame-retarded PUR products as well as in terms of fire safety implications.

4.2 Ban on the Marketing and Use of Penta-BDPE

Flame Retardant Suppliers

For flame retardant suppliers, Penta-BDPE represents only around 0.1% of all flame retardant sales in the UK (and around 0.3% of all brominated flame retardant sales). However, for the major supplier to the EU market, it represents around 5% of brominated flame retardant sales. Given the overall relatively small size of the market (up to £100,000 pa in the UK) and the fact that losses of sales will be offset within the industry by other flame retardant sales, the costs for flame retardant suppliers are expected to be minimal.

Polyurethane Product Manufacturers

Products in which Penta-BDPE is used in the UK are estimated to have the following values:

- it is used in 350 tpa of PUR foams for automotive applications, estimated to be worth around £490,000 pa in terms of direct market value and £12.3 million pa in terms of downstream market value;

- it is used in 50 tpa of PUR foams for domestic furniture, worth around £60,000 pa in terms of direct market value and £700,000 in terms of downstream market value; and
- it is used in 12 tpa of non-foamed products (assumed to be elastomers), with a market value of around £20,000 directly and £50,000

downstream.

These figures compare with a total of 2.3 million tonnes of PUR sold in the EU each year, having a market value of £3.3 billion directly and £28.5 billion in terms of the downstream market. Comparable data are not available for the UK, but the UK market is thought to comprise around 15% of the EU market, equating to around 345,000 tonnes sold per year, with a market value of £0.5 billion directly and £4.3 billion in terms of downstream products.

Although the quantities and values of PUR in which Penta-BDPE is used are not insignificant, substitution of Penta-BDPE with other flame retardants will generally be possible. The additional costs of such substitution for one company producing automotive PUR products have been estimated as[5]:

- new streams required: £50,000 one-off cost;
- potential increase in process scrap: £50,000 per year; and
- customer trials and approvals: £150,000 one-off cost.

These costs are set against the company's sales of products containing Penta-BDPE of £1 million pa (3% of sales). If substitution does not prove possible, this business would be lost, along with employment losses of 5% (15 people).

However, substitution is anticipated to be possible in all sectors though it would probably be more problematic for the automotive components that for domestic furniture.

Costs of substitution of Penta-BDPE for all three sectors have been estimated and are summarised in Table 1. Total costs have been calculated over a two and five year period following substitution (the estimated times over which ongoing costs of substitution would be incurred, which would depend upon the specific products).

Table 1: Estimated Maximum Costs for PUR Manufacturers

Sector	Material use (tpa)		Estimated costs (£ '000)			
	Penta-BDPE	PUR	One-off	Ongoing	2 yr. PV	5 yr. PV
Automotive	14 to 35	350	500	125 p.a.	854	1,152
Dom. furniture	5	50	32	0	32	32
Non-foamed	1.2	12	7	0	7	7
Total	20 to 41	412	539	125 p.a.	893	1,191

1. Total present value (PV) costs are calculated assuming one-off costs are incurred immediately upon entry into force of restrictions and ongoing costs for a subsequent 2 or 5 years. A discount rate of 6% is used.
2. No recurring costs are assumed for domestic furniture or use in non-foamed PUR since substitution is expected to be less problematic for these uses.

[5] This company is thought to be representative in terms of PUR foam for the automotive application. Costs for companies producing PUR for domestic furniture are thought to be lower.

Thus, the total estimated maximum costs for PUR producers is estimated to be around £0.9 million over the period to two years following implementation and £1.2 million for five years. However, these should be viewed as maximum costs since substitution would be less problematic for the domestic furniture and non-foamed PUR uses than for the automotive sector and also because the annual costs are likely to decrease over time. Overall, the costs are not expected to be prohibitive.

Users of Finished Products

Given that there are suitable substitute flame retardants available, it is not anticipated that there would be any increase in fire-related injuries as a result of a ban.

Since there is likely to be some increase in PUR product manufacturers' costs (mainly one-off costs), it is possible that there would be a small increase in the market price of finished products in the short term. However, any costs that are passed on are likely to be lower than the total costs to PUR manufacturers given that end-users should be able to obtain products from alternative sources in many cases (since the PUR market affected is only a small proportion of the total UK market). Nonetheless, it is possible that some costs will be passed on in certain niche markets.

Summary of Costs of a Ban on Penta-BDPE

Table 2 provides a summary of the total estimated UK costs of introducing a ban on the marketing and use of Penta-BDPE.

Table 2: Summary of Maximum Cost Implications for a Ban on Penta-BDPE

Value of Penta-BDPE in UK	£100,000	Loss of market will be offset to some extent by substitute flame retardants
Costs for PUR Manufacturers (2 year)	£0.9 million	Total present value costs 2 and 5 years following substitution (depending upon products)
Costs for PUR Manufacturers (5 year)	£1.2 million	
Costs for Users of Finished Products	-	Some proportion of PUR manufacturers costs may be passed on

4.3 Environmental Quality Standards and Limit Values

As indicated above, the legal and practical means of implementing this option have not yet been developed. Therefore, it has not been possible to quantify the associated costs.

However, where such limits would necessitate introduction of emissions abatement equipment, there would be associated costs. Consultation during development of the risk reduction strategy indicated that the associated costs are uncertain given that industry is unsure as to the techniques that would be adopted to control emissions. The costs for regulators associated with monitoring such standards would be passed on to industry and are estimated to be of the order of £10,000 annually per site (and thus at least £30,000 pa in

total given that there are at least three sites using Penta-BDPE in the UK). The cost of monitoring, therefore, is of a similar magnitude to the annual value of Penta-BDPE used in the UK though less than the cost of the finished PUR products. However, the cost of introducing emissions abatement equipment could be expected to approach or exceed the value of the finished products (which, in the case of the latter, would lead to either adoption of a substitute flame retardant or discontinuation of the product).

4.4 Integrated Pollution Prevention and Control

As with the previous option, the mechanisms for implementation of emissions controls using IPPC have yet to be developed in legislative and technical terms. However, since such controls would also be targeted at PUR facilities, it is envisaged that similar types of abatement equipment would be required. The associated costs could, therefore, be expected to be of a similar magnitude (or perhaps slightly higher, given that emissions to and via other environmental media would be controlled).

4.5 Controlling Emissions from Finished Products

Since no viable techniques for controlling emissions of Penta-BDPE from finished products have been identified in technical terms, it has not been possible to estimate the associated costs. However, consultation indicates that the research and development costs would render such an option not viable.

5. PREFERRED OPTION

Risks to the environment relate not only to the production of polyurethane foam (at which point EQSs/limit values or IPPC would apply), but also to emissions of Penta-BDPE from finished polyurethane foam articles. Only a ban upon the use of Penta-BDPE provides a means to address all of the risks to the environment since no appropriate means has been identified to address the risks associated with emissions of Penta-BDPE from products during use.

Whilst there is some potential to extend the analysis in terms of developing more detailed cost estimates for introduction of abatement equipment, etc., this is considered to be unnecessary given that only a ban will achieve the required level of risk reduction.

The preferred option, therefore, is a ban upon the marketing and use of Penta-BDPE and upon products containing Penta-BDPE (which, it is envisaged, would be provided for at the EU level). Such a measure would eliminate the risks associated with Penta-BDPE (over time) and would, it is anticipated, lead to an overall reduction in risks when the risks associated with substitute flame retardants are taken into account[6].

Costs associated with a ban, as detailed in Table 2, are not considered to be prohibitive since substitution with alternative flame retardants will be possible in the majority of cases. Moreover, the size of the PUR market affected is

[6] Note that risk assessments under Council Regulation 793/93/EEC are soon to be undertaken for a number of potential substitutes. However, these will not be available in the near future.

relatively small in proportion to the UK's PUR market as a whole. A ban upon the marketing and use of Penta-BDPE is, therefore, considered proportionate, taking into account the relative costs and benefits of this and the other options considered.

6. SECURING COMPLIANCE

Securing compliance with a ban is expected to be less problematic than with the other options considered. Rather than monitoring environmental concentrations and emissions of Penta-BDPE, the regulatory authority need only ensure that Penta-BDPE is no longer imported into or supplied within the UK.

Whilst there may remain a small number of companies obtaining Penta-BDPE through illicit means, it is expected that an EU-wide ban upon its marketing and use will ensure a high level of compliance.

7. IMPACT ON SMALL BUSINESS

No small-sized businesses were identified during the consultation conducted for the risk reduction strategy. Therefore, it is not expected that any such companies would be disproportionately affected by any option taken forward.

8. CONSULTATION

During development of the risk reduction strategy, extensive consultation was undertaken with companies and trade associations involved in supply of Penta-BDPE and with polyurethane manufacturers (including companies using Penta-BDPE). Consultation was also undertaken with companies and trade associations related to the end-user sectors (automotive, furniture, etc.) as well as with competent authorities in several EU Member States and an environmental organisation.

This consultation had an EU-wide scope but was concentrated in the UK. In particular, all of the companies identified as using Penta-BDPE in the risk reduction strategy are located in the UK.

9. MONITORING AND EVALUATION

It is expected that progress towards and compliance with a ban on the marketing and use of Penta-BDPE could be easily monitored through communications with the current suppliers to the UK market. The actual costs of substitution may be evaluated through communications with the users of Penta-BDPE (i.e. PUR manufacturers), as well as with the suppliers.

10. RECOMMENDATION

It is recommended that a ban upon the marketing and use of Penta-BDPE and articles containing Penta-BDPE be introduced to implement the proposed ban at the EU level (as and when appropriate).

No other option has been identified that will adequately control both the risks associated with emissions of Penta-BDPE during polyurethane manufacture and also those associated with releases during the life of finished polyurethane products. Both types of releases lead to unacceptable risks to the environment.

The costs of this option are not believed to be prohibitive given that suitable substitutes generally exist in terms of environmental hazard and technical suitability (including fire safety). Moreover, the option is believed to represent the most appropriate, taking into account the balance of costs and benefits.

11. DECLARATION

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

Signed: Alun Michael

Date: 12th February 2004

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Addendum to the Pentabromodiphenyl ether Regulatory Impact Assessment

Octabromodiphenyl ether

At the beginning of September 2002 the risk assessment regarding octabromodiphenyl ether, which revealed definite risks for the environment and human health, was concluded. The results highlighted that there is a risk for secondary poisoning via the earthworm route for hexabromodiphenyl ether in the commercial product of octabromodiphenyl ether. For human health, there is a risk relating to systemic, developmental, female fertility and local toxicity, resulting from dermal exposure in the workplace. Furthermore, the risk assessment identified areas where there is a need for further information and/or testing for example octabromodiphenyl ether and its lower conegers (ie pentabromodiphenyl ether) are being found in human breast and cows milk and could indicate a risk to breast-feeding infants. Given the uncertainties, the need for precautionary action to be taken to reduce the risks was proposed.

The Scientific Committee on toxicity, ecotoxicity and the environment (CSTEE) confirmed the conclusions of the risk assessment and the need to reduce risks to protect the environment. Further more the Committee confirmed that in its opinion of 19 June 2000, the concern about exposure of breast fed children to pentabromodiphenyl ether might be the result of use not yet identified.

On this the basis the Council accepted the European Parliaments wish to include a ban on octabromodiphenyl ether into the pentabromodiphenyl ether proposals (24th amendment to Directive 76/769/EC relating to the restrictions to the marketing and use of pentabromodiphenyl ether) in order to take into account the concerns about infants exposed via milk without delay.

There are only two measures that would ensure that the environmental risks associated with octabromodiphenyl ether are reduced. A ban through marketing and use restrictions would prevent any environmental emissions from occurring as a result of the substance no longer being used in the EU. Alternatively, if octabromodiphenyl ether were to be classified as a priority hazardous substance under the Water Framework Directive, a cessation or phase-out of discharges, emissions and losses would be required, thus reducing the risks to an acceptable level (since there could effectively be no entry into the environment). However, measures under the WFD would not necessarily address all of the human health issues and could potentially take over 20 years to address all of the concerns. Therefore, the only measure that could address all of the areas where a potential need for precautionary action has been identified would be a ban through marketing and use restrictions (given that it is not possible to identify an 'acceptable' level of risk for these concerns).

COSTS

The potential costs to EU industry of this strategy have been estimated at around €7.5 to €12 million over five years. If these increased costs were passed on to the consumer, the percentage increase in the average price of products would be between 0.19% and 0.30%, based on an estimated 3 million products on the market per year.

The introduction of marketing and use restrictions for octabromodiphenyl ether, could have a range of cost implications for various stakeholders. These costs would arise

primarily through the need to substitute octabromodiphenyl ether with an alternative flame retardant substance or an alternative technology. Economic impacts will be experienced by the producer of octabromodiphenyl ether. Obviously, there would be a loss of sales related to the substance in the EU amounting to an estimated €1.6 million. However, since the company in question also produces a number of potential substitute flame retardants, it could be expected that any loss of sales of octabromodiphenyl ether would be compensated for by an increase in sales of the alternatives. There would also be a probable loss of sales in octabromodiphenyl ether amounting to an estimated €3.2 million relating to use of the substance in master batch (or finished articles) imported into the EU. Again, it could be expected that any such loss would be compensated for by an increase in sales of alternatives.

In some cases, the cost of the substitute flame retardant is likely to be greater than that of octabromodiphenyl ether. Some of the flame retardants that are used in the same plastic (mainly ABS) are up to 30% more expensive than octabromodiphenyl ether. Likewise, where substitution with an alternative polymer-flame retardant system takes place, the costs of the system could increase by up to 10%. If another brominated flame retardant were used instead of octabromodiphenyl ether, it may be the case that a higher loading of the substitute in the polymer would be required. This is due to the need to maintain an equivalent concentration of bromine in the product. For example, if TBBPA were used, around 34% extra flame retardant would be required in order to maintain the same level of fire retardancy. There would also be costs associated with research and development (R&D) in order to design products such that the alternative flame retardant or polymer-flame retardant system can be used. These costs would be borne by the plastics processors but also by compounders/master batchers and the producer of the flame retardant itself (given the need to ensure an effective product throughout the supply chain). Estimates have been made below as to the likely costs of substitution, taking into account the possible increased price of alternatives and the need to undertake R&D to effectively utilise the alternative.

It should be noted that the cost estimates derived above represent likely minimum costs. It is possible that there would be additional costs for companies undertaking polymer processing using octabromodiphenyl ether. In particular, it has been highlighted that some companies may need to replace the moulds that are currently used in order to effectively use a substitute. Costs of new moulds, depending upon the size and complexity of the product have been estimated at £50-100,000 (€80-160,000). The British Plastics Federation has indicated that a typical SME in ABS processing would have around 15 to 20 moulds. Given the reluctance of companies using octabromodiphenyl ether to provide any information for risk reduction strategy, it was necessary to make some assumptions regarding the likely costs of replacing moulds where required for technical reasons. Using the data regarding the size distribution of companies in the plastics and rubber industry, along with the above information regarding costs of replacing moulds, it has been possible to make some highly tentative estimates of the costs of replacing moulds in order to use alternative flame retardants or plastics. The indicative costs could be around €5m including the costs for mould replacement and machine downtime. This represents an increase in the average product price of around 0.11%, making a total increase of 0.30%. However, these costs are only intended to be indicative. Thus, the total estimated costs to industry, taking into account the likely increased cost of substitutes and the potential need to replace moulds is around €7.5 to €12 million over five years. If these increased costs were passed on to the consumer, the percentage increase in the average price of products would be between 0.19% and 0.30%, taking into account an

estimated 3 million products on the market per year.

If the data on average turnover of companies in the plastics and rubber industry are examined it is evident that, for a small company, the costs of substituting octabromodiphenyl ether could be significant, depending upon the replacement route taken. Costs would be minimal where a substitute of equivalent or lower cost (e.g. TBBPA) is used, with no need for use of new moulds. However, the cost of replacing one mould at €120,000 represents over 20% of the annual average turnover of small plastics companies, and a greater proportion of those within the smaller size brackets. In the event that marketing and use restrictions were introduced, consideration should be given to the timescales of implementation, in order that the costs are not excessive (since SMEs could bear a proportionately greater cost burden as a result of a ban).

Additionally, there will be costs for legislators and regulators in developing and implementing restrictions on the marketing and use of the substance. The possible substitutes identified in the risk reduction strategy are those that could be used to retain the same level of fire protection as that afforded by use of octabromodiphenyl ether. Thus, there should not be any increase in deaths or injuries associated with use of these alternatives. However, if the level of fire safety is reduced, there could be costs to society associated with an increase in the incidence of fires. In the risk reduction strategy estimates have been made of the benefits associated with a reduction in fire incidence for certain appliances. The estimated benefit of reducing a fatal injury is €1.25m and for a non-fatal injury is €0.15m. Thus, if a compromise in fire safety led to an increase in 100 fires per year, for example, the estimated cost would be around €6.3m per year. It is, therefore, important that at least the same level of fire protection is afforded by any alternative flame retardant.