

## **EXPLANATORY MEMORANDUM TO STATUTORY INSTRUMENTS**

### **TITLE**

1. The Controls on Nonylphenol and Nonylphenol Ethoxylate Regulations 2004, SI 2004 No.1816

### **Laying Authority**

1.1 This explanatory memorandum is laid before Parliament by Command of her Majesty using powers available under Section 2(2) and Schedule 2 of the European Communities Act 1972. Its purpose is to protect the environment from hazardous substances.

### **Responsible Department**

- 1.2 Department for Environment, Food and Rural Affairs

### **Description**

2. This SI prohibits the use or placing on the market of nonylphenol or nonylphenol ethoxylates as a substance or constituent of preparations in concentrations equal to or higher than 0.1% by mass for the purposes listed in the SI.

### **Matters of interest to the JCSI/ SCSi**

3. None.

### **Legislative Background**

4. This instrument implements EU Directive 2003/53/EC which amends for the 26<sup>th</sup> time Council Directive 76/769/EC relating to the restrictions on the marketing and use of certain dangerous substances and preparations.

A transposition note is attached.

The proposals were submitted for Scrutiny on 7 November 2002, Commons gave Scrutiny clearance 27 October 2002 and the Lords on 6 May 2003.

### **Extent.**

5. The SI extends to Great Britain. The Northern Ireland Office intends to lay regulations in July 2004.

### **European Convention on Human Rights**

6. N/A

### **Policy Background**

7. NP, which is a degradation product of NPE, is persistent, bioaccumulative and toxic and a risk to the aquatic and terrestrial environment. It is also a suspected endocrine disrupter. Member States therefore agreed, based on recommendations from the UK Competent Authority, that risk reduction measures should be considered. The proposals by the Commission in the form of Directive 2003/53/EC are expected to remove nearly 80% of environmental exposure and 65% of use of NPE and represent the first stage in the implementation of the risk reduction strategy. The remaining exposure will be addressed by other pollution prevention measures.

Industry has been fully engaged in the development of this directive and the subsequent GB SI. Industry has in fact pre-empted the requirement of this SI by developing voluntary agreements to reduce the risks from Nonylphenol, and its ethoxylates. This voluntary agreement also extends to octylphenol and goes further than the requirements within the SI.

Directive 2003/53/EC also requires controls to be placed on the marketing and use of Chromium VI in cement. This element is the responsibility of the Health and Safety Executive and will be enacted by a separate SI using powers under the Health and Safety at Work Act.

### **Impact**

8. See the attached RIA

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## **TRANSPPOSITION OF COMMISSION DIRECTIVE 2003/53/EC – RESTRICTIONS ON THE MARKETING & USE OF NONYPHENOL, NONYLPHENOL ETHOXLATE and CEMENT**

The Directive has been transposed in Great Britain by the following measure:

*The Environmental Protection (Controls on Dangerous Substances)  
Regulations 2004, SI 2004 NO.*

EC Directive 2003/53/EC (Official Journal No. L178/24, 17 July 2003) amends for the 26<sup>th</sup> time, Directive 76/769/EEC and places restrictions on the marketing and use of nonylphenol, nonylphenol ethoxylate and cement.

Statutory Instrument 2004 No. ,The Environmental Protection (Controls on Dangerous Substances) Regulations 2004 transposes into UK law Directive 2003/53/EC to restrict the marketing and use of nonylphenol and nonylphenol ethoxylate in:

- (a) industrial or institutional cleaning, other than—
  - (i) controlled closed dry cleaning systems where the washing liquid is recycled or incinerated; and
  - (ii) cleaning systems with special treatment where the washing liquid is recycled or incinerated;
- (b) domestic cleaning;
- (c) textiles or leather processing, other than—
  - (i) processing with no release into waste water; and
  - (ii) systems with special treatment where the process water is pre-treated to remove the organic fraction completely prior to biological waste water treatment (such as degreasing of sheepskin);
- (d) emulsifier in agricultural teat dips;
- (e) metal working, other than uses in controlled closed systems where the washing liquid is recycled or incinerated;
- (f) manufacturing of pulp or paper;
- (g) cosmetic products;
- (h) other personal care products, other than spermicide; or
- (i) co-formulants in pesticides or biocides.

(2) These regulations shall not prohibit the placing on the market or use of any pesticides or biocidal products containing nonylphenol ethoxylate as a co-formulant if, and to the extent to which, such placing on the market or use is authorised by a relevant approval. In paragraph (2), a “relevant approval” means a valid approval granted before 17th July 2003 under—

- (a) the Control of Pesticides Regulations 1986<sup>(1)</sup>;

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<sup>(1)</sup> S.I. 1986/1510. As amended by the [Control of Pesticides \(Amendment\) Regulations 1997](#) (S.I. 1997/188), the [Registration of Homeopathic Veterinary Medicinal Products Regulations 1997](#) ([SI 1997/322](#)) and the [Biocidal Products Regulations 2001](#) (S.I. 2001/880).

- (b) the Plant Protection Products Regulations 2003<sup>(2)</sup>; or
- (c) the Plant Protection Products (Scotland) Regulations 2003<sup>(3)</sup>.

Point 47 of Annex 1 of Directive 2003/53/EC that relates to the restrictions on the marketing and use of cement are not implemented by this Directive. These will be implemented by the Health and Safety Executive under separate regulations using the powers of the Health and Safety at Work Act .

### ***Background***

Directive 2003/53/EC puts in place controls to restrict the marketing and use nonylphenol and nonylphenol ethoxylate and is the 26<sup>th</sup> amendment (Directive 89/677/EC) to Directive 76/769/EC. Nonylphenols are toxic to fish, aquatic invertebrates and algae, affect plant growth, and impact upon the reproduction and mortality of terrestrial invertebrates. They can also affect organisms higher up the chain through consumption of lower organisms (particularly for terrestrial organisms).

Northern Ireland Office intends to lay regulations in July 2004.

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<sup>(2)</sup> S.I. 2003/3241.  
<sup>(3)</sup> S.S.I. 2003/579.

## **Transposition of Nonylphenol and Nonylphenol ethoxylate : Regulatory Impact Assessment**

### **Issue**

1. Transposition of Directive 2003/53/EC relating to the restriction on the marketing and use of certain dangerous substances and preparations (nonylphenol and nonylphenol ethoxylate) into UK law.

### **Objective**

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

### **Background**

3. On 18 June 2003 the European Union issued a Directive banning the marketing and use of nonylphenol and nonylphenol ethoxylate.

Under Regulation (EC) 793/93, nonylphenol was a priority substance for risk assessment and, where necessary, risk management, at the European Union level. Risks were identified in several environmental compartments and a regulatory impact assessment was prepared on behalf of Defra by Risk and Policy Analyst Ltd. This is attached at annex A. This helped to inform the UK negotiating position in determining the most appropriate option for controlling the risks associated with nonylphenol and nonylphenol ethoxylate.

On this basis UK supported a ban on the marketing and use of nonylphenol and nonylphenol ethoxylate for the following purposes: industrial, institutional and domestic cleaning, textile processing, leather processing, emulsifiers in agricultural teat dips, metal working, pulp and paper processing, and cosmetics. This was agreed by the Council and European Parliament.

### **Options**

4. As indicated above, it was concluded that EU wide marketing and use restrictions on nonylphenol and nonylphenol ethoxylate, 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 26<sup>th</sup> amendment to Council Directive 76/769 relating to the restriction on the marketing and use of certain dangerous substances and preparations.

4.1 To enact the requirements of the Directive two options were considered.

- Do nothing.

Under the treaties establishing the European Union, EU law has precedence over Member State law. Consequently, the United Kingdom would be in breach of its treaty 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.

- Appropriate implementation into UK law of the marketing and use ban.

This is the preferred option. Such a measure would eliminate the risks associated with nonylphenol and nonylphenol ethoxylate over time. The approach to transposition suggested is in line with previous transpositions of the marketing and Use amendments, of which this is the 26<sup>th</sup>.

With many Marketing and Use amendments the restrictions proposed stop short of a completed ban. These restrictions are expected to remove nearly 80% of environmental exposure and 65% of use of nonylphenol ethoxylates and represents the first stage in the implementation of the risk reduction strategy. The remaining exposure will be addressed by other pollution prevention measures such as Integrated Pollution Prevention and Control and environmental quality standards. The need for further marketing and use restrictions will be reviewed if other measures are shown to be inadequate.

## **COSTS**

**5.** Cost associated with conforming to the requirements of the marketing and use restrictions are detailed in the regulatory impact assessment at Annex A but in summary:

The costs and benefits expected to result from managing NP/E exposure vary widely across industry sectors. Total costs of a ban for the UK on *all uses* have been estimated to be around £182 million for the UK. However, some of the estimates used are based on extrapolations from the EU situation where inadequate data are available for the UK.

The marketing and use restrictions proposed will be introduced across a number of sectors (industrial and institutional cleaning products; leather processing; metal processing; pulp, paper and board; and textile processing) at an estimated cost of £16 million to the UK. Moreover, since use of nonylphenol and nonylphenol ethoxylate has fallen significantly so have the costs; the consultation on the Directive in October 2002 revised down the costs to £4.3m from the previous estimate of £16m.

It is important to note that reducing the emissions from these sectors would reduce the background concentration (which poses a widespread environmental risk) to an acceptable level in the UK.

**5.3** Overall, the costs are not believed to be prohibitive given that suitable substitutes generally exist in terms of environmental hazard and technical suitability. There may be some additional costs associated with changes in environmental and/or human health effects where the substitutes for nonylphenol and nonylphenol ethoxylate present higher or new risks. Where the risks are similar (or less) the type of effect may differ. However, it is not

expected that such effects should arise as the most likely substitutes for the majority of substitutable uses are alcohol ethoxylates, which are generally associated with lower risks

### **Benefits**

6. Full benefits are outlined in the regulatory impact assessment at annex A. However in summary the restrictions will mean a reduction over time of nonylphenol and nonylphenol ethoxylate in the environment.

### **Securing Compliance**

7. See regulatory impact assessment at annex A

### **Impact on Small Business**

8. See regulatory impact assessment at annex A

### **MONITORING AND EVALUATION**

9. See regulatory impact assessment at annex A

### **CONSULTATION**

10. 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 nonylphenol and nonylphenol ethoxylate.

**Declaration**

11. I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

**Signed by the responsible Minister: Alun Michael**

**Date: 12<sup>th</sup> July 2004**

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# **Nonylphenol Regulatory Impact Assessment**

(Risk & Policy Analysts, 16 September 2002)

## **1. Purpose and Intended Effect of the Measure**

### **1.1 The Issue and Objective**

#### *The Issue*

Nearly 80,000 tonnes of nonylphenol (NP) were used in Europe in 1997, most of which was also manufactured in Europe. NP is used almost exclusively as an intermediate in the production of other chemicals, with some 60% used to make nonylphenol ethoxylates (NPEs) and the remainder to make other NP derivatives.

A risk assessment undertaken under the Existing Substances Regulation (EEC 793/93) indicated unacceptable risks to the environment from use of nonylphenols and nonylphenol ethoxylates (NP/Es) in a wide range of sectors. Nonylphenols are toxic to fish, aquatic invertebrates and algae, affect plant growth, and impact upon the reproduction and mortality of terrestrial invertebrates. They can also affect organisms higher up the food chain through consumption of lower organisms (particularly for terrestrial organisms).

#### *The Objectives*

The proposed regulatory measures are intended to:

- reduce the continental burden and background concentration of NP/Es;
- reduce the residual risks (regional and local); and
- identify options for dealing with the remaining use categories.

### **1.2 Risk Assessment**

The primary source of NP in the environment is considered to be NPEs, which can break down into NP after being released during their production, their formulation into various other products, and the use of such products.

Table 1 summarises the risks to the aquatic environment, as identified through the risk assessment. The relative usage of NP/Es is given, along with the contribution to the continental environmental burden of NPs. At a local level, the implications of introducing marketing and use restrictions for several sectors are also described (see Section 3.2).

A total of 12,000 tonnes per annum (tpa) of EU usage of NPE (16% of total usage and 24% of the NP environmental burden) is allocated to 'other niche markets', of which 5,600 tpa is unaccounted for. The NP burden is only calculated individually for some of these sectors. This uncertainty has implications for the Regulatory Impact Assessment.

## **2. Options**

### **2.1 The Options**

For the risks posed by NP/Es to both human health and the environment, the following options have been identified as meriting consideration:

- marketing and use restrictions (a ban);
- IPPC licensing;
- limit values and/or environmental quality standards (EQSs);
- voluntary agreements to prevent use of NP/Es; and
- classification and labelling.

### **2.2 Issues of Equity or Fairness**

Given the number of sectors of concern, the variation in their relative contribution to environmental risks and the fact that voluntary actions have been undertaken in some sectors, a number of equity issues are relevant.

1. Would a ban result in loss of product for sectors which are not considered to cause an unacceptable environmental risk?
2. Are the costs unequally distributed?
3. Are the benefits unequally distributed when compared with the costs?
4. Would sectors which have already made a commitment to reducing NP/E releases be impacted to a greater degree than those sectors which have not made a commitment (e.g. through increased costs of further reductions)?

## **3. Benefits**

### **3.1 Identification of the Benefits**

The benefits of the proposed regulatory measures are a reduction in the environmental (and human health) risks posed by the release of NP/Es from production, formulation and end use.

### **3.2 Quantification and Valuation of Benefits**

In the Risk Assessment, there is no link made between potential and actual harm. Benefits of risk reduction measures are, therefore, assessed in terms of how effective they are in reducing the ratio between the predicted concentrations in the environment and the concentrations at which no adverse effects are deemed to occur<sup>1</sup>. Whilst this does not allow a strict quantification of the benefits, the reduction in local environmental concentrations and, particularly, in the widespread environmental burden can be used to measure the benefits. The benefits of each of the options in qualitative terms are considered below.

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<sup>1</sup> As described by the ratio of predicted environmental concentration to predicted no-effect concentration (PEC/PNEC ratio).

### ***Marketing and Use Restrictions***

A ban across all sectors could effectively eliminate all environmental and human health risks. However, a ban on those sectors which contribute most to the continental loading could eliminate the unacceptable continental-level risks and reduce the need for action by certain other sectors which pose only marginal risks. Table 1 indicates the benefit of marketing and use restrictions upon the local concentrations for various use sectors<sup>2</sup> and upon the general background concentration.

Alternative substances may introduce new risks, although most substitutes appear to be either less hazardous or give rise to no greater risks than NPEs for sectors where marketing and use restrictions are proposed (further details are provided in Section 2.7 of the risk reduction strategy report).

### ***Integrated Pollution Prevention and Control (IPPC)***

IPPC covers only certain industry sectors and applies to only medium and large businesses. It would not eliminate all emissions of NP/Es but could reduce them to acceptable levels in those sectors to which it applies. It has the potential to reduce risks for all environmental compartments and is also a cost-effective option since the operator can choose the least-cost means of meeting the limits.

### ***Emission Limit Values and Environmental Quality Standards (ELVs/EQs)***

An EQS/limit value approach would target facilities identified as leading to unacceptable levels of discharge to the aquatic environment. Individual operators would then have a choice as to how to go about reducing risks. It would provide a means of tackling any uncertainties within the risk assessment with respect to individual operators who, although their sector is not specifically targeted may, in individual cases, still pose a risk.

Under the Water Framework Directive, nonylphenols have been included among a list of 'priority hazardous substances'. The European Commission will submit proposals for a cessation or phasing-out of discharges, emissions and losses of such substances, with a timetable not exceeding 20 years after the adoption of the proposals. These measures will be brought forward through 'daughter' directives.

### ***Voluntary Agreements***

Several existing voluntary agreements to eliminate the use of NPEs in domestic cleaning products in various EU countries have been partially effective in that the large (and many medium-sized) manufacturers are reported to have moved away from NPEs. However, it appears that use for this sector continues in some cases, especially by smaller manufacturers, many of which are not members of the trade organisations that are party to the voluntary agreements. The situation is similar for a number of voluntary agreements adopted for industrial and institutional products.

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<sup>2</sup> Industrial and institutional cleaning products; leather processing; metal processing; pulp, paper and board; and textile processing.

The large number of industry sectors and applications that give rise to unacceptable risks makes a strategy based on voluntary agreements less manageable than for other substances where use is more confined. However, it is suggested that, to avoid the adoption of more costly regulatory measures, those sectors that fall under the EQS category in particular may want to come forward with voluntary agreements.

A recent development is the issue of a statement by the UK Chemicals Stakeholder Forum. The Forum wishes to see voluntary industry action to implement the marketing and use restrictions proposed in the risk reduction strategy in advance of any legislation. In addition, the Forum wishes to see voluntary action taken to implement best practice to minimise discharges to the environment as a result of the following activities:

- production of nonylphenols and octylphenols and their ethoxylates;
- captive use;
- manufacturing and formulation of preparations, including phenol/formaldehyde resins, plastic stabilisers and emulsion polymerisation; and
- disposal of products containing these substances.

### ***Classification and Labelling***

Classification and labelling proposed in the risk assessment applies only to NPs, and not to NPEs. Since the main sources of NPs in the environment are from the manufacture and use of NPEs, classification and labelling is not considered to be a reliable mechanism for reducing the environmental risks.

## **4. Compliance Costs for Businesses**

### **4.1 Business Sectors Affected - Non-Production Industries**

Table 2 presents estimates of UK usage of NP/Es within the industry sectors for which marketing and use (M&U) restrictions are proposed. The table also provides an indication of the industry sector profile, in terms of the proportion of small, medium and large companies, and the degree to which NP/Es have been/are being phased out.

### **4.2 Business Sectors Affected - Production Industries**

Of nearly 80,000 tonnes used in Europe in 1997, most was also produced in Europe. NP is then used in the production of various derivatives, of which the largest use is for NPEs (47,000 tonnes).

### **4.3 Compliance Costs for a 'Typical' Business**

Given the wide range of use sectors, it is considered that costs for a 'typical' business will not clarify issues concerning the incidence of any cost impacts. Indicative cost estimates developed for individual sectors are provided below with more detail provided in the fuller risk reduction strategy report.

## 4.4 Total Compliance Costs

### *Marketing and Use Restrictions*

Data provided by industry in 1995 indicated that a complete ban on NPs and NPEs introduced at that time would cost industry just over £1 billion for the whole EU, where this includes both one-time reformulation costs plus the change in raw materials costs for one year resulting from the use of alternatives. However, these costs now represent overestimates since several industry sectors have reported that substitutes are under development. Thus, some proportion of the reformulation and commercialisation costs have already been incurred (sunk costs).

The total costs of introducing marketing and use restrictions excluding sunk costs is now estimated as £0.8 billion for the EU as a whole. This represents the upper bounds of estimates since several voluntary actions to reduce use have been in place for a number of years. Total costs of a ban for the UK on *all uses* have been estimated (see Table 3) to be around £182 million for the UK. However, some of the estimates used are based on extrapolations from the EU situation where inadequate data are available for the UK.

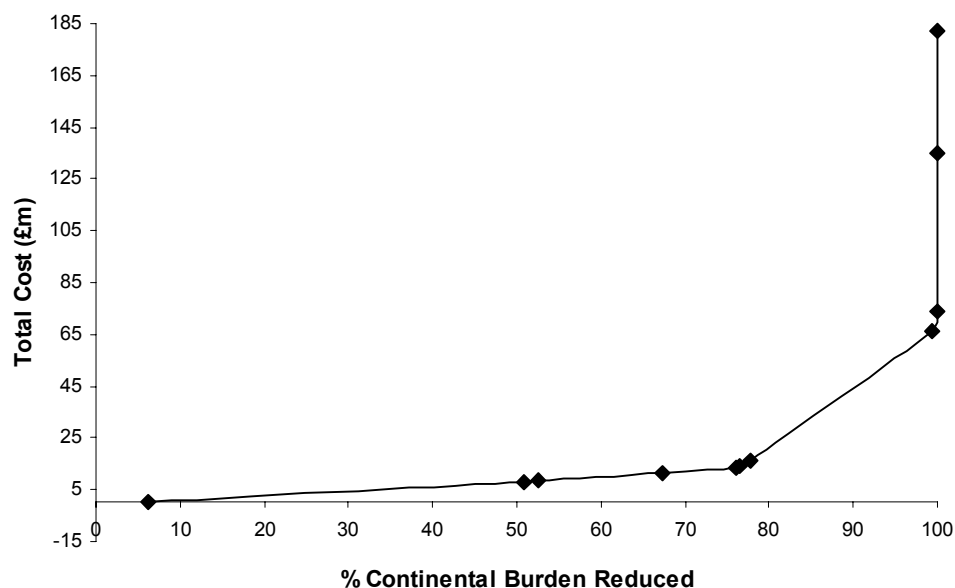
Costs are significantly higher for some sectors than others and are not proportional to either the volume used or the relative contribution to the total NP burden by the various sectors. For example, when taken together, the production of NP and its derivatives, captive use and emulsion polymerisation account for a very significant proportion of the costs, but only a very small amount of the environmental burden at the EU level (the ‘continental burden’).

Conversely, the costs to the industrial and institutional cleaning products (I&I) sector of a complete ban would amount to less than 5% of the total costs for the UK, yet would reduce risks by almost 45% (again the level of risk is only specified at the EU level). Figure 1 illustrates the costs of reducing the continental burden by introducing marketing and use restrictions starting from the most cost effective sectors. It is evident that around 70% of the continental burden<sup>3</sup> can be reduced relatively cost-effectively but to reduce the levels further would entail significant additional costs. To achieve this 70% reduction in the continental burden, marketing and use restrictions could be introduced for several sectors (industrial and institutional cleaning products; leather processing; metal processing; pulp, paper and board; and textile processing) at an estimated cost of £16 million to the UK.

It is important to note that reducing the emissions from these sectors would reduce the background concentration (which poses a widespread environmental risk) to an acceptable level in the UK.

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<sup>3</sup> Assuming that the relative contribution to the risks of each sector is the same for the UK as it is for the EU.



**Figure 1: Cost for Progressive Reduction (by Sector) in Continental Burden through Marketing and Use Restrictions in the UK**

### ***Integrated Pollution Prevention and Control (IPPC)***

The current trend away from the use of NPEs in many of the sectors to which IPPC could be applied (including textiles, leather processing, metalworking and the pulp and paper industry) suggests that switching to alternatives is considered by industry to be acceptable in cost terms. However, some companies would respond to the introduction of limits to discharges of NPEs through further recycling of NPE-containing fluids and additional treatment as required. The additional costs were indicated as being low or negligible.

For other sectors, the cost of switching to alternatives would be far greater and, by managing exposure through IPPC, costs could be reduced significantly. For example, for use in emulsion polymerisation, it is estimated that the costs of reducing emissions through IPPC would be substantially less than one half of the costs of a ban.

In addition, costs to competent authorities should be low as the additional requirements can be brought in as part of every day licensing activities.

### ***Limit Values and Environmental Quality Standards (EQSs)***

The major impact of the introduction of this approach would be similar to the use of the IPPC regime in terms of controls on manufacture and uses. In general, it can be expected that industry would adopt the least-cost method of meeting the EQS or limit values. The impact would therefore be similar to that of IPPC, although it would also fall on smaller facilities and on those sectors not covered by IPPC.

Most countries already have sampling programmes for water and effluent monitoring. For routine sampling of a range of products, costs would therefore be minimal. For non-routine sampling, where this is done to monitor compliance specific to NP/Es, costs would be associated primarily with staff time. For the UK, it has been suggested that these costs

would be in the range of £50-£100 per sample. The resulting costs at a national level would then relate to the number of water bodies where such monitoring would be required.

### ***Voluntary Agreements***

If a voluntary agreement to remove all use of NP/Es (either for a single sector or overall) is entirely effective, it would theoretically result in the same costs as would be incurred from a ban upon marketing and use, although the greater flexibility afforded may offer some cost reductions. Where it is partially effective, the costs will obviously be lower. It is assumed that participation in any voluntary agreement will be greater amongst companies where the associated costs are considered acceptable or where other pressures, such as the desire to demonstrate environmental performance/commitment, are the highest.

### ***Classification and Labelling***

Industry has provided no information on the likely costs of additional labelling, although these are likely to be low. Experience with the classification and labelling of other substances indicates that any subsequent cost impacts with regard to changes in practice would also be low and, at the extreme, should be no higher than the costs associated with a switch to alternative formulations.

## **5. Consultation with Small Businesses: ‘The Litmus Test’ Impact on Small Businesses**

Marketing and use restrictions are expected to place the greatest cost burden on those small companies who would have to undertake product development and testing activities to develop the substitute products required for their full range of activities. In many cases, it appears that the more specialist the product or use the more difficult and, hence, costly substitution is likely to be.

For use in I&I, costs are expected to be minimal. For example, one company using 500kg of NP/E products per year estimates that per unit costs of developing alternatives would be £6,000. Even if there was immediate action taken (i.e. a ban on products containing NP/Es), they would not be greatly affected.

One company using NP/E products in leather processing reduced consumption of NP/E containing products by 57% between 1997 and 1998. However, further product development would be required to remove NPEs from the remaining uses. A move to alternatives would, therefore, be associated with a substantial cost increase (of between 50 and 75%) related to the increased costs of the substitutes, process development, marketing verification and promotion. Operational costs are not expected to change.

One company producing metalworking fluids containing NPEs expects the end price of the product to increase by 10% where alternatives are being developed and 16% where no alternatives are currently available. A second company has indicated that costs may increase by less than 2%, assuming that much of the costs could be absorbed into other reformulation work undertaken at the same time. The reformulation costs (without absorption) are estimated as about 7% of current per unit costs. This second company anticipates that it will take between two and five years for NP/E substitution.

## 6. Other Costs

There may be some additional costs associated with changes in environmental and/or human health effects where the substitutes for NP/Es present higher or new risks. Where the risks are similar (or less) the type of effect may differ. However, it is not expected that such effects should arise as the most likely substitutes for the majority of substitutable uses are alcohol ethoxylates, which are generally associated with lower risks.

## 7. Results of Consultation

Detailed consultation was conducted during the development of the full risk reduction strategy under the EU guidelines applying to existing substances. This has been followed by further consultation as necessary during the development of the RIA.

## 8. Summary and Recommendations

### 8.1 Summary

The costs and benefits expected to result from managing NP/E exposure vary widely both across industry sectors and according to the risk reduction tools considered. In order to achieve a balanced strategy, the above options have been comparatively assessed. Through this process, it has been concluded that no single tool is the most appropriate for all sectors, but that a mix of tools is required in order to adequately balance the costs and benefits associated with risk reduction. Table 4 is an extract from the Risk Reduction Strategy that shows the relative effectiveness of the options against the decision criteria.

As can be seen from Table 3, for the seven sectors contributing most to environmental burden, the estimated costs of marketing and use restrictions for the UK are roughly £16 million in present value terms as compared to the estimated £182 million for restrictions on all uses<sup>4</sup>. This figure takes into account trends in the use of NPEs by the various sectors up to 2000 and assumes that use of NPEs in certain sectors will continue to reduce significantly in the absence of marketing and use restrictions (for example, due to international initiatives such as OSPAR<sup>5</sup>). Any delays in the introduction of marketing and use restrictions could be expected to reduce the costs of the regulations as industry continues to reduce use voluntarily.

It is more difficult to estimate the costs of adopting either IPPC or EQSs as the basis for controlling emissions from the other sectors. As indicated above, in some cases these will be zero as industry is already likely to meet any emission limits which would apply (a point stressed by many consultees). In other cases, further effluent treatment or specialist waste disposal costs would be incurred. However, UK industry sources were unable to estimate the likely magnitude of these. In all cases, adoption of such approaches was seen as a lower cost option to marketing and use restrictions. Estimates of these costs is further complicated

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<sup>4</sup> These cost estimates comprise total reformulation costs, which are assumed to be borne over two years, as well as the total cost of using substitutes over five years. Costs are given in present value (PV) terms and are discounted at 3%.

<sup>5</sup> OSPAR requires a phase out of all significant sources of emissions to the environment by 2005.



by current uncertainty within the European Commission as to how such measures could best be adopted in the short-term.

In summary, given the trends away from use of NP/NPEs, the total costs of adopting the proposed strategy are predicted at £16 million from marketing and use restrictions alone. One would expect this figure to be two, or at most three, times higher for the full strategy. However, total costs of the strategy are likely to be significantly lower than this due to measures taken under various other initiatives. It is worth noting that a recommendation to substitute NP/Es as being good practice has recently been introduced in several of the official reference documents under the IPPC regime.

## **8.2 Recommendations**

### **Recommendation 1: Marketing and Use Restrictions**

Under EC Directive 76/769/EEC, the marketing and use of NPEs should be banned for I&I (where this includes industrial and institutional cleaning/detergent products, as well as domestic cleaning/detergent products); textiles; leathers; agriculture<sup>6</sup>; metals; pulp and paper; cosmetics (where this also includes shampoos and other personal care products).

Marketing and use restrictions would be the most appropriate tool for these sectors since they have, on the whole, the greatest emissions to the environment and the lowest relative costs for using alternatives. There are considered to be less hazardous substitutes available for all of the uses where marketing and use restrictions are proposed.

### **Recommendation 2: Integrated Pollution Prevention and Control**

Under EC Council Directive 96/61/EC, the following sectors should be required to operate under integrated pollution prevention and control (IPPC) licenses: production of NPE; captive use; production of phenol/formaldehyde resins; production of other plastic stabilisers; and emulsion polymerisation. These industry sectors are generally characterised by a lower level of risk and much higher associated costs for the use of substitutes (making a ban inappropriate).

### **Recommendation 3: EQS/Limit Values**

Using the Water Framework Directive, EQSs and/or limit values should be developed to deal with the remaining risks associated with NP/Es (where the balance between costs and benefits is more marginal than for sectors where marketing and use restrictions are proposed). This should be used for targeted monitoring of the following sectors: formulation (in sectors where NP/E use will continue); civil and mechanical engineering; electronics/electrical engineering; mineral oil and fuel; and the photographic industry (large facilities).

This approach will also be useful for protecting against unacceptable environmental risk associated with continued use of NPEs in paints, by small photographic users and for the 'miscellaneous other' uses which were not specifically addressed in the risk

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<sup>6</sup> For veterinary medicines only. Other measures are proposed for pesticides, as outlined in Commission Recommendation 2001/838/EC.

assessment. Since this instrument will take some time to develop fully, consideration should also be given to voluntary agreements across these remaining sectors in the interim.

#### **Recommendation 4: Derogations**

In some select cases, the potential need for derogations from marketing and use restrictions has been indicated. The need is most clear for spermicidal products, where no suitable alternatives have been identified to date. It is expected that a derogation would be needed to cover the short- to medium-term, until a viable alternative has been found.

The need for derogations in other applications has been suggested, but is less clear. Information collected for the risk reduction strategy (in 1999) suggested the potential need for derogation in some cases. More recent information suggests that the companies and applications in question will no longer require a derogation. However, no comprehensive review of the need for derogations has been made.

### **9. Enforcement, Sanctions, Monitoring and Review**

In the case of sectors where NP/E use is banned (marketing and use restrictions), monitoring of compliance should be possible since the number of producers is relatively small (seven in the EU). Also, a number of industry sectors (such as I&I) are already phasing out the use of NPEs on a voluntary basis, in response either to existing voluntary agreements or to customer demand.

However, given that the strategy recommends marketing and use restrictions only for certain sectors, it will be important to ensure that imports of products from outside the EU which may contain NP/Es are monitored.

For monitoring environmental concentrations of NP/E for sectors covered by IPPC, the equipment needed as part of any monitoring and sampling requirements should be available to regulatory authorities. However, the Environment Agency has indicated that an 'NP equivalence' index may be required to be developed and applied much like the index used for the monitoring and measurement of dioxins (due to the variations in toxicity with varying chemical structures of the NPEs).

Monitoring programmes for the EQS/limit value approach will be developed under the Water Framework Directive.

To date, it appears that effective monitoring of voluntary agreements remains difficult. In Germany, however, industry and government have met regularly to discuss and report on progress with a 1986 voluntary agreement (to remove NPEs from certain detergents and cleaning agents), indicating that effective monitoring can be achieved.

It has been suggested that the costs for routine sampling would be negligible, while non-routine sampling undertaken to monitor compliance specific to NP/Es would cost in the range of £50 to £100 per sample. In general, facilities covered by IPPC are likely to be monitored regardless of any requirements relating to NPE. The associated monitoring costs should, therefore, only be incrementally higher. For the EQS approach, the resulting costs at a national level would relate to the number of water bodies where such monitoring would be required.

<b>Table 1: NPs and NPEs - Usage, Contribution to Continental Environmental Burden and Risk Ratios <sup>a</sup></b>				
	<b>% of EU Usage (NP or NPE)</b>	<b>% Continental NP Burden</b>	<b>PEC/PNEC before M&amp;U</b>	<b>PEC/PNEC After M&amp;U <sup>b</sup></b>
<b><i>Direct releases of nonylphenol</i></b>				
Nonylphenol production	n/a	0.003	<0.6 to <1.8	<b>&lt;0.6</b>
Nonylphenol ethoxylate production	60	5.82	5.91 to 1,394	4.6 to 909
Nonylphenol/formaldehyde resin production	29	0.007	4.9 to 9.7	5.5 to 8.5
TNPP production	5	0	n/a	n/a
Epoxy resin manufacture	2	0.004	1.97	<b>0.67</b>
Production of other plastic stabilisers	1	0.02	11.3	8.9
Phenolic oxime production	3	0	1.79	<b>0.5</b>
<i>Subtotal</i>	<i>100 (NPs)</i>	<i>6</i>		
<b><i>Indirect releases via nonylphenol ethoxylates</i></b>				
Formulation	n/a		5.79 to 39.4	4.3 to 38.2
Pesticide application	6	0.54 <sup>c</sup>	2 to 2.8	<b>0.76 to 1.5 <sup>d</sup></b>
Captive use by chemical industry	9	0.1	1.88	<b>0.58 <sup>e</sup></b>
Electrical engineering applications	<1	0.001	11	9.8
Industrial and institutional cleaning	30	44.7	79.7	<b>0.52 <sup>g</sup></b>
Leather processing	8	6.09	52.4 to 255.8	<b>0.52 <sup>g</sup></b>
Metal processing and extraction	3	1.22	427	<b>0.52 <sup>g</sup></b>
Fuel and oil additives (manufacture and blending)	<1	0.008	4.8 to 108	3.6 to 106
Photographic materials	<1	0.16	2.06 to 6.45	<b>0.55 to 5.2 <sup>f</sup></b>
Polymer production/emulsion polymerisation			5.55	4.3
Pulp, paper and board industry	1	1.72	50	<b>0.52 <sup>g</sup></b>
Textile processing	13	14.7	1060	<b>0.52 <sup>g</sup></b>
Paint production	see below>>	see below>>	16.7	15.5
Paint use	5	0.04	1.8	<b>0.55 to 0.58</b>
Civil engineering	<1	0.02	94.8	93.6
Misc. other (incl. unallocated tonnage)	10	23.5	n/a	n/a
<i>Subtotal</i>	<i>100 (NPEs)</i>	<i>94</i>	<i>n/a</i>	<i>n/a</i>
<b><i>Background risks</i></b>				
Regional PEC/PNEC ratios	n/a	n/a	1.78	<b>0.52</b>
<p><i>Notes:</i></p> <p><sup>a</sup> - Where the risk is reduced to an acceptable level, this is indicated in bold text</p> <p><sup>b</sup> - Note that the other measures (e.g. IPPC) will reduce the concentrations further where these are applied</p> <p><sup>c</sup> - % burden for pesticides assumed to be half of % burden for all agricultural use</p> <p><sup>d</sup> - Higher value to use of NPEs wetting agents, lower relates to use as emulsifiers</p> <p><sup>e</sup> - Risk eliminated for aquatic environment but not terrestrial environment</p> <p><sup>f</sup> - Risk eliminated for small scale sites only</p> <p><sup>g</sup> - PEC/PNEC ratio same as regional (where marketing and use restrictions applied)</p>				

<b>Table 2: Use of NP/Es within Industry Sectors in the UK</b>						
<b>Sector</b>	<b>EU Use (t/a)</b>	<b>UK Use (t/a)</b>	<b>Phasing-out?</b>	<b>% (No.) of companies</b>		
				<b>Small</b>	<b>Medium</b>	<b>Large</b>
I&I	23,000 (1997)	2,760 (based on 12% of remaining accounted for by UK specialist products)	Under PARCOM 92/8, use in industrial cleaning agents is to be phased out by 2000; BACS and SDIA - phase-out NPEs by the beginning of 1998; encouraging non-members to comply with agreement (about 20% are non-members)			
Textiles	8,000 (1997)	16% <sup>1</sup> 1,280 of total; 740 excluding exports	Voluntary agreement requires elimination of APE emissions. Largest companies had switched to alternatives or reduced emissions by 1997. Use figure likely to be an overestimate	72% <sup>2</sup> (366)		
Leather	6,000 (1997)	45	NPE use reducing and predicted to be zero by end of 2000	58% (73)	36% (45)	6% (8)
Agriculture (veterinary medicines)	< 5,000 (1997)	Around 25 products registered in UK	Some reluctance to phase out NPEs, but some substitution may have begun			
Metalworking	2,000 (1997)	175 <sup>3</sup>	UK-based formulators have made a commitment to reducing NPE usage	36% 50% <sup>4</sup>	16%	49% <sup>3</sup>
Pulp and paper	1,000 (1997)	100	Trade associations indicate that industry aim is to move away from NPEs by 2000, with only specialist uses remaining	100 in total; good % are large		
Personal care	<4,000 <sup>5</sup> (1997)	200 (based on trade association data)	The major trade association indicated that respondents had in place plans to reduce the vast majority, if not all, NPEs in their products either 'as soon as possible' or 'by the year 2000'. But greatest impact expected to be on small companies			

Notes: <sup>1</sup> L'Observatoire Européen du Textile et de l'Habillement (1995): **Données Structurelles sur l'Industrie des Textiles & de l'Habillement dans l'UE 1998-1994**, Brussels, OETH

<sup>2</sup> 72% employ less than 20 people, however, these account for only 18% of the workforce and generate only 15% of total turnover; total of 509 companies in UK in 1994 (OETH, 1995)

<sup>3</sup> upper limit of use in the Netherlands (Westra J & Vollebregt LHM (nd): **The Use of Alkylphenol Ethoxylates in the Netherlands**, Consultancy and research Centre on Chemistry, Occupational Health and Environment, University of Amsterdam, Amsterdam. Assumed that UK is same as Netherlands, since use patterns are of the same order (although pattern of company size is generally very similar across whole EU)

<sup>4</sup> 50% of metal finishing is by small companies

<sup>5</sup> estimated - included in 'other uses' - no further breakdown given

**Table 3: Estimated Costs of Marketing and Use Restrictions for the UK**

Use Sector	UK Use (tonnes per year)	% Continental NP Burden	Reformulation Cost (£m)	PV Substitute Cost (£m)	Total PV Cost (£m)	£'000 per tonne used	£m per % burden
<i>Sectors where Marketing and Use Restrictions are Proposed</i>							
Industrial and institutional cleaners	2,760	44.7	1.37	6.54	7.91	2.87	0.18
Textile processing	1,280	14.7	0.17	3.04	3.21	2.50	0.22
Leather processing	45	6.09	0.07	0.11	0.17	3.88	0.03
Veterinary medicines	62.5	0.54	0.03	0.15	0.17	2.77	0.32
Metalworking	175	1.22	1.70	0.41	2.11	12.09	1.73
Pulp and paper	100	1.72	0.07	0.24	0.31	3.05	0.18
Personal care products	200	8.80	1.70	0.47	2.17	10.87	0.25
<i>Subtotal</i>	<i>4,623</i>	<i>77.8</i>	<i>5.10</i>	<i>10.96</i>	<i>16.06</i>	<i>3.47 (aver.)</i>	<i>0.21 (aver.)</i>
<i>Sectors where Marketing and Use Restrictions are not Proposed</i>							
Chemical intermediates (excl. NPE)	4,875	0.031	14.27	46.58	60.85	12.48	1,963
Emulsion polymerisation	2,000	0.002	42.89	4.74	47.63	23.82	23,817
Pesticides	312.5	0.540	7.03	0.74	7.77	24.87	14.4
<i>Subtotal (excl. 'other')</i>	<i>7,188</i>	<i>22.2</i>	<i>64.19</i>	<i>52.07</i>	<i>116.26</i>	<i>16.18 (aver.)</i>	<i>5.23 (aver.)</i>
<p><i>Notes: The remaining 21.7% of the continental burden is made up of emissions from other uses, some of which are unaccounted for. These sectors are not included here because the figures provided in this table are for illustrative purposes (rather than being comprehensive). Additionally, it has not been possible to provide estimates of the cost implications of marketing and use restrictions for all sectors but the costs for other uses are expected to be around £50m (making total costs around £182 million). Reformulation costs are assumed to be borne over two years and increased costs of substitutes over a period of five years, with costs presented here being <b>total</b> costs. A discount rate of 3% is used.</i></p>							

<b>Table 4: Performance of Possible Risk Reduction Options Against the Evaluation Criteria</b>				
<b>Option</b>	<b>Effectiveness</b>	<b>Practicality</b>	<b>Economic Impact</b>	<b>Monitorability</b>
<b>Marketing and Use Restrictions</b>	<p><b>Instrument:</b> Amendment to the Marketing and Use Directive 76/769/EEC.</p> <p><b>Timing:</b> year 2001 at the earliest.</p> <p><b>Coverage:</b> addresses risks across the production, formulation and all uses, and across the EU.</p> <p><b>Specificity:</b> Addresses aquatic, terrestrial, secondary poisoning and any human health risks associated with production, formulation and use of NP/Es.</p> <p><b>Level of Risk Reduction:</b> eliminates risks associated with the use of NPE.</p> <p><b>Potential for Increased Risks:</b> alternative substances may introduce new risks. However, most alternatives appear to be either less hazardous or give rise to no greater risks than NPEs.</p>	<p><b>Implementability:</b> a ban on the use of NPEs should be straightforward in implementation.</p> <p><b>Flexibility:</b> Inflexible, as users of NPEs are forced to adopt alternative substances.</p>	<p><b>Numbers of Affected Organisations:</b> All producers and users of NPEs.</p> <p><b>Costs:</b> some or all of the following costs would be incurred: reformulation costs; increased surfactant costs, reduced performance; and loss of business.</p> <p>Other, more flexible, options are likely to be less costly for particular sectors.</p> <p>Monitoring costs are proportional to the scale and number of uses, but would be lower than for standards based approaches.</p>	<p>Monitoring by Member States and the Commission would be required.</p> <p>Monitoring costs would be dependent upon the scale and number of uses.</p>

**Table 4: Performance of Possible Risk Reduction Options Against the Evaluation Criteria (con't)**

Option	Effectiveness	Practicality	Economic Impact	Monitorability
<p><b>IPPC</b></p>	<p><b>Instrument:</b> Integrated Pollution Prevention and Control Directive.</p> <p><b>Timing:</b> IPPC Directive is due to be implemented in 1999 and fully operative by 2007.</p> <p><b>Coverage:</b> addresses risks across the EU but not across all sectors of use. In addition, releases from smaller facilities would not be covered.</p> <p><b>Specificity:</b> Not limited to aquatic risks; aims to minimise releases across all media.</p> <p><b>Level of Risk Reduction:</b> achieves the required level of risk reduction for the aquatic environment and thus would reduce secondary poisoning risks. Also a requirement to minimise releases rather than simply meet any emission standard.</p> <p><b>Potential for Increased Risks:</b> Avoids diversion of risks from one environmental compartment to another.</p>	<p><b>Implementability:</b> Emission standards may be as low as 0.33 µg/l of NP (but almost certainly higher).</p> <p><b>Flexibility:</b> Companies are able to choose the means of compliance as long as BAT or standards are met; options may include: improvements to storage, handling and use; process changes; installation of treatment systems; changes in disposal route; and/or the use of alternative products.</p>	<p><b>Numbers of Affected Organisations:</b> All large and medium-sized facilities which fall under the IPPC licensing and which discharge NPEs would be affected.</p> <p><b>Costs:</b> Only those costs which are additional to the costs arising from the implementation of the IPPC Directive in its current form are of relevance.</p> <p>This option gives companies the choice of compliance method, although it is likely to be more costly than EQS and limit values as BAT is specified.</p> <p>Monitoring costs are not known and could be high as the emission standard is close to the level of detection for NPEs.</p>	<p>Monitoring would be required by all controlled industrial facilities releasing NPEs and also at sewage treatment works.</p> <p>Monitoring costs would also be incurred by regulatory authorities. However, affected facilities are likely to be monitored regardless of NPE requirements; thus associated monitoring costs should be only incrementally higher.</p> <p>Effectiveness of this option is heavily reliant on monitoring capabilities.</p>

**Table 4: Performance of Possible Risk Reduction Options Against the Evaluation Criteria (con't)**

Option	Effectiveness	Practicality	Economic Impact	Monitorability
<p><b>Limit Values/EQS</b></p>	<p><b>Instrument:</b> Water Framework Directive</p> <p><b>Timing:</b> Establishing community wide controls could thus take time. National limits could be introduced in interim.</p> <p><b>Coverage:</b> addresses the risks from all use categories across the EU. Releases from those industrial facilities which discharge direct to the aquatic environment and sewage treatment plants would be affected.</p> <p><b>Specificity:</b> Specific to aquatic risks. Affects only those facilities which release 'unacceptable' levels of NPE.</p> <p><b>Level of Risk Reduction:</b> could achieve the required level of risk reduction for the aquatic and secondary poisoning compartments.</p> <p><b>Potential for Increased Risks:</b> where treatment is used to meet the option, levels of NP in sludge may increase. This may increase risks to the terrestrial environment.</p>	<p><b>Implementability:</b> The EQS may be as low as 0.33 µg/l of NP, although operational values adopted have been higher at 1 µg/l.</p> <p>Some difficulties in monitoring at necessary limits and for individual substances may arise.</p> <p><b>Flexibility:</b> Companies are able to choose the means of compliance from: improvements to storage, handling and use; process changes; installation of treatment systems; changes in disposal route; and/or the use of alternative products. Sewage treatment plants will be forced to install additional treatment where risks arise from effluents over which they have no control (e.g. domestic uses).</p>	<p><b>Numbers of Affected Organisations:</b> Most sewage treatment plants would need to take action. Only those companies which discharge NPEs above a certain level would be affected.</p> <p><b>Costs:</b> Only those with unacceptable releases would be affected by this option.</p> <p>This option gives companies the choice of compliance method. It should therefore be the least cost option. However, monitoring costs are not known and could be high as the PNEC is close to the level of detection for NPEs and the scale of monitoring required is at this time unknown.</p>	<p>Monitoring would be required at sewage treatment works and in surface waters. Monitoring may also be required by dischargers.</p> <p>The effectiveness of the option is heavily reliant on monitoring capabilities.</p>



**Table 4: Performance of Possible Risk Reduction Options Against the Evaluation Criteria (con't)**

Option	Effectiveness	Practicality	Economic Impact	Monitorability
<p><b>Voluntary Agreement</b></p>	<p><b>Instrument:</b> Targets would be set in line with Resolution 97/C 321/02 and Recommendation 96/733/EC.</p> <p><b>Timing:</b> relatively short but actual risk reduction is dependent upon individual responses</p> <p><b>Coverage:</b> depends on the actions of industry. With 100% involvement would address risks across the EU and all uses of NPE. Most likely to affect uses with simple replacements.</p> <p><b>Specificity:</b> Not specific to aquatic risks. Not targeted at the greatest contributors to risks. Effect on users of NPE depends on the actions of industry.</p> <p><b>Level of Risk Reduction:</b> depends on actions of industry. Without 100% industry involvement some degree of risks will remain.</p> <p><b>Potential for Increased Risks:</b> alternative substances will introduce new risks. However, most appear to be either less hazardous or give rise to no greater risks than NPEs.</p>	<p><b>Implementability:</b> a voluntary agreement which involves 100% of industry will be virtually impossible to achieve.</p> <p><b>Flexibility:</b> Inflexible, as those which comply are forced to use alternative substances.</p>	<p><b>Numbers of Affected Organisations:</b> Depends on the level of industry involvement.</p> <p><b>Costs:</b> some or all of the following costs would be incurred: reformulation costs; increased surfactant costs, reduced performance; and loss of business.</p> <p>Other, more flexible, options are likely to be less costly.</p> <p>Monitoring costs will be proportional to the scale and number of affected uses.</p>	<p>Monitoring by industry and the Commission would be required.</p> <p>Monitoring costs would be proportional to the scale and number of uses.</p>

**Table 4: Performance of Possible Risk Reduction Options Against the Evaluation Criteria (con't)**

Option	Effectiveness	Practicality	Economic Impact	Monitorability
<p><b>Classification and Labelling</b></p>	<p><b>Instrument:</b> Directive 1999/45/EC</p> <p><b>Timing:</b> introduction of classification and labelling relatively short but reductions in risk depend upon actions of industry and other users</p> <p><b>Coverage:</b> depends on the actions of industry and other users. May vary according to country, use category, market pressures, and the nature of alternative products.</p> <p><b>Specificity:</b> Not targeted at the greatest contributors to risks. Effect on industry and other users will be determined by their response.</p> <p><b>Level of Risk Reduction:</b> depends on actions of industry and other users. Will vary by sector and country.</p> <p><b>Potential for Increased Risks:</b> low if alternative substances are similarly and correctly labelled.</p>	<p><b>Implementability:</b> involvement of 100% of industry is impossible to achieve.</p> <p><b>Flexibility:</b> Inflexible, as those which comply are forced to use alternative substances.</p>	<p><b>Numbers of Affected Organisations:</b> Depends on the level of industry involvement. Relatively few producers and formulators would incur costs from labelling and classification itself.</p> <p><b>Costs:</b> costs of implementing the measure are low, but subsequent costs to industry will depend on response. Likely to be the lowest cost option for industry.</p> <p>Monitoring costs will be associated with surveys of industry and other users.</p>	<p>Monitoring by the Commission would be required.</p> <p>Monitoring costs would be proportional to the scale and number of uses.</p>