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4-tert-Octylphenol
Risk Reduction Strategy and Analysis of Advantages and Drawbacks

Final Report

June 2008

SCOTTISH EXECUTIVE

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prepared for

Department for Environment,
Food and Rural Affairs

RPA

August 2006

Risk Reduction Strategy and Analysis of Advantages and Drawbacks for 4-tert-Octylphenol

Final Report – August 2006

prepared for

Department for Environment, Food and Rural Affairs

by

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LIST OF ACRONYMS

AP(s)	Alkylphenol(s)
APE(s)	Alkylphenol ethoxylate(s)
AP/E(s)	Alkylphenol and alkylphenol ethoxylate(s)
BAT	Best Available Technique
CEPAD	Conseil Européen des Phénols Alkylés et Derivés (European Council for Alkylphenols and Derivatives)
CTPA	Cosmetic, Toiletry and Perfumery Association
Defra	Department for Environment, Food and Rural Affairs
ELV	Emission limit value
EPRA	European Phenolic Resins Association
EQS	Environmental quality standard
ESD	Emission Scenario Document
ESR	Existing Substances Regulation (Council Regulation (EEC) 793/93)
EUSES	European Union System for the Evaluation of Substances
IPPC	Integrated Pollution Prevention and Control
MAC	Maximum allowable concentration
NP(s)	Nonylphenol(s)
NPE(s)	Nonylphenol ethoxylate(s)
NP/E(s)	Nonylphenol and nonylphenol ethoxylate(s)
OP(s)	Octylphenol(s)
OPE(s)	Octylphenol ethoxylate(s)
OPE-S	Octylphenol ether sulphates
OP/E(s)	Octylphenol and octylphenol ethoxylate(s)
OSPAR	Oslo and Paris Convention for the protection of the marine environment of the Northeast Atlantic
PBT	Persistent, bioaccumulative and toxic
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
RBMP	River Basin Management Plans
RCR	Risk characterisation ratio
RER	Risk Evaluation Report (for 4-*tert*-octylphenol)
RRS(s)	Risk Reduction Strategy(s)
SIDS	Screening Information Data Set (OECD)
TGD	Technical Guidance Document
WWTP	Wastewater treatment plant

PART A

PROPOSAL FOR ADDRESSING THE RISKS FROM 4-*TERT*-OCTYLPHENOL

THE OCTYLPHENOL RISK REDUCTION STRATEGY

Background to the Study

Octylphenols (OPs) refer to a large number of isomeric compounds of the general formula $C_6H_4(OH)C_8H_{17}$. They belong to the wider family of alkylphenols (APs) which encompasses a range of C_1 to C_{12} alkyls including butylphenol (C_4), nonylphenol (C_9) and dodecylphenol (C_{12}). APs are also the building blocks (as well as breakdown products) of the alkylphenol ethoxylates (APEs) group of non-ionic surfactants of which the most well known ones are the nonylphenol ethoxylates (NPEs) and OP ethoxylates (OPEs). In 2000, it was estimated that nonylphenols (NPs) and their ethoxylates made up 90% of all APs and APEs with the remainder being mostly OPs and OPEs (RPA, 2000).

Amongst the OPs, 4-*tert*-octylphenol (CAS No. 140-66-9) has been identified by industry as the only OP isomer currently commercially available in Europe. For the purposes of this study, therefore, unless otherwise specified, the term 'octylphenol' or 'OP' is assumed to refer to 4-*tert*-octylphenol.

4-*tert*-octylphenol is a high production volume chemical and is the most likely immediate replacement for NP which was assessed for risks to the environment and human health under the Existing Substances Regulation (ESR) 793/93/EEC and is currently the subject of marketing and use restrictions under Council Directive 76/769/EEC. On this basis, the Environment Agency for England and Wales commissioned a detailed environmental risk evaluation to cover the current lifecycle of OP and to investigate whether its use as a NP substitute is likely to give rise to risks. This followed an earlier study which identified OP as a high priority amongst other APs for risk assessment (EA, 2005b). 4-*tert*-octylphenol has also been identified by the Oslo and Paris Convention for the Protection of the Marine Environment of the Northeast Atlantic (OSPAR) as a substance for priority action and has been included in the EU Water Framework Directive (2000/60/EC) list of priority substances (Annex X to the Directive).

The environmental risk evaluation report (RER) for 4-*tert*-octylphenol is now complete and indicates the need to reduce the predicted risks for the freshwater and marine aquatic (including sediment) compartments, waste water treatment plants (WWTP) and the terrestrial compartment associated with a number of lifecycle stages (EA, 2005a).

In light of the findings and conclusions of the RER, the UK Department for Environment, Food and Rural Affairs (Defra) appointed Risk & Policy Analysts Ltd (RPA) to carry out an environmental risk reduction strategy (RRS) that will effectively reduce risks to the environment, while imposing the minimum necessary burden on society as a whole. This RRS should thus be considered as a UK action; however, the results will be presented to other EU Member States with the aim of pressing the European Commission to take any action deemed necessary at the EU level. To this end, the RRS follows the provisions of ESR according to which, when controls on the marketing and use of particular substances are proposed, an analysis of the advantages and drawbacks of the substance(s) should be undertaken. All measures considered in this RRS have been assessed on the basis of their effectiveness, practicality, economic impact and monitorability.

The aim of this RRS is to propose measures that will take into account the current (and foreseeable) controls/measures (including those which affect NP) that impact upon the levels of environmental risk from OP. It should, however, be noted that while it is imperative to consider existing controls when evaluating further controls, the objective of this RRS will not be to alter or revise the RER which is now final.

This RRS (and the RER) has been undertaken as part of the UK Co-ordinated Chemicals Risk Management Programme.

Objectives and Approach to the Study

As set out in the Project Specification, the objective of this study is to assess the advantages and drawbacks of different risk management options for the environment to:

- enable judgement as to whether the benefits of adopting the restrictions, outweigh the consequences to society as a whole of imposing the controls;
- determine the best RRS offering the greatest net benefits;
- review the efficacy of the industry voluntary agreement to reduce the risks from NP, NPEs, OP and OPEs in terms of both process and regulatory outcomes; and
- review the NP RRS alongside the OP work to assess the advantages and drawbacks of different risk management options for those uses of NP that pose a risk but were not dealt with as part of the original NP RRS due to insufficient data (i.e. resins and plastic additives).

The approach to this study is based on the existing guidelines for the development of a RRS which are set out in a Technical Guidance Document published by the European Commission (CEC, 1998). Based on this approach, there are four key stages in the development of a RRS:

- ***Stage 1***: Data gathering and evaluation of all known uses of OP. Establishment of the range of potential risk management options and current control measures in place.
- ***Stage 2***: A systematic qualitative assessment of the advantages and drawbacks for each option identified for the current uses of concern.
- ***Stage 3***: Either a semi-quantified or a fully-quantified assessment, examining one or more options for the current uses of concern.
- ***Stage 4***: Preparation of the final RRS, presenting all available cost and benefits information for each option considered and any assumptions made in the assessment.

This approach has, however, been modified to take into account the new EU regulatory framework for chemicals known as REACH (Registration, Evaluation and Authorisation of CHemicals). The main objectives of the proposed REACH Regulation are to (a)

improve the protection of human health and the environment while (b) maintaining the competitiveness and enhancing the innovative capability of the EU chemicals industry.

Under REACH, responsibility for the management of the risks of chemical substances should lie with the enterprises that manufacture, import, place on the market or use these substances. Manufacturers, importers and downstream users will be required to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Manufacturers and importers will be required to generate data on the substances they manufacture or import, use these data to assess the risks related to these substances and develop and recommend appropriate risk management measures. However, where such risk management measures are considered to be insufficient, appropriate Community-wide restrictions (under a Restrictions procedure) may be introduced.

The Restrictions procedure enables the introduction of Community-wide conditions for the manufacture, placing on the market or use of dangerous substances or the prohibition of any of these activities, if necessary. Any substance on its own, in a preparation or in an article may be subject to Community-wide restrictions, if it is demonstrated that risks are not adequately controlled. Thus, the Restrictions procedure will act as a safety net that will replace the current system of risk reduction based on the preparation of RRSs for existing chemicals in accordance with the ESR (which will be repealed twelve months after entry into force of the REACH Regulation).

Proposals for restrictions will be prepared by Member States or by the Chemicals Agency (which will soon be established) on behalf of the Commission in the form of a structured Dossier. This Dossier (also known as an Annex XIV dossier) is required to demonstrate that there is a risk to human health or the environment that needs to be addressed at Community level and to identify the most appropriate set of options for risk management.

The European Chemicals Bureau is currently developing (as part of the REACH Implementation Project (RIP) 4.4[1] and with the help of a consortium which includes RPA) a Technical Guidance Document on the preparation of restrictions dossiers in accordance with Annex XV of the REACH Regulation. This Technical Guidance Document on the preparation of Annex XV dossiers (which is in the final stages of development) has influenced the content and layout of this RRS for OP with the aim of ensuring that the final RRS is consistent with the requirements and spirit of REACH.

In discussing REACH, it is important to bear in mind that OP exhibits endocrine disrupting effects and as such, would be subject to the authorisation process. The authorisation process is intended to address substances of very high concern where these include substances having *serious and irreversible effects to human health and the environment*. Such substances will be prioritised by the Chemicals Agency and may be included in Annex XIV of the REACH regulations. Substances included in Annex XIV

[1] The aim of the RIPs is to ensure an efficient implementation of the REACH regulation through the development of guidance and IT-tools for the Agency, industry and the authorities. The RIPs include 7 main areas and a number of sub-subjects. RIP 4 projects are specifically aimed at developing guidance documents for authorities.

shall not be used or placed on the market, unless the use is authorised by the Commission in accordance with a regulatory committee procedure. Authorisations may be granted for (specific) uses for which the applicant shows that the risks posed by a substance are adequately controlled or where the socio-economic benefits for those uses outweigh the risks and there are no alternative substances or technologies. Decisions on authorisation will take into account the opinions of the Agency Committees on risk assessment and socio-economic analysis.

This Report presents the **final RRS** for addressing the risks from OP. The data used in the report are based mainly on the information presented in the RER, a review of relevant literature and information submitted by industry during consultation. RPA prepared and disseminated questionnaires requesting information primarily on the use and emissions of OP in the industry sectors of concern. A list of the organisations contacted with regard to the study is included in Part E (Section 12) and the information received has been incorporated in the appropriate sections of this Report.

Proposal for Addressing the Risks from OP (Draft Recommendations)

Preventing the re-occurrence of historical uses, the continuation of dispersive and uncontrolled uses, and the development of new uses with the potential to release OP to the environment is viewed as being essential to the success of this RRS in addressing the environmental risks associated with OP. A reduction in releases of OP from point sources which are responsible for significant releases into the environment, as well as curtailing unaccounted uses which may be unknown to manufacturers of OP (including the manufacturers of OP-based resins and OPEs) and regulatory authorities, is also considered crucial.

In determining the appropriate risk management measures, the assumptions within the RER, the use of generic (default) scenarios for some of the sectors and the possible exaggeration of risks has been taken into account. The relevance, performance and implementation of existing risk management measures have also been taken into account, particularly, the UK Voluntary Agreement on NP/Es and OP/Es, the full implementation of the IPPC Directive in 2007 and the future implementation of the Water Framework Directive over the next 20 years. Notably, the Water Framework Directive will require a progressive reduction in discharges, emissions and losses of OP to the environment and, as such, this RRS should, *inter alia*, support the achievement of this objective.

On the basis of the findings of the RER and the information collected for the purposes of this RRS, the following recommendations for a RRS are made.

Recommendation 1

It is recommended to consider at UK level, marketing and use restrictions under the Technical Standards Directive 98/34/EC (subject to clearance from EC authorities) for **all uses of octylphenol**, except in:

- manufacture and use of OP and OP-based resins in:
  - rubber formulation;
  - insulating varnishes;
  - printing inks;
  - paints and coatings; and
- manufacture and use of OPEs in the manufacture of emulsion polymers for use in paints.

These uses will be subject to a five-year derogation (subject to review at the end of this period) pending provision of information which shows that the risks posed by OP/Es are adequately controlled, the socio-economic benefits for these uses outweigh the risks and there are no alternative substances or technologies.

Recommendation 2

For manufacture and use of OP, OP-based resins and OPEs in rubber formulation, insulation varnishes, printing inks, paints and coatings and emulsion polymer manufacture in the UK (i.e. the derogated uses) and all uses of 4-*tert*-octylphenol in the EU[2], it is further recommended that:

- emission limit values or equivalent parameters or technical measures regarding octylphenol are set out in the permits issued under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) in order to operate by the end of October 2007 according to the best available techniques taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions; and

- to facilitate permitting and monitoring under Council Directive 96/61/EC (Integrated Pollution Prevention and Control), the results of the OP RER should be taken into account in developing guidance on Best Available Techniques. Also, the results of the RER should be taken into account in the next revision of the relevant BREFs.

Recommendation 3

For possible releases of OP/Es as an impurity in commercial NP/Es, the uncertainties regarding the presence of OP in specific NP/E isomers, the changes in NP/E tonnages in various industry sectors in the last ten years and the existing marketing and use restrictions on certain uses of NP/E have been taken into account. It is thus recommended that further sampling, monitoring and analysis is undertaken to confirm the presence and resulting risks of OP in the NP/E processes at specific industrial sites and where these are found to be significant (i.e. the PEC is greater than the PNEC), IPPC

[2] While all efforts were made during the development of this RRS to obtain information at an EU level for the uses of 4-*tert*-octylphenol, it is recognised that the information received, while significant, does not provide sufficient evidence on which to recommend marketing and use restrictions at an EU level. This would have to be the subject of a more detailed investigation which is strictly outside the scope of the terms of reference for this study.

controls are put in place, as appropriate. Information provided in Annex 2 on the critical loads of OP can also be taken into account by regulatory authorities in this regard.

Recommendation 4

Finally, for possible releases of OPEs from imported textiles, it is recommended that further analysis is undertaken to ascertain the scale of this problem at the UK and EU levels and a peer review of the available data is undertaken prior to consideration of any further risk management action. The aforementioned analysis would aim to clarify, *inter alia*, the amount of OPEs present in finished textiles and the total amount (or proportion) of textiles imported into the UK/EU actually containing OPEs.

Structure of this Report

The remaining sections of this report are arranged as follows:

- **Part B: Information on Hazard and Risk:**
  - Section 1 sets out the **physical and chemical properties** of OP;
  - Section 2 provides background information on the **manufacture and use of OP** in the UK and EU;
  - Section 3 provides an overview of the **results and conclusions of the RER**;
  - Section 4 discusses **existing controls** on releases of and exposure to OP/Es;
- **Part C: Information on Alternatives:**
  - Section 5 outlines the existing information on possible **alternatives** to OP (including its resins) in various products and/or processes;
- **Part D: Justification for Proposed Risk Reduction Strategy:**
  - Section 6 describes a range of **potential risk management options** and outlines how they could apply to those uses where a need for risk reduction has been identified;
  - Section 7 sets out **the risk management options taken forward** following from the screening of measures in the previous Section;
  - Section 8 presents the **qualitative assessment** of the further risk management options against the standard decision criteria of their effectiveness, practicality, and monitorability;
  - Section 9 presents the **socio-economic assessment** of the proposed measures.

- Section 10 addresses **derogation** issues;
- Section 11 provides the **overall justification for the proposed risk management options**; and

- **Part E: Information on Stakeholder Consultation:**
  - Section 12 provides a **list of consultees** contacted for this study and a list of references cited.

Annex 1 provides an assessment of the impact of the UK Voluntary Agreement on NP/Es and OP/Es and its implications for this RRS while Annex 2 provides a calculation of the critical emission loads for octylphenol.

PART B

INFORMATION ON HAZARD & RISK

1. PHYSICAL AND CHEMICAL PROPERTIES OF OCTYLPHENOL

Table 1.1: Summary of Physico-chemical Properties of 4-*tert*-octylphenol	
Property	**Value**
IUPAC Name:	4-*tert(iary)*-Octylphenol
EINECS Name:	4-(1,1,3,3-Tetramethylbutyl)phenol
EINECS Number:	205-426-2
CAS Number:	140-66-9
Molecular Formula:	$C_{14}H_{22}O$
Structural Formula:	HO-C_6H_4-C_8H_{17}, where C_6H_4 is a benzene unit substituted at the 1,4- position.
Molecular Weight:	206.33 g/mole
Synonyms:	octylphenol PT, para-(or p-)*tert*-octylphenol, p-(1,1,3,3-tetramethylbutyl)phenol
Physical state at n.t.p	White or light pink flakes
Melting / freezing point	Intermediate value of 80.5°C may be considered representative
Boiling point	Intermediate value of 281.5°C is considered representative
Vapour pressure	0.21 Pa at 20ºC (no method specified)
Water solubility	19 mg/L at 22ºC (for an aquatic test water)
Partition coefficient n-octanol/water (log value)	log K_{ow} 4.12 at 20.5ºC (OECD 107 shake flask method)
Dissociation constant	>9.9 and <12.19
Source: EA, 2005a	

2. PRODUCTION AND USES OF OCTYLPHENOL

2.1 Production of Octylphenol and its Derivatives

2.1.1 Production of Octylphenol

There are two main routes used in the production of OP, both of which involve the reaction of phenol and *tert*-octene (di-isobutene) in the presence of:

a) an ion-exchange resin or boron trifluoride complex in a batch reactor; or
b) a fixed bed ion-exchange resin in a continuous process.

The *tert*-octene is produced by dimerisation of isobutene which ensures that the octene is branched rather than linear. The purity of isobutene also means no other homologues are expected. Reaction with phenol leads predominantly to substitution by *tert*-octene in the 4- (para-) position (see Figure 2.1 below). In the first process, the neutralised and/or deactivated catalyst is disposed of via authorised waste facilities in accordance with existing regulations; in the second process, it is discharged directly into an incineration plant (EA, 2005a).

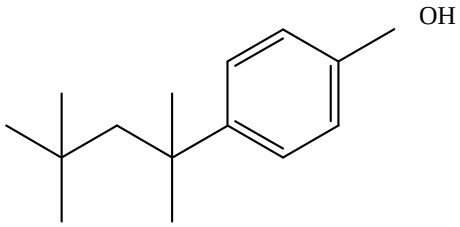

Figure 2.1: Structure of 4-*tert*-octylphenol

In 2001, production of 4-*tert*-octylphenol was undertaken at six European sites located in Germany, Belgium, France, Switzerland and the UK. The latest information for 2005 provided in the RER indicates that due to some restructuring within the sector, there are only three companies producing 4-*tert*-octylphenol at five sites, none of which are in the UK. Information received from industry for the purposes of this RRS confirms that this information is accurate for the year 2006. Table 2.1 below reproduces the information in the RER regarding European production volumes, exports and imports of 4-*tert*-octylphenol from 1997 to 2001.

Table 2.1: European Production Volume, Exports and Imports of 4-*tert*-octylphenol

	Amount (tonnes/year)				
	1997	**1998**	**1999**	**2000**	**2001**
Production volume	17,520	18,259	19,626	22,215	22,633
Exports	234	104	6	0	150
Imports	1,035	1,337	1,240	1,308	375
Tonnage used	**18,051**	**19,492**	**20,928**	**23,523**	**22,858**
Captive use*	14,969	16,074	17,592	19,910	20,060

* Used on-site to produce other substances (for instance, OP resins or OPEs)
Source: CEPAD (2002) in EA (2005a)

The production data provided in Table 2.1 shows that in the 5 years from 1997 to 2001, there was a steady growth in the production and use of 4-*tert*-octylphenol with an annual growth rate of approximately 1%. The estimated EU production tonnage for 2006 (based on industry data) is around **24,000 tonnes** (of which around 80% is indicated as captive use).

Overall, 4-*tert*-octylphenol has two main direct uses:

- the production of phenol-formaldehyde resins (or phenolic resins) (and their subsequent derivatives); and
- the production of OPEs (and their subsequent derivatives).

2.1.2 Production of Octylphenol Derivatives

Production of Phenol-Formaldehyde (or Phenolic) Resins

The use of 4-*tert*-octylphenol as an intermediate in the production of phenol-formaldehyde (or phenolic) resins is indicated as the major use of 4-*tert*-octylphenol accounting for 98% of the use volume in 2001 (~22,500 tonnes). These phenolic resins tend to be produced captively (i.e. at the same site as OP production) but used non-captively (i.e. at a different location to their production). According to the RER, there are between 10 and 15 companies producing phenolic resins in the EU, with the largest using around 9,000 tonnes of 4-*tert*-octylphenol per year (EA, 2005a).

Phenol–formaldehyde resin manufacture is based almost exclusively on discontinuous batch processes using a traditional reactor or 'kettle'; the resins being formed by a step-growth polymerisation reaction in which 4-*tert*-octylphenol is used as a monomer. The phenol–formaldehyde resins may be made with 4-*tert*-octylphenol alone (which is the base assumption in the RER) or in admixture with other phenols depending on the properties desired for the final resin. Most of the 4-*tert*-octylphenol in the resins is chemically bound and cannot be released even on subsequent chemical or biological degradation, but the resins may also contain a small proportion (~3-4%) of unreacted OP (EA, 2005a).

There are two main types of phenolic resin:

a) *novolacs*, which are made with a molecular excess of phenol over formaldehyde and are usually catalysed with acid (e.g., hydrochloric, sulphuric or oxalic acid); and

b) *resoles*, which are made with a molecular excess of formaldehyde over phenol and are usually catalysed with alkali (e.g., sodium hydroxide, ammonia or amines).

Most OP-based resins produced and used in the EU are of the novolac type, where the phenol is in excess, so 4-*tert*-octylphenol makes up at least 90% by weight of the resins. The RER assumes (for simplicity) that the resin consists only of 4-*tert*-octylphenol (i.e., the formaldehyde has been neglected).

Production of Octylphenol Ethoxylates

OPEs are manufactured by the addition of ethylene oxide to OP under pressure; OP is thus an intermediate in this use.

According to the RER, OPE production is thought to be a minor use of 4-*tert*-octylphenol in the EU accounting for only 400 tonnes, or 2% of the total use volume, in 2001. The total EU consumption of OPEs was estimated at around 1,050 tonnes in 2001; 1,000 tonnes were produced in the EU and 50 tonnes were imported. Information received from consultation, however, indicates that there were sales of at least 2,000 tonnes of OPEs in 2005 in the EU – with around 100 tonnes sold in the UK.

The RER estimates that there were four or five companies manufacturing OPEs on a non-captive basis in 2001; information received from consultation provides a similar picture. In general, industry indicates that the overall trend in the UK and EU has generally been downwards (i.e. rapid decline) - with a corresponding price increase - due to the EU restrictions on NP/Es and the subsequent replacement of NP/Es (and AP/Es in general) by other surfactants.

Production of Octylphenol Ether Sulphates (OPE-S)

The production of ether sulphates involves the use of the OPEs as intermediates in what is considered a relatively specialist process. The RER considers that there may be three or four small companies in Europe producing around 250 tonnes/year of OPE-S (from 200 tonnes of OPEs). Information provided by the Conseil Européen des Phénols Alkylés et Derivés (CEPAD) in the RER indicates that it is not certain that the production of OPE-S from OPEs still occurs in the EU; the market for OPE-S is said to be declining gradually (apart from in water-based paints where substitution may be difficult) (EA, 2005a). No information was received on this use while preparing the RRS.

The sections that follow provide a detailed discussion on the uses of 4-*tert*-octylphenol and its derivatives by sector.

2.2 Identified Uses of Octylphenol

2.2.1 Rubber Industry

Use of OP-based Resins in Rubber Formulation

CEPAD (2002) indicates that the majority of the phenolic resins produced from 4-*tert*-octylphenol are used in the production of tyres. In 2001, around 18,500 tonnes of OP were used for this purpose - equivalent to around 80% of the total use of OP in the EU (EA, 2005a). Information received for the purposes of this RRS, however, indicates that around **24,000 tonnes** of OP were used in rubber formulation in 2005 (where some of this was manufactured outside the EU).

OP-based resins are used to increase the tackiness[3] of the rubber and improve adhesion of the different layers during vulcanisation (hence, they are referred to as tackifiers). According to a major manufacturer/supplier of OP to the tyre industry, the primary function of a tackifier resin is to maintain the internal structural integrity of a green tyre prior to curing by high temperature vulcanisation. Due to rate-limiting factors in tyre manufacture, green tyres must be stored several days prior to curing; during this storage period, any de-lamination[4] of the green tyre could lead to defects expressed as lost production or, as a worst case, catastrophic tyre failure (if de-lamination effects are not detected in the finished tyre).

In rubber formulation, the OP-based resins are combined with other components of the rubber (e.g. cross-linking agents, reinforcements, extenders, etc.) to produce formulated rubber which is then used to manufacture tyres. The resins are usually added to rubber in amounts up to 1.5% of the rubber formulation although the maximum figure for the percentage of resin in rubber used in tyres could be as high as 10% (EA, 2005a).

According to the RER, tackifier resins were produced at four sites in the EU in 2001: two in France, one in Belgium and one in the UK (which has now closed). The vast majority of these tackifier resins are manufactured captively while a small amount is sold to third parties who then sell to tyre manufacturers. According to BLIC (the European Association of the Rubber Industry, now known as ETRMA - European Tyre & Rubber Manufacturers' Association), there are 87 tyre manufacturing plants located in 17 European countries responsible for 33% of the world market of nearly 1 billion tyres. In 2002, the main producing countries were Germany (59 million tyres), France (54 million), Italy (28 million), Spain (34 million) and the UK (22 million) (BLIC, 2006).

Information from manufacturers/suppliers (responsible for producing over 70% of OP-based resins for tyre manufacture in the EU) indicates that EU consumption of octylphenol for producing tackifier resins in tyres is generally stable, tending towards decline, due primarily to an increasing market share of Asian tyre manufactures.

2.2.2 Paints, Printing Inks and Coatings Industry

Use of OP-based Resins in Insulating Varnishes

OP-based resins are used for secondary insulation of electric windings (e.g. in motors and transformers) to improve insulation and to bond windings together. Phenolic resins are preferred in this role due to their high dielectric strength, superior insulation resistance and high temperature resistance. The use of resins in this application involves heat curing of the resin which requires further cross-linking and reaction; the resin thus acts as a cross-linking agent. The demand for 4-*tert*-octylphenol for this specific use was estimated to be 2,000 tonnes in 2001 - equivalent to around 9% of the total volume of OP used in the EU (EA, 2005a).

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[3] Tack is the ability of two materials to resist separation after being in contact for a short period under light pressure.

[4] De-lamination refers to the process whereby the tyre separates into its component parts. A 'green tyre' is one whose manufacture is complete except for the heat-induced curing and vulcanisation steps.

While no specific information was received from industry during development of this RRS on the use of OP in insulated wires, Table 2.2 below shows the UK market for cables (and winding wires, in particular) (based on information collected by Europacable, the European trade association representing around 90% of EU cable manufacturers).

Table 2.2: Production of Cables in the UK in 2003 and 2004 (€ million)		
Type	**2003**	**2004**
General wiring cables	300	310
Electricity utility cables	180	150
Information cables	230	240
Winding wires	40	40
Total	**~750**	**~750**
Source: Europacable website (www.europacable.com)		

Information received for the purposes of this RRS from the European Stabiliser Producer Association (ESPA) also indicates that a small amount of OP is still used (as an antioxidant) in some older formulations of stabilisers for PVC cable jacketing. Manufacturing takes place outside the UK and this use is expected to cease in the near future as new formulations do not contain OP (and the demand of OP for this use has decreased significantly in the last five years). It is understood that other antioxidants (based on other phenol chemistries) are used to replace OP in this application.

Use of OP-based Resins in Printing Inks

Printing inks are effectively a mixture of colouring matter (pigment) dispersed or dissolved in a carrier (or vehicle) with some additives (e.g. extenders) to form a fluid or paste which can be printed on a substrate and dried. A typical vehicle consists of a resin, oil and solvent acting in such a way that, during printing, the solvent is absorbed by the paper leaving a thin ink film of resin and oil that binds the pigment to the paper and hardens by oxidation. Basically, printing inks are manufactured in high-temperature processes in which the OP-based resins are reacted with other resins and oils and then diluted in ink solvents and pigmented (Kirk-Othmer, 1996; Danish EPA, 2004).

OP-based resins act as vehicles which provide the ability for lithographic and letterpress printing inks to carry colour onto a variety of printing surfaces (e.g. paper, plastic and metal) quickly and accurately, and with faster drying of the newly applied printed surface. They also offer performance characteristics such as gloss, brightness and rub/scratch resistance (EA, 2005a).

Information from the British Coatings Federation (BCF) confirms that octylphenol is one of a number of starting components used in the manufacture of phenolic resins, which are then reacted with rosins to produce phenolic-rosin resins. These phenolic-rosin resins are the basis of offset printing inks, providing the necessary physicochemical parameters for optimum application and stability on press, as well as the required technical and functional performance of the print on the surface.

A major manufacturer/supplier of OP to the printing inks sector is of the opinion that while these polymeric resins are only present to the extent of a few percent of the finished ink formulation, they are critical in preventing smudging of the freshly printed surface and in allowing efficient throughput of stock through printing equipment.

The volume of 4-*tert*-octylphenol used in printing inks was estimated to be 1,000 tonnes in 2001 (EA, 2005a). The BCF indicates that the phenolic-rosin resins used in the manufacture of inks in the UK run into hundreds of tonnes per annum; however, these phenolic-rosin resins are not based entirely on 'pure' octylphenol – instead, they are based on alkylphenol mixtures, the composition of which will be source- and final product-specific.

One manufacturer/supplier of OP to the printing inks industry suggests that OP consumption for ink resins is generally steady; although another major manufacturer reported zero sales in 2005 (after yearly reductions in sales of 40% in 2003, 75% in 2004 and 100% in 2005); the reasons for this reduction are unclear.

Use of OP-based Resins in Marine Paints

Marine paints are indicated as a major 'other use' of OP-based resins accounting for a significant proportion of 800 tonnes of 4-*tert*-octylphenol (allocated to 'other use'). The OP-based resins are used as binders[5] in marine coatings with the resin content in the paints at around 25% (although not all of this may be 4-*tert*-octylphenol). These resins are reportedly used in special paints for marine applications due to the high resistance to saline waters which they provide.

The RER uses worst case assumptions based on 800 tonnes of resin being used in this application (neglecting any other possible uses and the contribution of the formaldehyde) and, as such, 3,200 tonnes of paints have been assumed to contain the resin. For the application of the paints, use in an industrial situation has been assumed, rather than use by the public (EA, 2005a).

Information from industry, however, indicates that only a few kilograms per annum of phenolic-rosin based marine coatings are used in the UK.

Use of OPEs and OPE-S in Water-based Paints

According to the RER, OPEs act as emulsifiers and dispersants in water-based paints, with the emulsifying properties being more dominant. 50 tonnes of OPEs were used in this application in 2001 (equivalent to 20 tonnes of 4-*tert*-octylphenol). The RER also estimates that around 200 tonnes of OPE-S (equivalent to 64 tonnes of 4-*tert*-octylphenol) were used in such paints.

[5] Binders have four main roles in paints; they hold pigment together when in dry film form; act as a 'vehicle' that carries pigment when applied; determine the durability of end product; and provide adhesion to the surface to which it is applied. The main performance properties of paint (washability, adhesion and colour retention) are thus determined by the nature and amount of binder – which is consequently one of main factors controlling the price of a paint coating.

The RER assumes that all of the paint is used industrially and that the emulsion polymers (see Section 2.2.3 below) produced using OPEs are also used in paints. This adds a further 220 tonnes of OP to the amount used in paints, giving a total of 304 tonnes of 4-*tert*-octylphenol (equivalent to 760 tonnes of OPEs) (EA, 2005a).

According to the BCF, industry surveys identify only a couple of tonnes per annum of OPEs used in the manufacture of specific industrial coatings in the UK; this represents 0.001% of the total quantity of raw materials used in industrial coatings manufacture. For the purposes of this RRS, three major manufacturers of decorative coatings in the UK - responsible for the manufacture of around 300,000 tonnes of water borne decorative emulsion paint in the UK - have confirmed (via the BCF) that none of the raw materials they use in these products contains OPEs and OPEs are not added at the product (paint) formulation stage. While uses of OPEs have been identified in specific industrial paint products, these are expected to account for only a few tonnes (BCF, 2006).

2.2.3 Chemical Industry

Use of OPEs in Emulsion Polymerisation and Emulsion Polymer Manufacture

Emulsion polymerisation is basically a type of polymerisation (e.g. to make styrene–butadiene polymers or PTFE polymers) which takes place in an emulsion typically incorporating water, monomer and surfactant. The surfactant (also known as emulsifier) stabilises the emulsion (or polymer particles) to prevent unwanted fusion or coagulation.

OPEs may be used as emulsifiers during polymerisation or may be added to the emulsion after polymerisation. They play an important role in providing good stability both during the polymerisation process and during storage and transport. They may also affect performance properties of the polymer such as pigment binding power and water sensitivity. In most surfactant formulations, a combination of anionic and non-ionic surfactants is used. Anionic surfactants provide shear stability to the latex during the polymerisation reaction while non-ionic surfactants (such as APEs) provide electrolyte stability and contribute to mechanical and freeze-thaw stability (Veova, 2006).

The end applications for the polymer dispersions based on OPEs include paints, paper, inks, adhesives and carpet backings[6] - consultation for this RRS, however, suggests that paints is the most relevant end application.[7] In 2001, 550 tonnes of OPEs (equivalent to 220 tonnes of 4-*tert*-octylphenol) were used as emulsifiers. Information received from consultation indicates that this tonnage is still relevant for 2005.

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[6] The European Polymers Council indicates that the major end uses of emulsion polymers are: paints and coatings (27%), paper and board (23%), adhesives (22%), carpet backing (11%) and other (textiles, packaging and construction) (18%). It also sets out the major product classes of emulsion polymers as follows: styrene-butadiene latex (32%), acrylics (27%), vinyl acrylics (15%), vinyl acetate polymers (14%), ethylene vinyl acetates (7%) and other (5%).

[7] Following from the RER, there are considerable difficulties in trying to differentiate between the use of *'OPEs in Water-based Paints'* and the use of *'OPEs in Emulsion Polymer Manufacture used in Water-based Paints'*. For the purposes of this RRS, the former is taken to refer to paints which are only used industrially while the latter covers paints which are used in industrial as well as end uses.

Use of Ethoxylated Resins in the Oil Industry

In the oil industry, ethoxylated resins - manufactured from the reaction between phenolic resins and ethylene oxide - are used as emulsifiers to separate water from oil during oil recovery on offshore production platforms. The resins (with a negligible amount of residual 4-*tert*-octylphenol) are added in very small amounts, often as low as a few parts per million and allow for a high degree of separation.

The demand for this specific use was estimated to be 200 tonnes of 4-*tert*-octylphenol in 2001, although it is currently unclear if this is an on-going use in the UK. While a past use of OP as a production chemical at offshore oil and gas installations has also been suggested (CEFAS, 1997 in EA, 2005a), the RER considers that this use is no longer valid for the UK and may relate to the use of ethoxylated resins for oil recovery.

Information received from CEFAS (who are responsible for the Offshore Chemicals Notification Scheme) for the purpose of this RRS confirms that OP is currently not notified as being used in the UK oil industry. This has also been confirmed by information received from industry. It is also understood that the use of OPEs in oilfield applications is banned in certain sectors of the North Sea (Danish and Norwegian sectors).

However, it is also noted that OPEs which are converted into resins and then alkoxylated are still used as demulsifiers to remove water from oil/water emulsions.

2.2.4 Textile and Leather Industry

Use of OPEs in Finishing Agents

OPEs act as emulsifiers in finishing agents (which are mainly styrene butadiene copolymers) which are used as textile (and leather) auxiliaries (e.g., hot melts, textile printing, leather finishing). Finishing agents are used to cover textiles (and leather) with a thin polymer film to make the material more resistant to water, dust and light and provide a shiny appearance (for leather).

Information received for the RRS indicates that OPEs are normally used in the textile industry in specific emulsion processes (such as emulsion polymerisation, glues, emulsifiers for dyestuffs, etc.); however, it is unlikely to be used for washing purposes due to their rather high price. In contrast, one manufacturer/supplier of OPEs also indicates that OPEs may also be used either as cleaning products to remove oil from leather or as a component within a finishing formulation designed to improve suppleness of leather.

According to the RER, the OPE is physically bound in the polymer matrix which adheres to the substrate. In 2001, an estimated 150 tonnes of OPEs (equivalent to 60 tonnes of 4-*tert*-octylphenol) were used in this application. Information received for this RRS suggests instead that around 350 tonnes of OPEs were sold to the textile and leather auxiliaries sector in 2005. This is, however, at variance with information received from the textiles sector.

Information received from various companies and industry associations (involved in the textiles sector) indicates that OPEs are currently unlikely to be used in textile formulations supplied to the UK textile industry. It is claimed that industry has moved to various alternatives, for instance, the fatty alcohol chemistry (which may be more expensive and possibly less effective). One supplier indicated that OPEs have proven to be rather expensive in a competitive textile market and, as such, sales have virtually been eliminated. Also, some retailers insist that their suppliers do not use such substances in their products. Thus OPE replacement in the textile industry has been driven by cost rather than legislation (as was the case for NPEs). This also takes into account the fact that there are very few manufacturers of textile or leather auxiliaries left in the UK.

For leather, preliminary information received from COTANCE indicates that OPEs are not critical (or do not play a significant role) in the tanning industry and that there are available substitutes. Preliminary information obtained from the British Leather Confederation from the larger UK tanners indicates that they moved away from these products some years ago to ethoxylated fatty alcohols. On the other hand, the Textile Finishers Association (TFA) indicates that their members do not have adequate information about the chemical contents of the formulations and auxiliaries which they use in processing.

2.2.5 Plant Protection and Animal Health Products Industry

Use of OPEs and OPE-S in Pesticides

The RER notes that there is a small use in the UK of OPEs in pesticide formulations (100 tonnes of OPE, equivalent to 40 tonnes of OP), where they act as emulsifiers and aid dispersion of the pesticide emulsion as a very thin layer on the leaves of the plants. A small quantity of OPEs (~16 tonnes) was also used to produce 50 tonnes of OPE-S which also act as emulsifiers or dispersants in pesticide or herbicide formulations. The RER notes that the dispersant properties are more dominant compared to emulsifying properties due to the chain length of the ethoxylate group (approximately 10 ethyl oxide units per molecule) (EA, 2005a).

For the RER, the UK Pesticide Safety Directorate (PSD) identified only a handful of UK-approved plant protection products containing OPEs (many more products contained NPEs), although, the database mainly records information related to active substances of pesticide formulations. This appears to correlate well with information provided by the UK Crop Protection Association (CPA) under the UK Voluntary Agreement for NP/OP which shows that around 180 tonnes of NPEs were used in crop protection products in 2004 compared with around 40 tonnes of OPEs. Also, in 2005, around 100 tonnes of NPEs were used compared with less than one tonne of OPE in 2005. Notably, one major manufacturer/supplier of OPEs indicates that 300 tonnes of OPEs were sold *across the EU* for use in pesticides in 2005.

Information received from the PSD for the RRS indicates that - as a result of the UK Voluntary Agreement under which companies represented by the UK CPA agreed to redevelop formulations for plant protection products containing OPEs and NPEs and to replace them by 31 December 2006 - several products have been revoked as a result of

companies applying for replacement products. At the same time as this RRS, work has been undertaken by the PSD to identify crop protection products containing OPEs (as well as NPEs) which will be the subject of a revocation notice (which includes any parallel imports of these products). The PSD estimates that there are currently around 115 pesticide products with 30 different approval holders and around 70 adjuvant products containing OPEs or NPEs.

Use of OPEs in Veterinary Medicine

For the RER, the UK Veterinary Medicines Directorate (VMD) confirmed that there were two products with a marketing authorisation in the UK that contained OPEs in 2003. Both of these were ectoparasiticides, one for livestock and the other for use on companion animals. An estimated 3.4 tonnes of OPEs were sold in veterinary medicines per year in the UK, although the VMD reports that many companies were in the process of reformulating their products to replace APEs with alcohol ethoxylates.

Information received for the RRS indicates that there are still only two veterinary products authorised for the UK which contain OPEs, and these two products are manufactured by the same company. Consultation with this company shows that around 3.7 tonnes of OPEs/year were used from 2003 to 2005 in these two products. Information provided by this company indicates that work on replacing the OPEs in these products (with a polyethoxylated alcohol) will be completed by mid-2006 and the new formulations are expected to receive approval by the end of 2006 so that products manufactured in 2007 should not contain OPEs. It is also expected that many manufacturers throughout the EU are replacing OPEs in their products.

2.2.6 Summary of Applications of Octylphenol and Octylphenol Derivatives

Table 2.3 provides a summary of the production and use situation for the EU for 4-*tert*-octylphenol. According to the RER, 22,633 tonnes of 4-*tert*-octylphenol were produced in the EU, 375 tonnes were imported and 150 tonnes were exported, thus giving a total EU consumption of 22,858 tonnes (as shown in Table 2.3).

Table 2.3: Uses by Tonnage of OP and OPEs in the EU (2001)

Uses of OP	OP	OPEs	% Total OP Consumption
Rubber (tyres)	18,458*	-	80.7%
Insulating varnishes	2,000*	-	8.7%
Printing inks	1,000*	-	4.4%
Emulsion polymerisation	220	550	1.0%
Oil (offshore) use	200*	-	0.9%
Paints	84	210**	0.4%
Textiles	60	150	0.3%
Pesticides	56	140**	0.2%
Other uses	800*		3.5%
Total Consumption	**22,878**	**1,050**	**100%**

Source: EA, 2005a
** Used in the form of OP-based resins.*
*** Some of the OPEs are used directly while others are used indirectly as ether sulphates.*

For the UK, information provided for the purposes of the RRS indicates that there is currently no production of 4-*tert*-octylphenol in the UK and limited production of OPEs. This is significant within the context of this RRS, bearing in mind that phenolic resins tend to be produced captively (i.e. at the same site as OP production) and, as such, the formulation scenarios (in the RER) are of the particular significance in addressing the risks from 4-*tert*-octylphenol in the UK. Table 2.4 provides a summary of the production and use situation for the UK as it concerns OP/Es.

Table 2.4: Summary of UK Situation for OP and OPEs

Production	**Tonnage/Year**			
	2005	**2004**	**2003**	**2002**
Production of OP	0	0	0	0
Production of OPE	~180	~170	~150	~350
Current Uses of OP and OPEs				
Rubber formulation	Confirmed use of OP in the UK.			
Insulating varnishes	No information received to confirm this use in the UK or indeed, EU. The ESPA, however, indicates a minor use in PVC stabilisers and this does not apply to the UK.			
Printing inks	Although no specific company information has been received, this is considered a relevant use of OP in the UK.			
Emulsion polymer manufacture	Confirmed use of OP in the UK.			
Paints	Confirmed use of OP in the UK.			
Historic/Unconfirmed/Soon to be Discontinued Uses				
Oil (offshore) use	Historic use which has been discontinued for many years			
Textiles/leather	While the prevailing industry view is that this constitutes a historic (or at best, a minor) use of OPEs, the tonnage of OP/Es supplied to these sectors has increased significantly from the RER tonnage.			
Pesticides	Use of OP in pesticides is to be discontinued by December 2006 under the terms of the UK Voluntary Agreement.			

Source: EA, 2005a

2.3 Other Potential Uses of Octylphenol and Octylphenol Ethoxylates

In discussing other potential uses of OP/Es, it should be borne in mind that due to the unique nature of resin chemistry, it is theoretically possible that OP could be used in a vast majority of applications which involve phenolic (and possibly, other) resins. Also, as noted in the RER, there is some degree of interchangeability between NP and OP in resins which has the theoretical potential to result in some unaccounted uses.

As noted by one manufacturer, it is very difficult to describe the uses of OPEs in niche applications as, in general, a mixture of surfactants is used for each specific application to achieve optimal performance. These surfactant mixtures may vary from formulator to formulator as will the blending ratios; in addition, it is not often possible to know the final destination of OPEs which are sold to traders or 'middle men', although the sectors supplied may be expected to be similar to those already known. One company sold around 30 tonnes of OPEs to such traders in the last year.

As part of the consultation for the RRS, information was provided by a distributor of OPEs in the UK and the breakdown of sales is shown in Table 2.5 below. This table clearly shows that there are a number of sectors using OPEs which have not been directly accounted for in the RER. This highlights a major difficulty in studies of this nature which rely on the voluntary provision of information by industry. In the case of OPEs, it is possible that the manufacturers are not aware of downstream uses of the substance.

Table 2.5: Sales of OPEs by a Single Distributor in the UK

Market/Sector	Volume kg/Year		
	2004	**2005**	**2006**
Distribution	6,500	-	-
Metal cleaning	850	2,000	-
Fragrances	400	850	200
I&I cleaning	1,700	3,150	-
Construction	400	-	-
Floor finishes	400	-	-
Latex	200	200	-
Automotive care	200	-	-
Export	650	200	-
Household cleaning	200	-	-
Total	**~11,500**	**~6,500**	**200**

As a result, the uses identified below cover the uses of phenolic resins and OPEs which have been described in the RER and those identified in the course of consultation:

- **lubricant additives**: for the RER, the American Chemistry Council reported that some of their member companies used OP in this area. Consultation with a number of companies in Europe (for the RER) showed that, although a small quantity of OPEs is present in a range of lubricant types, none made use of the substance as such in lubricants and the scale of this use in the EU was very limited. Information received for the RRS, however, indicates that around 160 tonnes of OPEs were manufactured and supplied for use in lubricant additives in the EU in 2005. Consultation with a major global manufacturer of lubricants failed to highlight OP as an ingredient in their formulations; however, it was noted that some of their raw material suppliers specified 'alkyl phenols' as being present in some of the formulations that they supplied. The chemical composition of these raw materials (predominantly used in the formulation of engine oils) is, however, considered proprietary or confidential;

- **adhesives**: based on information from OECD Screening Information Data Set (SIDS,1994) and literature, resole resins are reacted with alkaline earth metal hydroxides to yield metal resinates, which are used as adhesives. It is also known that phenolic resins are widely used as binders in a variety of adhesives. Information received from one company for the RRS confirms the use of OPEs (when used in combination with other surfactants as an emulsifying agent for low molecular weight epoxy resin) as a coating binder on continuous filament glass fibre reinforcements.

The company reports growth in their use of OPEs due to an increase in the production volume of glass fibre product coated with this particular epoxy resin binder which is becoming more dominant in a number of market segments (e.g. wind energy – composite wind farm blades, etc). This company, however, notes that they are currently searching via numerous surfactant suppliers for a more environmentally friendly alternative and will be switching to such an alternative if it fulfils their technical requirements;

- **cleaning products**: information received from both the EU and UK associations representing manufacturers of cleaning products suggests that OP/Es are not used in cleaning products. According to UKCPI, their members manufacturing domestic cleaning product have not used NP/OP since the mid 1970s, while members in the Industrial and Institutional sector have not used them since the mid 1990s. One manufacturer/supplier, however, indicates that around 150 tonnes of OPEs were supplied for use in cleaning products in 2005. Table 2.5 above also shows that over 3 tonnes of OPEs were supplied for use in cleaning products. This suggests a possible replacement of NP/Es with OP/Es in these applications – on the basis that these are not historically significant uses of OP/Es in the cleaning sector;

- **metal cleaning applications**: the British Association for Chemical Specialities (BACS) reported a small use of OP/Es in the UK for the RER. Information received for the RRS indicates that at least 50 tonnes of OPEs were supplied to metal cleaning applications in the EU in 2005 – it is, however, unclear how much of this was used in the UK. One company which used around 2.5 tonnes of OPEs in the metal cleaning sector, however, provided information for the purposes of this RRS. The company notes that its products are used mainly as heavy duty cleaners and for non destructive testing (i.e. crack testing by chemical means of aircraft turbine blades) in the aerospace industry. These OPE-based products provide effective wetting of metal surfaces, are good surface tension reducers and emulsifiers.

  This company has developed alternatives to OPE; unfortunately, customer uptake of these alternatives is really low (and slow). For surface treatment applications, it observes that there are a number of alternative ways of reaching the same technical standards; however, customers are unwilling to change their processes. For use in critical applications (such as testing of aircraft turbine blades), it also considers that it has suitable alternatives within its product portfolio. These alternatives are suggested to present lower environmental and human health risks and any minor reductions in technical performance that might result could be compensated for by increased process intensity or temperature. The company expects that a substitution of OPEs in these applications would involve minimal costs and change-over time (~6 months) as the research and development of alternatives is already complete;

- **fragrances**: one EU manufacturer of fragrances indicated that they previously used OPE to aid solubility in low alcohol products; however, they do not use these OPEs anymore as the product in which it was used became obsolete before they could find a suitable alternative. Table 2.5 again shows that there are significant on-going sales of OPEs to the fragrance sector;

- **pharmaceuticals**: information received during the RRS shows that one EU manufacturer/supplier of OP/Es sells them to a pharmaceutical company within the EU (outside of the UK) producing active pharmaceutical ingredients and advanced intermediates. OP is used as an intermediate for further chemical reactions here. No further information on this use was received for the RRS;

- the **foundry industry**: while it is suggested in the open literature that phenolic resins are used in the foundry industry, there is no indication that these resins are based on octylphenol. No information has been received in the course of the RRS to indicate that this use is of relevance in the UK or EU;

- **paper coatings**: in theory, OP-based reins could be used to replace uses of NP-based resins in carbonless copy paper (CCP) coatings. However, the European Phenolic Resins Association (EPRA, 2004 in EA, 2005a) confirms that there is no record of any previous commercial use of OP in the European CCP industry, which is currently based entirely on NP-resin technology. This use is, therefore, considered not to be applicable to the UK or EU;

- **fuel oil stabilisers**: 2-5% of the OP (presumed to be 4-*tert*-octylphenol) produced in the USA is used in fuel for aeroplanes. CEPAD were unaware of such a use in Europe and no further information on confirming this use in the UK was received for the RRS;

- **injection moulding**: the RER notes a possible use in polycarbonates used in injection moulding, for example to produce compact discs, however, no further information on this use was received for the RRS; and

- **ultraviolet stabilisers**: the RER notes a reaction with sulphur dichloride to produce thio-bisphenol derivatives used as ultraviolet stabilisers, for example in polypropylene fibres used in outdoor carpets. While no information on this use within the UK was received for the RRS, A major manufacturer/supplier of OP has indicated that it uses around 450 tonnes of OP for the manufacture of an octylphenol derivative which is used as an antioxidant intermediate in the manufacture of UV stabilisers for coatings. This use, however, takes place outside the EU.

In general, for the purposes of the RRS, it is likely that some of these uses are now historical in the UK (and EU) and, if they still occur, they are probably only minor in tonnage terms. It is also likely that some or all of them relate to the use of the derivatives rather than the parent substance. It should also be borne in mind that the use pattern in the USA is likely to be different than in the EU because OP is less expensive there (because the availability of octene in Europe is more limited) (CEPAD, 2002 in EA, 2005a). On the other hand, it also appears that there are a significant number of unaccounted uses which are likely to contribute to releases to the environment. These should be borne in mind in preparing a RRS.

3. RESULTS OF THE HAZARD, RISK AND PBT ASSESSMENT UNDERTAKEN UNDER THE ENVIRONMENTAL RISK EVALUATION FOR OCTYLPHENOL

3.1 Overview

This section reproduces the main points, results and conclusions of the RER for 4-*tert*-octylphenol. The aim is to describe the nature of the environmental effects of 4-*tert*-octylphenol identified in the RER that are of importance to the RRS. The RER addresses not only the current use pattern of 4-*tert*-octylphenol but also the impact of future regulatory and market developments relating to NP/Es on OP emissions and exposure. Results of a risk assessment that assumes total replacement of NP by 4-*tert*-octylphenol in all of its applications is thus presented in Section 3.3, and the implications of the non-deliberate release of 4-*tert*-octylphenol as a consequence of NP production and use are presented in Section 3.4.

3.2 Risks Relating to Current Use Pattern

3.2.1 Overview of Risk Characterisation

Table 3.1 summarises the lifecycle stages and the associated environmental compartments for which conclusion (iii) has been reached in the RER.

Table 3.1: Lifecycle Areas of 4-*tert*-octylphenol Associated (✓) with Conclusion (iii) in the RER

Lifecycle stage		Terrestrial environment	RCR	Aquatic environment	RCR
Production of 4-*tert*-octylphenol		✓	76.2	✓*	44.5
Phenol–formaldehyde resins	Resin manufacture	✓	79.1	✓*	46.2
	Resins in rubber formulation	✓	1.49	✓	4.05
	Resins in varnishes	×	0.65	✓	1.82
	Resins in printing inks	✓	27.7	✓	64.4
	Ethoxylated resin production	✓	34.6	✓	80.3
	Marine paint - formulation	×	0.21	✓	1.17
	- application	✓	28.5	✓	66.2
	- disposal	✓	50.7	✓*	117
Octylphenol ethoxylates	Production	✓	82.9	✓*	25.6
	Formulation	✓	103	✓	10.9
	Emulsion polymerisation	✓	3.43	✓	1.03
	Textiles	✓	241	✓	24.6
	Paint - formulation	✓	64.4	✓	7.06
	- application	✓	1.03	×	0.79
	Pesticide application	✓	4.9	✓	2.56
	Veterinary medicines	×	0.51	✓	1.35
	Ether sulphate production	✓	481	✓	48.3
Regional risks		×	0.042	×	0.69
*WWTP risk also identified					

As can be seen from Table 3.1, the RER predicts risks for the freshwater and marine aquatic (including sediment) compartments, WWTPs (for some uses only) and the terrestrial compartment. No risks to the atmosphere or for secondary poisoning through the food chain have been identified at current levels of use.

With regard to the lifecycle areas set out in Table 3.1, it should be clarified that the predicted risks in the RER are for:

- the rubber formulation process, and not for tyre manufacture, use and/or disposal;
- varnish applications;
- the ink production (or formulation) process, and not printing processes or recycling of paper printed with these inks;
- chemical synthesis of ethoxylated resins, and not for oil recovery/offshore use;
- textile finishing activities, and not for textile use; and
- industrial use of paints, and not domestic and/or consumer use.

3.2.2 Key Assumptions Relating to Aquatic Risk Characterisation

Risks for surface water and sediment are predicted for all of the scenarios, with the exception of the application of paints formulated with OPEs. The RCR for the regional concentration in water is 0.69, which indicates no risk from the background concentration. However, the background concentration does make a significant contribution to the PEC for a small number of scenarios: marine paint formulation (RCR = 1.17), emulsion polymerisation (RCR = 1.03) and veterinary medicine (RCR = 1.35) applications. These three scenarios would not show a risk based on their local concentrations alone.

There are some uncertainties in the risk characterisation for the aquatic environment, as highlighted in the RER:

- **emissions and exposure**: the PECs have been calculated using default release estimations from the TGD and Emission Scenario Documents (ESD), and data on production and use tonnage supplied by CEPAD. Measured environmental levels tend to suggest that emissions might not be as high (or the substance is not as persistent) as predicted in the RER; the limited site-specific data for 4-*tert*-octylphenol producers indicate lower concentrations than those modelled. The RER also assumes, for simplicity, that the phenolic resins consist only of 4-*tert*-octylphenol (i.e. the formaldehyde has been neglected) and that the content of residual 4-*tert*-octylphenol in the resin is 3% of the 4-*tert*-octylphenol used[8];

- **regional contribution**: the calculated regional concentration is of the same order as the maximum measured values in surface water, and may therefore be an over-estimation. More extensive monitoring of levels in surface waters at suitable

[8] Information from BLIC (ETRMA) suggests a lower residual OP content in tyres of 1.5%; however, a major manufacturer indicates that residual is between 2 – 4%, hence, the 3% residual is an appropriate average.

locations (away from the direct influence of point sources) would allow a measured regional background concentration to be used, with an impact on the conclusions for those scenarios which currently have RCRs just above unity; and

- **effects**: the aquatic PNEC of 0.122 µg/L is derived using an assessment factor of 50.[9] By comparison with the data available for NP, further testing might be expected to lead to a NOEC of the order of 3 µg/L, which would give a PNEC of 0.3 µg/L with an assessment factor of 10. This value would remove from concern the use of resins in varnishes (RCR=1.82), marine paint formulation (RCR = 1.17) and the use of ethoxylates in emulsion polymerisation (RCR = 1.03) and in veterinary medicines (RCR = 1.35). Taking the current data set, the highest PNEC achievable with an assessment factor of 10 would be 0.61µg/L. This value would also remove the concern over the use of resins in rubber and pesticide applications (with OPEs). This would, however, still leave over half of the scenarios as showing a risk.

3.2.3 Key Assumptions Relating to Terrestrial Risk Characterisation

All local scenarios indicate a possible risk to the soil compartment, with the exception of the use of resins in varnishes, formulation of marine paints and use of OPEs in veterinary medicines. There are, however, uncertainties in the risk characterisation for the terrestrial environment.

Both the PEC and PNEC values are based on those for the aquatic compartment, which are, themselves, uncertain and there are also no monitored data to confirm the predicted levels. In practice, direct releases of OP to the terrestrial compartment are unlikely to occur given its production method and use pattern. However, high concentrations are predicted in all soil types because of the application of sewage sludge from some processes that use the substance (or its derivatives) and discharge aqueous effluent to water. There is, however, a paucity of specific information on the fate of sludges that contain 4-*tert*-octylphenol and the concentrations therein.

3.3 Risks Relating to Replacement of Nonylphenol by 4-*tert*-Octylphenol

The RRS for NP identified other APs (particularly OP) as the only alternatives to NP where they are used as an intermediate in the formation of derivatives other than ethoxylates (e.g., phenolic resins, phenolic oximes and plastic stabilisers). In addition, although OPEs were not identified as a likely substitute for NPEs, their similar chemical nature does not preclude the possibility. Indeed, NP can be substituted by 4-*tert*-octylphenol in most ethoxylate uses (as occurs in the USA) (EA, 2005a).

[9] The PNEC selected for this assessment is similar to the draft Maximum Acceptable Concentration quality standard for surface waters (0.13µg/L) proposed under the Water Framework Directive. The draft Annual Average quality standard (0.06µg/L) is lower by a factor of two (this is based on an assessment factor of 100 applied to the lowest 'traditional' fish NOEC of 6.1 µg/L).

Appendix 4 of the RER considers a hypothetical complete substitution scenario in order to investigate whether use of OP as a substitute for NP is likely to give rise to a similar level of risk. This required a number of assumptions to be made for comparative purposes and these are set out in the RER. Table 3.2 below summarises the lifecycle stages and the associated environmental compartments for which conclusion (iii) has been reached for this hypothetical substitution assessment.

Table 3.2: Lifecycle Areas Associated (✓) with Conclusion (iii) in the RER based on a Hypothetical Substitution of Nonylphenol with 4-*tert*-octylphenol

Scenario	Aquatic	Terrestrial	Secondary Poisoning
Direct Release of Octylphenol			
Production of octylphenol	✓	✓	
Production of ethoxylates	✓*	✓	✓
Alkylphenol–formaldehyde resin production	✓	✓	
Tris(alkylphenyl)phosphite (TAPP) production	✓		
Epoxy resin manufacture	✓		
Production of other plastic stabilisers	✓	✓	
Phenolic oxime production	✓*		
Indirect Release of Octylphenol from Ethoxylates			
Formulation of pesticides	✓*	✓	✓
Captive use by the chemical industry	✓	✓	✓
Use in electrical engineering	✓	✓	
Industrial and institutional cleaning	✓*	✓	✓
Use in leather processing	✓*	✓	✓
Use in metal processing and extraction	✓*	✓	✓
Use in the photographic industry	✓	✓	
Use in polymer production	✓	✓	
Use in the pulp and paper industry	✓*	✓	✓
Use in textile processing	✓*	✓	✓
Use in paints:			
- Production	✓	✓	✓
- Domestic use	✓	✓	
- Industrial use	✓	✓	
Use in civil/mechanical engineering	✓*	✓	✓
Regional from Direct and Indirect Releases			
Regional	✓	✓	
*WWTP risk also identified			

The results suggest a possibility of adverse environmental effects for all the endpoints considered, with similar risks as predicted for NP. This is to be expected in view of the similarities in environmental fate, behaviour and toxicity of the two substances. However, the assessment is simplistic and should be viewed as illustrative for three main reasons:

- a number of PNECs could be refined;
- the usefulness of any OP derivative for the intended use has not been considered; and

- given the hypothetical nature of the assessment, no real data were available to allow any refinement of the exposure assessment. Should 4-*tert*-octylphenol ever replace NP in some or all of the uses assumed here, there may be differences in the volumes, use patterns and releases (e.g., through differences in engineering controls arising from the different physical state of the two substances), which could not be predicted in this assessment.

On this note, it is understood that, while NP can be substituted by 4-*tert*-octylphenol in most ethoxylate uses and 4-*tert*-octylphenol is widely used in the USA for their production, similar use in Europe is currently limited to specialist applications, mainly due to:

- the high price of 4-*tert*-octylphenol (arising from the limited availability of octene feedstock); and
- difficulties in handling (NP is a liquid, whereas 4-*tert*-octylphenol is a solid at room temperature and, therefore, pumping of the material is only possible at temperatures around 90°C).

In addition, many uses of NPEs can be substituted by the use of fatty alcohol ethoxylates. These are significantly cheaper than OPEs (but slightly more expensive than NPEs) (CEPAD, 2002 in EA, 2005a).

In general, industry (especially the signatories to the UK Voluntary Agreement on NP/Es and OP/Es) is of the opinion that there has been no replacement of NP/Es by OP/Es. While it is understood that there has not been any overt marketing of OP/Es as substitutes for NP/Es, the discussion in Section 2.3 indicates that some uses of OPEs have emerged which suggest a replacement of NPEs with OPEs (e.g. in cleaning products). Any risk management measures recommended by this RRS will have to take this into account.

3.4 Risks Relating to Release of Octylphenol as a Consequence of Nonylphenol Production and Use

Branched OP isomers similar to 4-*tert*-octylphenol have been identified as a potentially significant impurity in commercial NP with exposure arising during the production and use of NP. PECs have been calculated using the EUSES modelling software for the production and use scenarios from the original nonylphenol risk assessment report. A typical impurity level of 5% has been assumed. The results are presented in Table 3.3 overleaf, which shows risks for several uses of NP. However, the assessment is simplistic and should, again, be considered as purely illustrative because:

- the tonnage of NP is likely to have changed, and is expected to change further once risk management measures (including the partial EU ban of several uses of NP) and the voluntary agreements are implemented; and

- the isomers involved might not actually include the 4-*tert*-octylphenol structure. However, they would be expected to behave in a similar way and so the properties of the latter substance were used in this assessment.

Table 3.3: Risks Associated (✓) with Unintentional release of Octylphenol		
Scenario	**Aquatic**	**Terrestrial**
Direct Release of Octylphenol		
Production of nonylphenol ethoxylates:	✓*	✓
Nonylphenol–formaldehyde resin production	✓	×
Production of other plastic stabilisers	✓	×
Indirect Release of Octylphenol from Ethoxylates		
Formulation of pesticides	✓	✓
Captive use by the chemical industry	×	✓
Use in electrical engineering	✓	✓
Industrial and institutional cleaning	✓	✓
Use in leather processing	✓	✓
Use in metal processing and extraction	✓	✓
Use in the photographic industry	×	✓
Use in polymer production	×	✓
Use in the pulp and paper industry	✓	✓
Use in textile processing	✓*	✓
Use in paints: production	✓	✓
Use in civil/mechanical engineering	✓	×
Regional from Direct and Indirect Releases		
Regional	×	✓
*WWTP risk also identified. *Note: 3 scenarios (textile processing, metal processing and extraction and production of NPEs) show risk endpoints for secondary poisoning (earthworm).*		

3.5 PBT Assessment and Endocrine Disruption

An assessment of OP against the TGD criteria for assessing the persistent, bioaccumulative and toxic (PBT) properties of a substance showed that (EA, 2005; OSPAR, 2004) with regard to:

- **persistence**: although OP is inherently biodegradable, it is not considered to be readily biodegradable and **meets** the screening criterion for **P** or **vP**;

- **bioaccumulation**: while the highest measured bioconcentration (BCF) factor in fish is 297, the predicted BCF from log K_{ow} is 634 - which is used in the RER as a reasonable worst case. Both of these values are below the B criterion (BCF >2,000) and, as such, OP **does not meet** the **B** criterion; and

- **toxicity**: the lowest chronic aquatic NOEC is 6.1 µg/l which exceeds the toxicity criterion (chronic NOEC <0.01 mg/L) and, as such, OP **meets** the **T** criterion.

In summary, OP meets the TGD criteria for persistence (P) and toxicity (T). While OP does not meet the TGD marine risk-assessment criteria for a PBT chemical; it meets the UK Government Chemicals Stakeholder Forum's (CSF) PBT criteria for substances of concern. This is because the CSF's bioaccumulation criterion is slightly less stringent (log K_{ow}>4 or BCF >500, where data are available).

OP also exhibits endocrine disrupting properties and snails have been shown to be a potentially sensitive group of organisms. It has thus been included in the candidate list under the EC Community Strategy on Endocrine Disruptors as an endocrine disruptor of medium concern. The Environment Agency in the UK has also published a strategy for endocrine disrupting substances in the environment and OP/Es are included on the list of substances for which endocrine-disrupting effects have been reported (OSPAR, 2004).

3.6 Monitoring Data

According to the RER, only limited monitoring of OP has been carried out in the UK. In general, the concentration of OP in surface water was below 1µg/L and in many cases it was below the limit of detection of the analytical method used. Similar values have been reported from elsewhere in Europe (as shown in Table 3.5 overleaf). Some higher concentrations were found in trade and sewage effluents, with the highest value (10.8 mg/L) reported from an untreated trade effluent from an OP manufacturing plant (EA, 2005a).

Table 3.4 sets out the main industrial point sources of OP/Es into the aquatic environment in the UK. As can be seen clearly, the main releases are from OPE-related processes, rather than OP and the sources of these emissions are known. In understanding the Table, it should be borne in mind that there are other emitters of OP/Es; however, their releases were reported as being below the reporting threshold (i.e. 100kg/year) for IPC/PPC sites.

Table 3.4: Releases of Octylphenol and Octylphenol Ethoxylates in the UK

	Yearly Discharges of Octylphenol to Controlled Water (Kg)							
	1998	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Company A	300	300	300	300	300	240	400	250
Company B	<1	2.5	4	9.8	<100			
Company C						170	130	120
	Yearly Discharges of Octylphenol to Sewer (Kg)							
	1998	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Company B		<1	<1					
Company D		23	38	<1				
	Yearly Discharges of Octylphenol Ethoxylates to Controlled Water (Kg)							
	1998	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Company A					175	200	400	300
Company B					9,282	12,103	11,740	7,619
	Yearly Discharges of Octylphenol Ethoxylates to Sewer (Kg)							
	1998	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Company B						500		3,143
Company E						663	376	

Source: The Environment Agency's Pollution Inventory

Table 3.5: Environmental Concentrations of Octylphenol and Octylphenol Ethoxylates Across the EU								
Country	**Substance**	**Year of sampling**	**No. of samples**	**Water**	**Min - Max**	**Median**	**Comment**	**Literature**
Austria	OP	1998	16	Influent to STP	43 – 362 ng /L	77 ng/L	only in 1 sample OP was > 100 ng/L	UBA Wien, report BE 151, 1999
Austria	OP	1998	17	Effluent of STP	57 – 241 ng/L		only in 1 sample OP was > 100 ng/L	UBA Wien, report BE 151, 1999
Austria	OP	1999	34	Rivers	n.d. – 240 ng/L	n.d.	only in 1 sample OP was detectable	UBA Wien, report BE 150, 1999
Netherlands	OP	1996		River Meuse		< 500 ng/L		S. Jobling, J.P. Sumpter, Environ. Toxicol. Chem. 15 (1996) 194-202
Netherlands	OPEs	1996		River Meuse		< 900 ng/L		S. Jobling, J.P. Sumpter, Environ. Toxicol. Chem. 15 (1996) 194-202
Netherlands	OP	1996		River Rhine		< 300 ng/L		S. Jobling, J.P. Sumpter, Environ. Toxicol. Chem. 15 (1996) 194-202
Netherlands	OPEs	1996		River Rhine		< 700 ng/L		S. Jobling, J.P. Sumpter, Environ. Toxicol. Chem. 15 (1996) 194-202
Netherlands	OP	1999		River Meuse		n.d.		Association of River Waterworks – RIWA, November 2000
Netherlands	OPEs	1999		River Meuse		n.d.		
Netherlands	OP	1999		River Rhine		n.d.		
Netherlands	OPEs	1999		River Rhine		n.d.		
Germany	OP	1998		Surface Waters in Berlin	max. 430 ng/L	120 ng/L	No OP detectable in the sediment	UBA report 216 02 001/12 Fromme, 1998
Germany	OP	2000		River Schussen		8 ng /L		Pfluger et al., research project PAÖ Ö-98004 of Baden Wuerttemberg, 2001
Germany	OP	1999		River Elbe	0.4 – 6.3 ng/L	1.0 ng/L	13 sampling points	ARGE Elbe report, 2000
Germany	OP + 1 mol EO	1999		River Elbe	0.75 – 6.3 ng/L	1.0 ng/L	13 sampling points	ARGE Elbe report, 2000
Germany	OP + 2 mol EO	1999		River Elbe	0.61 – 6.8 ng/L	1.0 ng/L	13 sampling points	ARGE Elbe report, 2000
Germany	OP	1999	40	Side rivers to river Elbe		3.3 ng/L		ARGE Elbe report, 2000
Germany	OP	1999		in sediments		55 ng /L		ARGE Elbe report, 2000
Germany	OP	2000		River Lockwitzbach		8 ng/L	river is located close to Dresden	Nagel, R., Dresden University, UBA project 29965221/05 of year 2000
Germany	OP	2000		River Körsch		105 ng/L	river is located close to Dresden	Nagel, R., Dresden University, UBA project 29965221/05 of year 2000

A monitoring exercise was carried out at two phenolic resin production plants to evaluate the levels of OP and NPE potentially released to aquatic systems. This Report was provided by EPRA for consideration in the RRS.

For the purposes of the RRS, a comparison was made between the measurements made at these two sites and the calculations in the RER for OP. Based on an analysis of the data provided, it is concluded that the data provided can only be used for the assessment of the two sites as specific locations. While it may be possible to apply a similar degree of removal in the WWTP at other sites where there is an on-site WWTP and the production process is similar in timing to those at the two sites, further information on sludge disposal would be needed to consider the possible soil exposure at other sites (or further measurements to demonstrate the fate of the octylphenol in the industrial WWTPs). In terms of the specific assessments for the sites, if the dilution factor (mentioned in the EPRA Report) is applied to the effluent from Site 1 (which can be more easily compared to the scenarios in the RER than Site 2), the highest concentration in the effluent gives a diluted concentration, which, when added to the regional PEC, is slightly above the PNEC and as such, would require risk management measures.

3.7 Additional Sources of OP Emissions

In undertaking the RRS, a number of additional sources of OP/E to the environment were identified - some of which have been discussed in Section 2. These calculations were undertaken by BRE Environment on the request of the Environment Agency.

Of potential significance within the context of the RRS is the additional emissions of OPE resulting from the washing of imported textiles. It may be assumed that these additional releases would take place to surface water via a waste water treatment plant (WWTP) and as such, would significantly affect the regional concentration of OP.

As this Scenario (i.e. emissions from washing of textiles) was not considered in the RER, Annex 2 calculates the additional load of OP required on a regional scale to increase the regional PEC for water to the PNEC value.

The release to surface water giving rise to a risk is 23 kg/day, compared to the current value of 12.6 kg/day for regional emissions to surface water. This is an additional 10.4 kg/day. If this was due to the release of OP, then the additional release to waste water needed would be 14 kg/day, or 5.1 tonnes per year. On the other hand, if this was due to the release of OPEs, then based on a yield of 2.5% octylphenol from OPEs, the additional release of OPEs to waste water would be 416 kg/day. This is equivalent to a release of 152 tonnes of OPE per year to WWTP. Assuming that the sources of these releases are dispersive, then the total EU releases would be 10 times higher than these values.

Hence, if an OPE content of 1 g/kg textile is assumed, then 152 tonnes of OPE would come from 1.52×10^8 kg (1.52×10^5 tonnes) of cloth for a region (EU imports would be 10 times larger). Available information suggests a level of APEs of 1-2 g/kg textiles, with no up-to-date and reliable indication of the proportion of APEs which could be OPE (0.5

g/kg textiles has been suggested). If OPE makes up only a fraction of the APEs, then the amount of textiles needed could be much higher. It has been suggested that up to 180 tonnes per year of OPEs may be entering the UK aquatic environment from textiles alone - this is based on certain assumptions which appear to be rather unrealistic.

At present, there is no up-to-date and peer-reviewed information on the actual proportion of textiles imported into the UK/EU which might contain APEs - and which proportion of these APEs are OPEs. It is considered that a worst case scenario - which assumes that all printed textiles imported into the UK/EU contain OPEs - may be rather unrealistic. In general, it is difficult to put the values into context within this RRS without a detailed peer review of the data.

Other possible sources of OP/Es are use areas indicated by the OPE distributor in Table 2.5 which are not covered directly in the RER. These include uses in cleaning products for institutional and industrial cleaning and in metal cleaning. These applications certainly have the potential to result in the complete release of the OPE used. The quantities quoted for the distributor could make a contribution of up to around 10% of the additional tonnage required as calculated above. This is despite only amounting to a relatively small fraction (around 1% at most) of the OPE use included in the RER. The level of sales from this distributor reduced over the period 2004-2006, so the 2004 values may be a worst case; against this, there may be other distributors with similar sales for whom information is not available. A key issue in this regard relates to whether the tonnage from the distributor is "new" substance not included in the quantities included in the RER, or if it replaces part of the substance addressed there. It is not clear if the distributed tonnage is new production of OP or OPEs, new import, or part of the tonnage included but allocated to different uses. There was no unallocated tonnage in the RER.

Calculations assuming that other products from the breakdown of OPEs have similar toxicity to OP have not been carried out for the regional emissions. These would require information on the properties of these other products, as they would be expected to behave differently from octylphenol in the environment. The calculations would also have to be applied to the existing emissions as well. However, a qualitative assessment can be made. The other products are likely to be more hydrophilic than octylphenol due to the presence of the ethoxylate and carboxylic acid groups; hence they will remain more in the aquatic compartment. This should mean that the combined concentration is higher than that of octylphenol, and hence that a smaller addition would be required. It could also be considered that these products may continue to degrade and will form some additional octylphenol in the course of this; hence the octylphenol yield will be higher than the 2.5% estimated initially. This will also mean that a smaller addition may be needed to give rise to a concentration equivalent to the PNEC.

4. EXISTING CONTROLS ON EMISSIONS AND EXPOSURE TO OCTYLPHENOL AND OCTYLPHENOL ETHOXYLATES

4.1 Overview

The following sections provide an overview of the various legislative and non-legislative risk management measures that are in place, or are likely to be implemented, to control the emissions and exposure to 4-*tert*-octylphenol. The analysis of the effectiveness of the existing controls will provide the basis of assessing whether these controls are sufficient to address the identified risks and, where not, what additional controls (or tightening of existing controls) may be required.

Firstly, an overview of the EU-wide legislative controls is provided. This is followed by a consideration of other international and national initiatives which are of relevance. Finally, there is a consideration of existing risk management measures in various use sectors, where this includes voluntary action in the UK (which is covered in detail in Annex 1).

4.2 EU-wide Legislation Controlling Emissions and Exposure

4.2.1 Integrated Pollution Prevention and Control Directive (96/61/EC)

At the Community level, the main existing legislation of direct relevance to controlling the risks from the point sources of 4-*tert*-octylphenol is the IPPC Directive (96/61/EC). The IPPC Directive lays down measures designed to prevent or, where that is not practicable, to reduce emissions to air, water and land from the activities mentioned in Annex I to the Directive, including measures concerning waste. It also makes reference to, or is referred to, by the main pieces of legislation in these compartments (e.g. the Waste Directives, Water Framework Directive, etc.).

All installations covered by Annex I of the Directive - mainly medium-sized and large scale industrial installations but also waste management installations - are required to obtain an authorisation (permit) from the authorities in the various EU countries[10]. Installations/sites should be operated (and permits granted) according to the 'best available techniques' (BAT) which are set out for the various process types covered in BAT Reference (BREF) Documents. The BREF Documents are only intended to assist the licensing authorities[11] as the final decision on emission limits and process conditions for individual sites is established by the Member States' competent authorities. Examples of some of the BREF Documents which are of relevance to this RRS include:

[10] New installations listed in Annex I require a permit from the competent authority before being put into operation. Existing installations will have to operate in accordance with the Directive by 30th October 2007 at the latest.

[11] Article 9 of the Directive states that authorities must take into account (a) the technical characteristics of the installation, (b) its geographical location and (c) the local environmental conditions.

- reference document on BAT for **large volume organic chemicals** – February 2003;
- reference document on BAT for the **textiles industry** – July 2003;
- reference document on BAT for the **manufacture of organic fine chemicals** – draft of December 2005; and
- reference document on BAT in the **production of polymers** – draft of April 2005.

Under IPPC, a permit application must include a description of the nature and quantities of foreseeable emissions from the installation into each medium as well as identification of significant effects of the emissions on the environment. Emission limit values (ELVs) may be set in the permit for all pollutants likely to be released in significant quantities. Permits issued by the authorities must also contain suitable release monitoring requirements, specifying measurement methodology and frequency, and the operator must provide monitoring data to enable compliance assessment.

IPPC does not impose any specific restrictions on the release of 4-*tert*-octylphenol or its ethoxylates to the environment. However, releases are restricted under the general principles of IPPC (as discussed earlier) and companies (in the UK) are required to report releases of OPs and OPEs to the Pollution Inventory. A reporting threshold of 100 kg/year to either sewer or controlled waters applies in the UK.

The IPPC Directive applies among others to the following types of installations (listed in Annex 1 of the Directive) of relevance to this RRS:

- chemical installations for the production of basic organic chemicals, such as:
  - oxygen-containing hydrocarbons such as alcohols, aldehydes, ketones, carboxylic acids, esters, acetates, ethers, peroxides, epoxy resins (*of relevance for production of resins and other OP derivatives*);
  - basic plastic materials (polymers, synthetic fibres and cellulose-based fibres) (*of relevance for emulsion polymerisation*);
  - synthetic rubbers (*of relevance for rubber formulation*);
  - dyes and pigments (*of relevance for printing inks and paints*);
  - surface-active agents and surfactants (*of relevance for emulsion polymerisation*);
- chemical installations for the production of basic plant health products and of biocides (*of relevance for veterinary medicines and pesticides*);
- plants for the tanning of hides and skins where the treatment capacity exceeds 12 tonnes of finished products per day (*of relevance for leather treatment*); and
- installations for the surface treatment of substances, objects or products using organic solvents, in particular for dressing, printing, coating, degreasing, waterproofing, sizing, painting, cleaning or impregnating, with a consumption capacity of more than 150 kg per hour or more than 200 tonnes per year (*of broad relevance to a variety of OP processes and sectors*).

4.2.2 Water Framework Directive (2000/60/EC)

The Water Framework Directive (2000/60/EC) (WFD) entered into force on 22 December 2000. It introduces a new framework for controls on certain 'priority substances' that present a significant risk to or via the aquatic environment. Member States are required to adopt measures to eliminate the pollution of water bodies by 'priority substances', as well as progressively reduce pollution by other substances which would prevent Member States from achieving the objectives set for surface waters.

4-*tert*-octylphenol has been included in the list of priority substances in Annex X to the Directive. This places an obligation on Member States to take action for the progressive reduction of emissions of this substance via the aquatic environment, through setting quality standards and establishing emission control measures. The proposed environmental quality standard (EQS) for 4-*tert*-octylphenol under the latest proposals from the Commission (July 2006) under the WFD are as follows:

- 0.12 µg/L and 0.012 µg/L as the annual average (AA) for 'inland surface water' and 'other surface water' respectively. Compliance with this standard means that for each monitoring point within the water body, the arithmetic mean of the concentrations measured at different times during the year should not exceed the standard; and

- 0.13 µg/L as the maximum allowable concentration (MAC) for both inland and other surface waters. Compliance with this standard means that the measured concentration at any monitoring point within the water body should not exceed the standard.

Prior to action under the WFD, the Environment Agency had proposed an operational EQS of 1 µg/L annual average and 2.5 µg/L MAC in both fresh and marine waters (EA, 2004c in (EA, 2005a).

In considering the relevance of WFD, it should be borne in mind that the introduction of actual controls and measures under the WFD is occurring over time, and the Directive provides a timetable for the identification of measures and river basin management plans (RBMPs).

While it cannot be estimated for certain what the impacts of the proposed EQS will be on OP emissions, it is worth noting that the proposed EQS is lower than the existing UK one by a factor of between 10 (AA) and 20 (MAC). Even if, as highlighted in Section 3, there is limited evidence to suggest that there is a wider UK problem (i.e. elevated background concentrations) with regard to OP/Es in the aquatic environment (apart from at specific 'hot spots'), it is likely that any further reductions (in order to comply with the WFD) will be achieved at the identified point sources of OP/Es to the environment.

4.2.3 Council Directive 67/548/EEC on the Classification, Packaging and Labelling of Dangerous Substances

The classification and labelling of a substance under this Directive is aimed at improving awareness of the 'proper' use, handling and disposal of the substance. To this end, the packaging of all classified substances must be labelled to show, *inter alia:*

- symbols indicating the danger involved in using the substance;
- symbols indicating the specific risks arising from use of the substance; and
- symbols relating to safe use of the substance.

According to the RER, agreement on the environmental classification of 4-*tert*-octylphenol according to Directive 67/548/EEC was reached at an EU expert meeting in September 2004. It is now classified as 'dangerous to the environment' with the following risk phrase: *R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment*. It is also understood that OP has been classified as an 'irritant' with the following phrases: *R38 - Irritating to skin* and *R41 - Risk of serious damage to eyes*. The UK Health and Safety Executive (HSE) is currently reviewing proposals for human health classification and labelling.

It is also understood that this classification is the same as the provisional classification currently included on manufacturers' Safety Data Sheets and the NP classification.

4.2.4 Marketing and Use Restrictions under Directive 76/769/EEC

As noted earlier, OP may be a potentially significant impurity in commercial NP with exposure arising during the production and use of NP. Directive 2003/53/EC[12] (amending for the 26th time Council Directive 76/769/EEC) places restrictions on NP/E and restricts its use as a substance or constituent of preparations in concentrations equal to or higher than 0.1% by mass for the following purposes:

- industrial and institutional cleaning (except controlled closed dry cleaning/cleaning systems where washing liquid is recycled or incinerated);
- domestic cleaning;
- textiles and leather processing (except processes with no release into waste water/pre-treatment to remove organic fraction);
- emulsifier in agricultural teat dips;
- metal working (except use in closed systems where washing liquid is recycled or incinerated);
- manufacturing of pulp and paper;
- cosmetic products;
- other personal care products (except spermicides); and
- co-formulants in pesticides and biocides.

[12] The Directive entered into force on 18 June 2003 and was to be implemented by 17 January 2005 by all Member States.

4.3 Other International Initiatives

At a ministerial meeting of the Contracting Parties to the OSPAR Convention in Sintra in 1998, it was agreed that man-made hazardous substances should not occur in the marine environment and that naturally occurring hazardous substances should not exceed natural background concentrations. To this end, it was agreed to make every endeavour to cease all discharges, emissions and losses of hazardous substances that could reach the marine environment by the year 2020 (OSPAR, 1998).

As a consequence of the hazardous properties of 4-*tert*-octylphenol, a variety of activities have been initiated in an attempt to control it. For example, it was placed on the North Sea Action Plan in 1990 (NAP, 1990 in EA, 2005a), and has been included on the OSPAR List of Chemicals for Priority Action (OSPAR, 2000). OSPAR has published a background document on 4-*tert*-octylphenol that was based on an earlier version of the risk assessment (OSPAR, 2004). 4-*tert*-octylphenol has also been considered in work for the development of the EC strategy on endocrine disruptors.

Some European countries have also introduced national restrictions on either APEs generally or more specifically against 4-*tert*-octylphenol. For example, the Norwegian Environment Ministry introduced restrictions from 1 January 2002 prohibiting the import, export, sale or use of NP and OP and their ethoxylates and preparations containing these substances. This prohibition does not apply to NP and OP and their ethoxylates in or for use in paints and varnishes and in lubricating oils (Norwegian Pollution Control Authority, 2002 in EA, 2005a).

4.4 Voluntary Risk Management Measures in Certain Industry Sectors

In 2001, the UK Chemicals Stakeholder Forum (CSF) undertook a review of the risks posed to the environment and to human health via the environment as a result of uses of NP/Es and OP/Es based on the NP RAR and RRS and the draft RAR for OP - which suggested that similar risks (to those from NP) would occur if OP replaced NP. Following this review, the CSF wrote to the UK Government in June 2002 advising that a formal voluntary agreement (VA) with industry should be established to speed up a substantial reduction in the use of NP/Es in sectors likely to lead to the greatest environmental exposure and where costs are proportionate. The CSF also concluded that similar action should be taken for OP/Es because they have similar properties and could potentially be used as substitutes, resulting in similar levels of risk.

On 18 October 2002, the Government announced its decision to accept the CSF's advice and at the same time called for industry to come forward with proposals for voluntary action. Following a series of meetings and discussions between Government departments and industry sectors, and between industry sectors themselves, industry representatives submitted on 1 August 2003 proposals for voluntary action to reduce the risks from NP/Es and OP/Es. In April 2004, a number of industrial sectors signed up to a VAto take action on NP/Es and OP/Es ahead of legislation and to phase-out their use as soon as possible.

While most of the actions to be taken relate to NP/E, they also include provisions in respect to not promoting OP/E as alternatives.

The following actions relate to OP/E only:

- the chemical supply companies agreed not to promote OPEs as substitutes for NPEs in applications subject to the (then) intended marketing and use restrictions, and to introduce harmonised environmental classification and labelling for OP and OPEs;

- companies represented by the Cosmetic, Toiletry and Perfumery Association (CTPA) agreed not to use OP or OPEs as substitutes for NP and NPEs, to reformulate any products containing OP or OPEs, and to stop the manufacture or import of such products by 31 December 2004;

- companies represented by the British Association for Chemical Specialities (BACS) agreed to a similar commitment;

- the Confederation of Paper Industries of Great Britain agreed to phase-out the use of any OP or OPEs in existing formulations by 31 December 2004, and not to use these substances in any new or revised process after November 2003;

- the UK Cleaning Products Industry Association has agreed not to use OPEs as substitutes for NP or NPEs in cleaning or maintenance products, to reformulate any products containing OP or OPEs and to stop manufacturing or importing such products by 31 December 2004;

- companies represented by the Crop Protection Association agreed to implement the redevelopment of formulations for plant protection products containing OPEs and to replace them by 31 December 2006. The European Adjuvants Association (EAA) has recently agreed to sign up to the voluntary agreement; and

- the British Fragrance Association agreed not to use OP or OPEs as substitutes for NP or NPEs and to reformulate any products containing OP or OPEs with completion by 31 December 2004.

In addition, there is an agreement to monitor and report on annual sales of OPE in the UK. As part of this commitment, the resin manufacturing industry is also intending to develop Good Practice Guidance on the handling of NP in resin manufacture (EPRA, 2004 in EA (2005a)). This document would be equally applicable to 4-*tert*-octylphenol.

4.5 Existing Risk Management Measures at Specific Sites

In preparing the RRS, information was received from various sites manufacturing and supplying OP and OPEs. The main points from these submissions are summarised below:

- existing permits/authorisations under IPPC and the Environmental Protection Act do not set emission limits on OP/E for discharges to controlled waters. Releases are, however, to be reported to the Environment Agency. There are emission limits for emissions to sewer which may occasionally be set by the sewage effluent undertaker;

- a number of companies have waste management and waste minimisation practices on-site for treating OP/Es where these range from use of OP/Es in contained areas to specialised on-site waste water treatment plants (WWTPs). One company works on the optimisation of the amount of OPE-based formulation used (i.e. applying just sufficient to the required functionality without using too much excess in the production process) and currently achieves an efficiency of around 90%. At another site, pre-treatment equipment (solvent extraction of waste water and burning of residues) followed by a secondary, regional industrial waste water treatment system is in place. All production is conducted in closed units and waste air emissions are collected and burned in a special waste air incineration system. This results in emissions to the industrial waste water treatment system of <2kg/year. As such, there are a number of sites/companies that do not believe (and may be correct) that additional measures are required for their production facilities;

- despite the waste treatment facilities that are in place on some sites, the presence of localised 'hot spots' may exist due to inadequate waste treatment at other sites and risks identified in the RER may relate to such areas; and

- in terms of achieving further reductions in releases of OP/Es, it has been indicated that while recovery and/or destruction of the OPE surfactant is possible, this route would be considered capital intensive and in this case, substitution of OP/Es for other materials would be considered Best Available Technique. One respondent notes that the technical feasibility and costs of separating and incinerating wastewater containing OP/Es are still unknown. Another respondent noted that it is typically not practical to treat or handle only one waste stream to reduce a specific target molecule. Current treatment systems operate on combined effluent streams so any practical improvement would be of plant scale not for one component only and major upgrades or installation of new control technology can cost tens of millions of Euros.

PART C

INFORMATION ON ALTERNATIVES TO OCTYLPHENOL

5. ALTERNATIVES TO OCTYLPHENOL

5.1 Introduction

In developing any strategy for reducing the risks relating to a given substance, it is important to consider the availability of alternatives for the applications of concern, where this includes alternative substances, technologies and/or processes. Such considerations are important since any proposed restrictions may instigate a shift to such alternatives. The TGD requires that the use of alternatives should not result in greater or equal risks to humans and the environment.

It is also of note that the draft Annex XIV dossier TGD suggests that any restrictions dossier should present any information available on alternatives and their availability but should neither aim to assess the risks and feasibility of alternatives to the same extent as the substance of concern nor to recommend any specific alternative as the most suitable substitute. Such assessments will be the responsibility of industry if an alternative is to be used in the place of the restricted substances.

Furthermore, if it is not possible to identify any suitable alternative, this will not automatically mean that a restriction cannot be proposed; it will only be imperative to make a convincing case that the risks from the substance of concern are such that a restriction is the most appropriate risk management option. To that end, a socio-economic assessment (SEA) may play a particularly significant role in justifying a proposed restriction.

In this regard, the replacement of 4-*tert*-octylphenol by another chemical or an alternative technology or process needs to take account of:

- the availability and technical suitability of the alternative;
- the environmental and human health risks of the alternative; and
- the economic and social implications arising from use of the alternative (or from the restriction if there is no alternative).

A discussion of the availability and suitability of alternatives for the continuing uses of 4-*tert*-octylphenol - rubber formulation, insulating varnishes, printing inks, and marine and/or water-based paints - is provided below. These three uses account for over 90% of the OP consumption in the UK. For textile finishing and plant/animal health products, a discussion of alternatives has not been provided as industry broadly indicates that the availability of substitutes (amongst other factors) has resulted in a decrease in the use of OP in these sectors.

More broadly, the discussion focuses on continuing uses rather than historical uses[13] (or unconfirmed uses) as substitution is considered to already have taken place in the latter. Potential future uses (for instance, as a hypothetical replacement for NP) are not

[13] It should also be borne in mind that for some of the use sectors, there is no evidence of actual use in the EU or UK and as such there is no need for any assessment of substitutes.

considered, on the basis that, with the exception of the sectors where a marketing and use restriction has been placed on NP, there is a realistically low possibility (and incentive) for companies to move from NP to OP (due to cost). Conversely, sectors where a restriction has been placed on NP/Es and there is a theoretical possibility of OP being a suitable alternative have been considered.

5.2 Alternatives to OP-based Resins in the Rubber Industry

Four main types of tackifiers[14] (apart from phenolic resins) have been identified in the literature as being suitable for use in rubber formulation. These are (Gent, 2001):

- rosin-based derivatives;
- coumarone-indene resins consisting of indene, coumarone, styrene, etc. obtained from coal coke oven light oils;
- aliphatic petroleum resins made from unsaturates obtained while cracking crude oil; and
- terpene oligomers of alpha- or beta-pinene obtained from pine tree stumps.

Of these groups, it appears that rosin based derivatives are the most widely known. It is understood that proprietary blends of rosin and tall oil along with pine tars have been used as rubber-processing aids since the early 1920s. However, as quality considerations became more demanding and tack variation became a focal point of concern, it was concluded that pine tars and rosin blends lacked the identifiability, uniformity, and predictability consumers wanted. A trend was thus developed towards using more petroleum-based products and phenolic (or OP-based) resins.

During the 1990s, the rosin blend family of tackifiers re-appeared in rubber formulations and exhibited the uniformity and predictability at the moderate cost levels needed to offset much higher cost tackifiers. It is now indicated that when used as tackifiers, rosins (and combinations of rosins with phenolic resins) provide significant cost savings compared to petroleum products and phenolic resins, while maintaining the superior physical characteristics of the finished rubber (Mobile Rosin, 2006).

While it is not clear that these rosin-based derivatives are currently used in the UK; one EU supplier of OP/E (conversant with the various technologies) was of the opinion that:

- rosin and terpene-based tackifier resins are definitely of relevance for a number of rubber and adhesive applications;

- there are certain tyre manufacturing applications where the required performance can only be achieved with the use of phenolic tackifiers. Large quantities of rosin-based tackifiers are supposedly required to achieve the required tack and this has a negative impact on the physical characteristics of the resultant product;

[14] Zinc oxide has been identified in the literature as being used to improve the tack in rubber; however, its recognised role is as an accelerator during rubber vulcanisation. Resorcinol has also been mentioned in the literature, although it is unclear whether this is as part of a resorcinol-formaldehyde novolac resin.

- despite the cheaper cost of rosin based tackifiers, phenolic tackifiers are used by all major automotive tyre manufacturers in the EU and USA. However, mixtures of rosin and phenolic resins are and will continue to be used as a cost effective option. It should be borne in mind that tackifier development is a complex process and tackifiers tend to be mixtures of different chemicals. It is thus possible that the alternative tackifiers (to OP-based resins) may not be suitable for certain specific applications if used alone; and

- phenolic resins provide added assurance to tyre manufacturers that there are no hidden defects in a tyre.

It is thus clear (and has been indicated) that the European tyre industry is keen to have the continued use of OP in tyre manufacture. This is in part due to the overall cost-effectiveness of OP as well as its enhanced performance over older technologies in producing tyres capable of handling highway speeds with a long service life (CEPAD, 2006). According to Goodyear (2006), because the tyre integrity and safety of the end user is paramount, it is essential that any substitution of OP-based resins is not undertaken until a thorough evaluation and acceptability of properties as they apply to safety, handling, durability, waste minimization and recycling is complete. The company also notes that simple changes in the formulation of a tyre result in long and often burdensome approval processes with their customers, hence, it is important that adequate testing is undertaken before customers are required to change to ensure that their needs are met.

BLIC has also mentioned *tert* butyl phenolic resins as a possible alternative to OP-based resins. It, however, notes that the technical suitability or implications on product performance would have to be ascertained by tyre manufacturers. There could also be problems for users and manufacturers relating to feasibility and availability at the supplier level. In addition, it is understood that this substance is currently the subject of an EU risk assessment and, as such, the environmental and human health risks cannot be stated with certainty.

5.3 Alternatives to OP/OPEs in the Paints and Coatings Industry

5.3.1 Crosslinking Agents in Insulating Varnishes

The main alternatives to phenolic resins in insulating varnishes identified to date are the epoxy resins. Epoxy resins form crosslinks when mixed with a catalysing agent or hardener in a process referred to as ‘curing’.

Although epoxy resins have been used in the coatings, aerospace and electrical industries for many years (owing to their high performance properties, superior chemical resistance, high mechanical strength, adhesion to a wide range of substrates and good thermal properties), their reliance on organic solvents as carriers made them unsuitable for some applications. It is understood that recent technology has made available a number of waterborne epoxy dispersions which are attractive alternatives to the solvent based

resins. This waterborne technology now makes epoxy resins suitable for several non-traditional application areas, including various types of industrial non-woven products (e.g. filtration media, electrical insulating materials and building products), fibre finishes, chemical resistant textiles and adhesion promoters for industrial fabrics (Hexion, 2006).

The bulk of epoxy resins used today is based on bisphenol-A; although other types of dispersions are commercially available including: urethane modified epoxies, rubber-modified epoxies and novolac epoxies (RPP, 1991; Hexion, 2006). While it is known that these waterborne epoxy dispersions are available in the UK, it is still unclear what (if any) process modifications are required when these epoxy resins are used.

5.3.2 Binders in Paints

There are five main types of binders currently used in commercial paints (Vansickle, 2006; Flexbon, 2006):

- **Acrylic (or acrylate) resins** are derived from the polymerisation of acrylic acid derivatives and used in water-based paints - almost exclusively for exterior paint coatings. They are indicated to be superior (to other binders) in areas such as: colour and gloss retention, alkali/oxidation (chalk) resistance, hardness, adhesive/cohesive strength, long-term flexibility, breathability and overall film durability. As a result, they are used in the highest quality latex paints for a wide variety of coatings.

  In practice, other binders (e.g. polyvinyl acetate resins, epoxy resins and styrenated resins) may be added to the acrylic binders to reduce cost or add specific properties. Styrenated resins – which may contain 4-*tert*-octylphenol – are included in the binder for enhanced water resistance, gloss development and cost reduction and can be found in some masonry sealers, gloss paints and direct-to-metal coatings. However, the amount of styrene that can be used is limited because too high a level can create a tendency to crack and to chalk excessively, leading to fading (PQI, 2006);

- **Polyvinyl acetate (PVA) resins** are derived from the polymerisation of vinyl acetate with a catalyst and used in water-based paints - mainly in interior paints. While they can be used in exterior paints either alone or in combination with acrylic, exterior moisture resistance and weathering of PVA is not as good as acrylic; and

- **Polyurethane resins** are used mainly on automotive coatings and in products that come in contact with concrete (household and industrial use).

Other alternatives to OPEs identified by industry are based on C_{10}–C_{15} alcohol ethoxylates.

5.4 Alternatives to OP/OPEs in the Chemical Industry

5.4.1 Emulsion Polymer Manufacture

With regard to non-ionic surfactants, substitution of OPEs with other materials appears to be actively undertaken by most manufacturers in the sector. It is recognised that recovery and/or destruction of the OPE surfactant is possible, though it is considered that this route would be capital intensive. As such, substitution of OPEs by other materials is considered by industry to reflect BAT.

Table 5.1: Alternatives to Octylphenol Ethoxylates

Relevant application	Possible alternative	CAS Number (for alternative substances)
Formulation of PTFE emulsion	Fatty alcohol ethoxylates	61725-89-1
	Fatty alcohol ethoxylates	65150-81-4
Formulation of PTFE emulsion	Ethoxylated secondary alcohol	25322-68-3

The performance of identified alternatives is considered to be inferior in the intended application; however, reformulation of products to mitigate changes in performance is currently being undertaken and one company expects that its substitution programme for OPEs will be complete with 3 years, with significant progress made in the next 12 months. The timescales are driven by a combination of product re-formulation, plant trials and customer trials. The unit cost of raw material to replace OPEs is expected to be twice that of the OPEs product. Costs for the substitution programme are estimated at around £50,000 in technical support, sampling and staff time. The expected cost of identified alternatives is approximately twice (100% increase) that of the OPEs surfactant currently used. This will result in increased unit cost of the final product to the customer.

Recent work undertaken under the OECD SIDS programme also indicates that while some fatty alcohols may be toxic to aquatic organisms, they do not bioaccumulate or have endocrine disrupting effects and are not expected to be as persistent as OP (personal communication, 2006).

PART D

JUSTIFICATION FOR PROPOSED ACTION

6. RANGE OF POSSIBLE RISK MANAGEMENT OPTIONS CONSIDERED

6.1 Overview

This Section discusses the types of risk management measures which are relevant to addressing the environmental risks of concern identified in the RER and the options available for risk management implementation.

The risks and risk endpoints for 4-*tert*-octylphenol identified in the RER have been described in Section 3 (Part B). Section 4 has also highlighted the existing controls on 4-*tert*-octylphenol that are operating at present and the possibility that further controls may already be under consideration to comply with regulation that, though in force, is still developing in terms of actual implementation (for example, the Water Framework Directive).

6.2 The Range of Possible Measures

Types of risk management measures (i.e. practical measures for risk control) that can be applied to chemical risks are outlined in the TGD (CEC, 1998) and the measures relating to manufacture, industrial and professional use of substances are outlined in Box 6.1.

Box 6.1: Possible Risk Management Measures for Manufacture and Industrial/Professional Use

- Controls on manufacture;
- restrictions on the marketing and/or use of the substance under Directive 76/769/EEC;
- re-designing the process itself, or changing the substances or materials used in it;
- safe systems of work, such as specified standards of physical containment or extraction ventilation;
- application of good manufacturing practice, for example, under ISO standards;
- classification and labelling;
- separation of personnel;
- monitoring and maintenance of equipment;
- dust suppression methods, such as the use of substances in tablet or pellet form;
- occupational exposure limits and/or air monitoring in the workplace;
- accurate hazard information (for example, safety data sheets), and/or better delivery of safety information, such as clearer labelling or the provision of warning signs in the workplace;
- biological exposure indices and/or biological monitoring of workers;
- medical surveys of workers;
- training;
- use of personal protective equipment;
- licensing of operators of certain operations;
- 'end-of-pipe' controls to minimise, neutralise or render less harmful any emissions that cannot practicably be avoided otherwise;
- limit values for emission and effluent monitoring; and
- environmental quality standards and/or environmental monitoring.

Source: CEC (1998)

6.3 Identification of Possible Risk Management Measures

6.3.1 Initial Screening of Possible Risk Management Measures

In order to identify measures that are suitable for further consideration in this strategy, the measures listed in Box 6.1 have been screened to eliminate those that are not relevant to the life-cycle stages or risks of concern. The following measures have thus been removed from further consideration:

- safe systems of work, such as specified standards of physical containment or extraction ventilation (of major relevance for risks to human health, rather than environmental risks; there is no indication from the RER that the risks associated with OP are a result of unsafe systems at work);
- application of good manufacturing practice, for example, under ISO standards (the RER does not suggest that risks associated with OP are a result of the lack of good manufacturing practice);
- classification and labelling (as discussed in Section 4, 4-*tert*-octylphenol has been the subject of recent classification and labelling);
- separation of personnel (of major relevance for materials such as radioactive ones, but not relevant to OP where risks relate to environmental releases);
- monitoring and maintenance of equipment (there is no indication from the RER that risks associated with OP are a result of the lack of maintenance. Instead, the identified risks are related to emissions from normal operational procedures);
- dust suppression methods, such as the use of substances in tablet or pellet form (the suggested means do not appear to be of relevance for the uses of OP);
- occupational exposure limits and/or air monitoring in the workplace (of major relevance for controlling the direct risks to human health, rather than environmental risks);
- accurate hazard information (for example, safety data sheets), and/or better delivery of safety information, such as clearer labelling or the provision of warning signs in the workplace (there is no indication from the RER that the risks associated with OP are a result of lack of accurate hazard information);
- biological exposure indices and/or biological monitoring of workers (could be useful for the risk identification and characterisation but cannot be considered as a risk management option and it is not directly relevant for the risks to the environment);
- medical surveys of workers (as above for biological monitoring);

- training (as above for occupational exposure limits);

- licensing of operators of certain operations (there is no indication from the RER that risks associated with OP are a result of unlicensed operators or activities); and

- use of personal protective equipment (as above for occupational exposure limits).

Accordingly, the following potential measures remain and are considered in more detail:

- controls on manufacture;
- restrictions on the marketing and/or use of the substance under Directive 76/769/EEC;
- re-designing the process itself, or changing the substances or materials used in it;
- 'end-of-pipe' controls to minimise, neutralise or render less harmful any emissions that cannot practicably be avoided otherwise;
- limit values for emission and effluent monitoring; and
- environmental quality standards and/or environmental monitoring.

6.3.2 Consolidation of Types of Measures

For the remaining potential measures, there are certain similarities in terms of the changes that they imply and their prospective means of implementation. We have thus divided the remaining measures into two categories namely: controls on marketing and use, and policy measures for emissions control. It is likely that measures taken forward in this study will fall into one of these two categories.

Controls on Marketing and Use

The relevant measure under this category involves placing restrictions on the marketing and use of OP and OPEs (including a limit on their concentration(s) in preparations). In theory, these could be applied to all or some of the uses of OP/Es that pose a risk, implying a restriction or cessation of use(s) or a phase-out over a certain period in time.

Policy Measures (Legislation) for Emissions and Exposure Control

The remaining possible measures can be categorised as measures for control of emissions that require regulatory instruments, potentially allowing individual industries or companies to choose the means of implementation. These include:

- controls on manufacture;
- re-designing the process itself, or changing the substances or materials used in it;
- 'end-of-pipe' controls to minimise, neutralise or render less harmful any emissions that cannot practicably be avoided otherwise;
- limit values for emission and effluent monitoring; and
- environmental quality standards and/or environmental monitoring.

6.4 Possible Means of Implementation of Risk Management Options

6.4.1 Summary of Possible Means of Implementation

In terms of implementation, the TGD (CEC, 1998) identifies a range of possible administrative, legal and/or other tools that can be used to take forward proposed risk management measures. These are:

- **information programmes** and other EC/government initiatives. This could take the form of the dissemination of hazard information to workers on OP/Es by industry or government departments and agencies;
- **technical standards and authoritative guidance** (statutory, advisory or voluntary);
- **unilateral action** by industry (the TGD indicates that additional risk management measures may be necessary unless unilateral action is taken by the majority of firms involved). Such action could be taken to alter the processes or products involved in order to reduce the risks, or to cease the use of OP/Es in certain processes;
- **voluntary agreements** (such as negotiated agreements between industry and governments). These could also be used to alter the processes or products involved in order to reduce the risks, to better control emissions of, or to cease the use of OP/Es in certain processes;
- **regulatory controls**, including more effective enforcement of existing controls, amendments to existing legislation or new legislation (such as uniform EU controls, target based controls - e.g. on the amount emitted to water - or restrictions on marketing and use); and
- **economic instruments** including taxes (such as emission or product taxes), subsidies or tradable permits. These could be used to either reduce emissions to the environment or to reduce the use of OP/Es.

6.4.2 Information Programmes, Technical Standards and Authoritative Guidance

Provision of information could involve the dissemination of information, in the form of guidance, by industry or government departments and agencies on the relevant risks from OP/Es. This is usually applicable and appropriate where there are hazards or risks to human health from the use of a substance, in which case, guidance could be targeted primarily at workers handling and being exposed to the substance(s). In considering this option, it should be borne in mind that this project is focused mainly on environmental risks (and risks to humans via the environment).

For 4-*tert*-octylphenol, such guidance would ideally target any losses of OP/Es into the environment during manufacturing and formulation, as well as describe what preventative and corrective action should be taken to minimise exposure to the substance.

These guidelines could then be circulated by producers and distributors of the substances and their preparations and could be taken into account when upgrading facilities and plant design. Any such guidance could be accompanied by training of employees - organised and delivered by the relevant industry trade associations in collaboration with the relevant Competent Authorities - aimed at the accurate and effective implementation of the guidance's provisions.

Provision of information in the form of guidance would require industry associations to take a pro-active approach in environmental issues, invest time and money in consulting and developing the guidance, and should ideally be wide enough to encompass the majority if not the entirety of the industry sector they represent. In most cases, industry associations only represent part of their sector; those often left out (for various economic and logistic reasons) are the SMEs who are also often not covered by wider EU legislation (such as IPPC).

As a risk management option, guidance can only appeal for voluntary action. Also, as with most forms of non-statutory industry guidance and standards, monitorability and enforcement is likely to be less robust than statutory conditions of use, as the agreements are, in part, based on trust. Overall, such guidance is usually more effective where it is set out in detail and more appropriately in other documents (such as the IPPC BREF documents and Safety Data Sheets). Alternatively, where there is a binding agreement between all relevant parties within a sector, it could be useful. For instance, as noted in Annex 1, the resin manufacturing industry intends to develop Good Practice Guidance on the handling of NP in resin manufacture, it is likely that this document would be equally applicable to 4-*tert*-octylphenol.

Fundamentally, any guidance cannot on its own guarantee the required level of emissions reduction because its success relies on the willingness of the polluters to comply with the guidance. In general, the provision of more information on hazards/risks and relevant training of personnel are options that complement the adoption of any further emissions controls within the industry sectors of concern. Any such guidance may thus be of more relevance when used as documentation of the aims and targets of other more binding options, such as legislation or as a walk-through for individual companies in choosing and implementing new technologies that will allow them to comply with new legislation.

Overall, this option will not be considered further in this RRS since its relevance is limited and its effectiveness cannot be guaranteed.

6.4.3 Unilateral Action by Industry and Voluntary Agreements

Unilateral action by industry refers to actions taken to either alter the processes involved in the manufacture (production and formulation) of OP/Es or to cease the use of OP/Es in certain processes in order to reduce the predicted risks. This type of risk management option requires the agreement of all relevant industry stakeholders (where these include the producers, formulators, suppliers, etc.) in a particular sector across the EU. Without the broad (usually voluntary) agreement of all players, the success of this option cannot be guaranteed.

Similarly, the starting point for any voluntary agreement (VA) is the willingness of industry to recognise the need for risk management measures and the need to introduce changes to current practices. The existing NP/E & OP/E VA indicates that a significant number of companies and sector representatives believe that there is a need for risk management action. Within the context of this RRS, this could provide an advantage in reaching an agreement with such sectors.[15] Conversely, it is to be expected that the experiences (where this includes the perceived relevance, effectiveness and resource implications) of the various sectors affected by the NP/E and OP/E VA will affect their interest and input in any new or amended VA.

In the case of 4-*tert*-octylphenol, such an agreement could take the form of:

- an agreement to modify the process technologies used, such that risks from OP/Es are below a certain level; or

- an agreement to phase-out the use of OP/Es or to reduce and limit use to a certain level.

Such a VA could, in theory, provide the same level of environmental protection as emission limits or quality standards established through the legislative route. The key difference being that, as with most voluntary agreements, there exists the possibility that some companies will not participate in the agreement or will not comply with its requirements. This could reduce the level of environmental protection afforded by the agreement and could also competitively disadvantage those companies that do comply. Similarly, a voluntary cessation or phase-out in the use of OP/Es for the applications of concern could essentially have the same effect as legal restrictions on marketing and use, in terms of reducing risks to the environment. There would, however, be questions regarding the potential substitution of OP 'risks' with those associated with substitutes.

If voluntary action is chosen as the way forward, it is generally the case that not all businesses would start from the same point. For instance, while some companies have invested in research and development on alternative substances (or processes) to OP/Es, others have not done so, perhaps because they do not have the means or resources to do so. Similarly, while the cost of transition to another substance or to a different process may be easily absorbed by large companies, this may not hold true for smaller companies. For them, the associated cost could be sufficiently high to make them avoid implementing any changes until such times as the change is legally enforceable.

This leads to one of the perceived advantages of VAs which is the ability of the contracting parties to choose the most cost-effective option in meeting their obligations under the agreement. On the other hand, it could be costly to 'police' compliance with the provisions of the VA, especially when dealing with a large number of SMEs.

[15] Sectors with limited awareness of the need for risk reduction could be quite challenging in terms of setting up a VA as they require a longer organisation, negotiation and implementation period.

Fundamentally, the nature of VAs cannot guarantee the absolute success of this option and the reduction of risks to an acceptable level. It may always be the case that individual companies do not wish to be involved in and bound by the agreement or they are not part of a wider organisation (an industry association) which can co-ordinate the actions of individual companies. An example of this 'non-binding nature' of VAs can be seen in the case of the fragrance company which continues to purchase OPEs (evidently to use in its formulations) even though this runs contrary to the terms of the voluntary agreement which the British Fragrance Association (BFA) signed up to (See Table 2.5). The binding nature of this agreement on this company, however, depends on whether the company is indeed a member of the British Fragrance Association. If it is not a member, this shows that even where willingness for participation by trade associations exist, a VA may still fail to ensure overall participation and compliance.

Within the context of this RRS, a review of the efficacy of the industry VA to reduce the risks from NP, NPEs, OP and OPEs in terms of both process and regulatory outcomes was undertaken (see Annex 1 of this RRS). Based on this review, it is considered that a VA is unsuitable for addressing the risks from OP and the effectiveness of a VA specifically aimed at OP/Es may be expected to be much lower – compared with that for NP – as there is no imminent threat of EU regulatory action. Also, information received from industry for the purposes of the RRS indicates that there is limited willingness or interest to undertake unilateral action or be involved in (or create) a VA to address the risks from OP/Es. On this basis, unilateral action or VA as a risk management measure (or means of implementation) will not be considered further in this RRS.

However, due to the presence of an existing VA on OP/Es, the advantages and drawbacks of a negotiated VA under which industry can amend the VA if they so require and be underpinned by legislation will be assessed further.[16] When negotiated properly, VAs between industry and governments can potentially allow for tailor-made solutions to reducing environmental emissions to be adopted in a more timely and cost-effective manner than through traditional command and control legislation.

[16] The introduction of relevant legislation provides re-assurance that the individual companies adhere to the provisions of the agreement. It ensures that (a) all companies are trading on an equal basis (or else companies opting for non-compliance will avoid costs incurred by those who opt to comply with the provisions of the VA and (b) an incentive for compliance (i.e. success of the agreement) is given.

7. RISK MANAGEMENT OPTIONS TAKEN FORWARD

7.1 Introduction

In Section 6, a range of possible risk management measures for addressing the risks from OP/Es were screened and the possible means of implementing the selected options assessed. This Section summarises the four main options for addressing the risks of OP/Es. These are:

- introducing total or partial controls on the manufacture and use of OP/Es;
- introducing or amending legislation to control the emissions and exposure to OP/Es;
- using economic instruments to provide a financial incentive to achieve reductions in emissions of OP/Es; and
- negotiated voluntary agreement to reduce emissions/use of OP/Es to specified levels.

7.2 Cessation or Phase-out of Use

The main means for introducing measures aimed at the cessation or phase-out of the use of 4-*tert*-octylphenol in the industry sectors of concern is through Directive 76/769/EEC concerning restrictions on the marketing and use of certain dangerous substances and preparations. At a Member State (i.e. UK) level, there are options to achieve cessation and phase-out within their own territory (subject to clearance from EC authorities) under the Technical Standards Directive 98/34/EC (TSD).

Measures introduced under either could require industry sectors to cease use of 4-*tert*-octylphenol by a certain deadline; place phased requirements on reductions in use and cessation; set conditions on use, for example, only in closed systems with containment followed by incineration of wastes; or set a limit on the concentration of the substance in preparations. To reduce risks from 4-*tert*-octylphenol as an impurity in NP, the restrictions would also have to be targeted at the use of NP in the applications of concern.

Use restrictions could be designed so as to only apply to particular applications or processes; for instance, those applications that may have significant socio-economic importance and for which suitable alternatives are not currently available may be either exempted from any marketing and use measures or be granted a derogation which could be time-limited or unconditional.

7.3 Legislation to Reduce Emissions and Exposure

The following measures (identified in Section 6) are relevant for reducing emissions and exposure to OP:

- controls on manufacture;
- re-designing the process itself, or changing the substances or materials used in it;
- 'end-of-pipe' controls to minimise, neutralise or render less harmful any emissions that cannot practicably be avoided otherwise;

- limit values for emission and effluent monitoring; and
- environmental quality standards and/or environmental monitoring.

These measures - which reflect changes in processes to reduce emissions of OP/Es rather than changes that eliminate the use of OP/Es (which constitute cessation or phase-out of use) - can be implemented by means of a range of existing Community-level legislation (transposed by legislation in the Member States).

As discussed in Section 4, the principal (existing) legislative means for reducing emissions of 4-*tert*-octylphenol to the environment is through the IPPC Directive and the Water Framework Directive (WFD). Although these could be treated separately, they could also be used in combination to complement each other, in order to provide adequate protection to the environment. Hence, for this assessment of possible risk management options, legislation on emissions and exposure shall be considered to be a combination of the IPPC and WFD and national legislation on emissions.

7.4 Economic Instruments

In relation to the sectors of concern, a number of economic instruments could, in theory, be effectively used in addressing the identified risks. These instruments could be used to provide a financial incentive to achieve reductions in emissions from the various uses of OP/Es or, alternatively, to reduce (and possibly eliminate) the use of OP/Es in the relevant sectors. They could also be used to limit the quantities of OP/Es that are used within those sectors. The following types of economic instrument may in theory be considered:

- **emissions charge**: this type of scheme could be used to levy a per unit charge on emissions of OP/Es to the environment;
- **product charge**: this could be developed by levying a charge on the use of OP/Es in all or certain applications of concern; and
- **tradeable permits**: a permit trading scheme could be developed to place a ceiling on the quantity of OP/Es consumed in the EU, or on emission levels, within the various industry sectors, with users then able to trade permit quantities.

It is currently unclear how economic instruments could be given legal force through EU legislation, Directive 76/769/EEC may, however, provide an appropriate legal framework.

7.5 Negotiated Voluntary Agreement

A negotiated voluntary agreement could either take the form of:

- an agreement to modify the process technologies used, such that emissions of OP/Es are below a certain level; or
- an agreement to phase-out the use of OP/Es or to reduce and limit use to a certain level.

8. ASSESSMENT OF THE POSSIBLE RISK MANAGEMENT OPTIONS

8.1 Introduction

The TGD - as well as the Annex XIV dossier - specifies that possible further risk management options should be examined against the following three decision criteria:

- **effectiveness**: the measure must be targeted at the significant hazardous effects and routes of exposure identified by the risk assessment. The measure must be capable of reducing the risks that need to be limited within and over a reasonable period of time;

- **practicality**: the measure should be implementable, enforceable and as simple as possible to manage. Priority should be given to commonly used measures that could be carried out within the existing infrastructure (though not to the exclusion of novel measures);

- **monitorability**: monitoring should be possible to allow the success of risk reduction to be assessed.

Note that while the RRS TGD requires that risk management options are assessed for their economic impact, this RRS follows the REACH Regulation provisions where economic impacts are part of a separate Socio-Economic Assessment.

In the context of OP, the focus for a RRS can be partitioned into two principal objectives:

- reducing risks associated with the continuing uses of octylphenol; and
- ensuring that the risks from historical or unregulated uses do not 're-occur'.

The following discussion provides an assessment of the risk management options for the uses of OP. Each of the possible options identified in Section 7 is considered in turn, with information presented on the performance of the options against the three key criteria described above.

8.2 Effectiveness of Possible Risk Management Measures

8.2.1 Introduction

There are three sub-criteria against which the effectiveness of risk management option may be assessed:

- the *risk reduction capacity* of the option: the most important characteristic of any risk management option should be the ability of the option to reduce the risk to acceptable levels. Generally, an option that cannot ensure a sufficient level of risk reduction will either have to be complemented by another option or will be eliminated from further consideration;

- the *timing* of implementation: the timing of implementation will be influenced by the scale of risk and the severity of its consequences. Generally, effective options that lend themselves to quick implementation and enforcement will have a relative advantage over options that require a longer timeframe to become effective; and

- the *proportionality* of the risk management option: the proposed option should be an option that:
  - targets the identified risk;
  - corresponds in amount or degree to the effects of the adverse effects suffered or the adverse effects that are being avoided taking into account the available scientific evidence;
  - requires that risk management action is taken by those responsible for the risks (and that these actors have the authority and information to act accordingly);
  - is consistent with other options taken forward in the past (but builds on past action and learns from past failures); and
  - ensures a good balance between costs and effectiveness.

  Issues of proportionality are relevant to the (potential) need for derogations and may also be addressed in an SEA of the proposed restriction.

8.2.2 Cessation or Phase-out of Use

A total ban upon the marketing and use of 4-*tert*-octylphenol would ensure that the environmental and human health risks arising from production, formulation and end use of the substance are eliminated. Whilst being the most straightforward risk management option available, any marketing and use restrictions that could, in principle, be recommended by this RRS may not directly address risks from 4-*tert*-octylphenol as an impurity in NP-related products and processes; however, it would ensure that the risk management measures are consistent with those taken for NP (also an AP) in the past.

For certain sectors, restrictions strictly targeted on OP/Es may be unlikely to provide a significantly higher degree of protection over the existing controls (particularly the existing restrictions on NP and the VA) or in sectors where OP/Es are currently not being used. In these instances, marketing and use restrictions will not affect the current emissions and exposure to OP/Es and, as such, the effectiveness can effectively be described as 'neutral'.

A cessation or phase-out of use would require companies to use alternative chemicals or techniques in order to replace 4-*tert*-octylphenol (assuming, of course, that these companies could continue to manufacture their products by using alternatives). The resulting reduction of risks, however, needs to take into account the possible (unknown) risks that would be introduced by alternatives (discussed in Section 5) and the relative impacts resulting from the substitution of the (known) environmental risks from the continuing use of OP/OPEs. Furthermore, there may be cases where the use of OP/OPEs may be critical to the use of more environmentally acceptable products; the effectiveness of a total ban needs to take this possibility into account.

An analysis of the potential alternatives to OP/Es in its various uses (as identified in the RER) has been undertaken. In general, the evidence suggests that there appear to be substitutes available for a number of the applications of concern; however, it is not clear that the substitutes provide sufficient technological, environmental and economic benefits compared to 4-*tert*-octylphenol. Even where the benefits of the substitutes appear to be relatively comparable, the uncertainties in the OP RER mean that such a measure may not be commensurate with the identified risks (for instance, where the risks are based on generic scenarios and/or the PEC/PNEC slightly exceeds unity). More importantly, knowledge of the possible effects of the alternatives on human health and the environment is limited (i.e. an ESR risk assessment has not been undertaken or completed for the substances in question). For those sectors where the use of alternatives would confer no reduction in risk, or indeed a net decrease in benefits, it is debatable whether a total ban is an appropriate measure or the most (cost-) effective approach.

Based on the above considerations, from an effectiveness standpoint, while marketing and use restrictions on all uses of OP/Es would provide certainty regarding the intended effect of the RRS, it would also be likely to constitute an exaggerated response to the imminence and degree of risks identified as well as the scope/size of the OP/Es problem in the UK (and possibly, EU) – in addition to any substitution and cost issues that may arise. It may thus be necessary, to consider the merits of targeted restriction on specific uses or sectors (or the possibility of derogating certain sectors – See Section 9) or even controls on specific sites.

8.2.3 Legislation to Reduce Emissions and Exposure

As noted in Section 4, the Environment Agency has put in a place an operational EQS of 1 µg/L annual average and 2.5 µg/L MAC in both fresh and marine waters. In theory, it will be expected that this EQS has been set at a level which will ensure that no risks to the environment arise. The tighter EQS limits which will come into force under the WFD may thus be expected to ensure an even higher level of protection for the environment. While it cannot be estimated for certain what this level of protection entails, it is worth noting that the tighter EQS is lower than the existing UK one by a factor of between 10 (annual average) and 20 (maximum allowable concentration). The proposed EQS is also the same as the PNEC derived in the RER. Thus, in terms of effectiveness, it can be said that the setting of an EQS for octylphenol provides significant certainty regarding the intended objective of this RRS; however, because of the current unknowns regarding how the WFD will be implemented in the UK, it may be necessary to consider some interim measure(s).

On this note, an emission limit value (ELV) could thus be set under existing legislation (IPPC specifically) at a level that would be effective at reducing the identified risks to an acceptable level. A major advantage of setting this ELV under the IPPC Directive is that the full implementation of the IPPC Directive should take place as early as October 2007. Also, it may be expected that the IPPC Directive would have a significant role to play in ensuring that the WFD requirements are complied with at the Member State (i.e. UK) level. Under Article 10 of the WFD (on the combined approach for point and diffuse sources), Member States are required to ensure the establishment and/or implementation

of emission controls based on BAT, relevant ELVs and in the case of diffuse impacts, best environmental practices as set out in the IPPC Directive (and other relevant Directives). Hence, the WFD could provide a framework (or approach) for ensuring that the OP emissions to the environment are minimised.

The need for this underlying framework becomes apparent when set against the potential drawbacks of an approach for addressing the risks from OP/Es, based on IPPC only, where these include:

- IPPC pursues an integrated approach with the aim of minimising the total environmental impact of an installation. Hence, the reductions of various impacts on the environment achieved by the different techniques used to achieve BAT are weighed against each other (i.e. the risks of OP may be given lower priority to those of another pollutant);

- for some sectors or processes, IPPC has a threshold for minimum throughput and, thus, may not be applicable across all the installations or sites concerned (i.e. where there are small processes releasing OP, these are unlikely to be covered by IPPC controls); and

- BREFs do not always provide emission limit values on specific substances and the contents of the BREFs are not binding for the Member States. The method of implementation at Member State level also varies (i.e. the actual implementation of BAT at industrial installations depends on the understanding of different Member States, the local permitting authorities and the sites).

In general, a key benefit of introducing emissions controls is that it would require emissions reductions (and associated resource inputs) only for those sites where there is a need for limiting the risks. Other sites, those already in compliance, would not be required to take such measures. It should also be noted that the issuing of permits under IPPC takes account of the specific characteristics of each individual site and tailors the requirements of the permit to accommodate these characteristics. One of the advantages of this approach is that sites are allowed to choose their means of meeting the requirements of their permit. In most cases, this means that companies will invest in technology (if they cannot meet these requirements already) rather than replace the 'offending' chemicals. By not replacing these chemicals, a substitution (and possible increase) of risks due to the use of more hazardous alternatives is avoided.

In summary, from an effectiveness standpoint, there are benefits associated with introducing emissions control (using the WFD and IPPC), in particular, the ability to take into account and address the risks and emissions of each sector individually. It would also allow potential releases of OP from NP-related processes to be addressed. There are, however, concerns relate to the ability of these regulatory frameworks to capture minor, unconfirmed and/or historic uses (which often involve SMEs).

8.2.4 Economic Instruments

Emissions charge: Under an emissions charging regime, a charge would be levied on each unit of OP/OPE emissions from sites that use OP or OPEs. In order for an emissions charge to be effective, it would have to be set at a level high enough to ensure that any companies giving rise to risks introduce the necessary controls to adequately limit the risks.[17] The advantage of this approach is that it provides an incentive to all dischargers to reduce emissions but penalises most those with higher emission rates. Fundamentally, emissions charges provide no certainty in reducing the environmental risks to acceptable levels; they would act to provide an incentive to sites to reduce emissions, but companies may prefer to pay the charge rather than to respond by introducing further emission controls.

Product charge: In order to create a sufficient price differential to stimulate changes in the use of OP/Es in industrial production, a charge on products containing OP/Es would need to be high enough to make it a market differentiating factor. This means that the increase in price for products containing OP/Es would have to outweigh other factors, such as the costs of switching to alternative substances or processes. Its effectiveness would depend upon the level at which the charge was set; in this regard, companies may be willing to pay the higher cost if there are significant technical benefits or the clients demand the use of OP. Assuming a price is set sufficiently high, an incentive to move to substitutes should be provided and most companies would be likely to shift once substitutes were developed that provided the appropriate level of performance, given the competitiveness of the market. In this respect, the previously highlighted issues regarding the potential risks associated with substitutes should be borne in mind.

Tradeable permit systems are generally thought of in terms of trading in emissions of OP to the environment or setting a ceiling on the quantity of the commercial product that could be consumed within the UK/EU. Permits would then be auctioned to prospective users and acquired by the highest bidders. Tradeable permits would provide certainty in terms of the overall amounts emitted (as the amount of OP which can be emitted or consumed by a sector is fixed) but would not ensure that local emissions at any one site are reduced to a protective level. More importantly, the performance of tradeable permits will depend on market interactions among the permit holders which cannot be guaranteed.

In summary, whilst the use of economic instruments can provide an incentive to companies to reduce their emissions of OP and may, indeed, be effective at reducing the overall quantity of OP/Es emitted to the environment, it does not guarantee that local risks associated with any one site[18] are reduced to a 'protective' level or even the desired reduction of OP emissions to acceptable levels. This is an important point bearing in mind the 'captive' use pattern of OP.

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[17] Owing to a lack of specific information on the emissions and costs of adopting (further) controls at individual sites, it is not possible to calculate a minimum charge rate at present.

[18] For example, the financial incentive to reduce emissions provided by an emissions charge may not (on its' own) be sufficient to induce any one company to introduce additional emissions controls.

It may also be worth noting that under REACH, the scope for considering economic instruments as a risk management option under a restrictions procedure will be extremely limited once the REACH Regulation is implemented.

8.2.5 Negotiated Voluntary Agreement

An agreement to ensure that emissions from the processes of concern are below a specified level could, in theory, provide the same level of environmental protection as an ELV or EQS established through the legislative route. Similarly, a voluntary cessation or phase-out in the use of 4-*tert*-octylphenol for the applications of concern could essentially have the same effect as legal restrictions on marketing and use, in terms of reducing risks to the environment.

As with most such VAs, there exists the possibility that some companies will not participate in the agreement or will not comply with its requirements. This has already been seen in Section 2 where sectors which supposedly have no use of OP/Es are being supplied OP/Es in significant quantities. This could reduce the level of environmental protection afforded by such a mechanism and could also competitively disadvantage those companies that do comply. It may also be the case that individual companies do not wish to be involved in and bound by the agreement or they are not part of a wider organisation (a trade association) which can co-ordinate the actions of individual companies (although the introduction of relevant legislation may provide re-assurance that the individual companies adhere to the provisions of the agreement). There would also be the already highlighted issues regarding the availability, suitability and potential risks associated with substitutes.

In summary, the nature of VAs cannot guarantee the absolute success or effectiveness of the measure and the reduction of risks to an acceptable level.

8.3 Practicality of Possible Risk Management Measures

8.3.1 Introduction

There are three sub-criteria against which the practicality of a risk management option may be assessed:

- *implementability*: a suitable option should lend itself to practical implementation, i.e. the industry sectors involved should be capable of practically complying with the new requirements. To achieve this, the necessary technology, techniques and alternatives (if required by the selected risk management option) should be available for adequate control of emissions and exposure. As a general (but not binding) rule, options that can be implemented within the existing infrastructure may be given priority;

- *enforceability*: a suitable option is an enforceable option. An enforceable option is one that introduces legally binding conditions on the way the substance is manufactured, marketed or used, the success of which is followed up by the

responsible authorities and its compliance is ensured by monitoring, inspection and sanctions. Penalties imposed on offenders in the event of non-compliance may be an important deterrent. Monitoring mechanisms should either exist already (which would be the ideal scenario) or they should be able to be readily set up and operated; the most effective option may have no effect if those supposed to comply with it fail to do so and the competent authorities in Member States are not able to oblige them to comply; and

- *manageability*: a suitable option should be simple to manage (taking into account the characteristics of the sectors concerned, for instance, the number of SMEs) and understandable to affected parties; the means of its implementation should be clear to those involved and access to the relevant information should be easy. Enterprises, professionals and consumers are more likely to implement an option if it is simple and does not require great levels of effort for compliance and monitoring of performance. It may also be helpful to a user of the substance if the option results in a single straightforward binding requirement rather than a combination of legislative (or regulatory) measures that may or may not apply to him. Note that the need for a non-excessive administrative burden is relevant to both industry and the authorities.

8.3.2 Cessation or Phase-out of Use

Marketing and use restrictions are, in principle, compatible with all applications and industry sectors of concern to this RRS. The procedure for restricting the marketing and use of substances at the EU level under Directive 76/769/EEC is well established, with various substances already subject to restrictions. Amendments to Directive 76/769/EEC have been introduced several times and in this respect it is a simple measure to introduce and implement and Member States are considered to have suitable procedures in place or implementing its requirements. At a Member State level, there are also experiences to draw from under the Technical Standards Directive 98/34/EC.[19]

In discussing the practicality of marketing and use restrictions, an issue to be borne in mind is the extent and magnitude of risks in the context of the existing risk management measures. The discussions in Sections 3 and 4 indicate that:

- existing legislation already provides some powers for addressing some of the risks identified (the TGD notes that this should be considered before recommending new or amending legislation);

- it is possible that the implementation of existing controls could be made more efficient and, if so, this may remove the need for further controls. In this regard, IPPC BREF documents can be reviewed and updated as appropriate to reflect the future change in best available techniques;

[19] For example, a notification by the Netherlands to introduce national measures concerning wood treated with copper substances was considered by CSTEE in 2002 and Denmark has introduced legislation banning the production of new materials containing cadmium, and draft legislation on recycling PVC containing lead.

- for some sectors, the practicality of marketing and use restrictions cannot be guaranteed especially considering the international nature of some of the markets in question. The marketing of 4-*tert*-octylphenol to countries and markets outside the EU would also not be targeted by any such restrictions (accompanying these are potential trade barrier issues).; and

- marketing and use restrictions are likely to be disproportionate (as a risk management measure) to the imminence (i.e. whether there are threats of serious or irreversible damage) and degree of risks identified in some of the industry sectors (where these may include those endpoints that only represent a risk because of elevated background concentrations).

In summary, marketing and use restrictions are a useful tool for controlling the risks identified in the RER, although a blanket approach may not be appropriate.

8.3.3 Legislation to Reduce Emissions and Exposure

In terms of implementing emissions controls to the specific local risks identified in the RER, the IPPC Directive and WFD apply to all of the industry sectors of concern.

If ELVs were to be introduced under the IPPC Directive, there is an existing regulatory regime across the Member States through which these could be enforced. Any new requirements under the IPPC regime could be introduced through the relevant BREF notes for the sectors concerned. It should be borne in mind that irrespective of the recommendations of this RRS, procedures for introducing IPPC measures are in place or will be by the end of October 2007.

If emission limits were to be introduced through the Water Framework Directive and/or national legislation and requirements concerning discharge of industrial effluents to water, it is likely that the measures could be implemented in a practical manner, albeit in a somewhat more complex way than under the IPPC regime. For example, there will be a number of situations where sites discharge directly to surface water (following any on-site treatment), in which case the authorities would be responsible for ensuring compliance with any emission limits. Similarly, sites may discharge to a municipal WWTP, in which case the local sewerage undertaker would be responsible for issuing a discharge consent to the site and would also have a discharge consent (from the authorities) themselves for emissions to controlled waters.

The combination of these measures may not be the simplest option (compared with marketing and use restrictions), however, the frameworks under which these measures will be introduced have existed for some time (or are in the late stages of development) and installations should be familiar with negotiating their actions within these frameworks. For sites covered by IPPC, the authorities issuing permits should be in a position to provide guidance (especially to smaller companies) on meeting the requirements of legislation. Where such smaller companies are not covered by IPPC, they are likely to be picked up in the RBMP to be prepared under the WFD.

8.3.4 Economic Instruments

Emissions charge: The practicality of the measure relies heavily on the structure of the sectors involved and also the differences across the sectors. The companies involved would have to register their use and emissions of OP on an annual basis. This could be a complex procedure if a large number of companies are subject to the measure and/or in sectors where OP/ES are not a specific or intentional input.

Product charge: The introduction of a product charge would entail the setting of the charge, which as described above, is not always a straightforward task for the regulators. From an administrative point of view, there would be a need to trace the supply of OP from the producers/suppliers to the sectors of concern. Both producers and importers would have to declare and register the quantities that they supply to their downstream users for the charges to be levied upon the users of OP.

Tradeable permits: In relation to tradeable permits, this would again require accurate information on the amounts of OP being sold to each of the sectors of concern (as with a product charge) and would also require accurate information on emissions at individual sites (as with an emissions charge). In this respect, such a scheme would be less practical in terms of implementation than the other two instruments considered.

In summary, in terms of practicality, economic instruments are unlikely to be easy to set up or manage, especially where a large number of SMEs are involved. Also, it is currently unclear how economic instruments could be given legal force through EU legislation. Directive 76/769/EEC may provide appropriate legal frameworks.

8.3.5 Negotiated Voluntary Agreement

The starting point for any VA is the willingness of industry to recognise the need for risk management measures and the need for introducing changes to current practices. Based on consultation undertaken for this RRS, the level of support which would be garnered for a negotiated VA amongst the sectors of interest is unlikely to be sufficient.

During consultation for the RRS, companies were asked whether they would be prepared to voluntarily discontinue the use of OP/Es over a specified period and/or agree to ensure that emissions to the environment are below specified levels, ensuring no unacceptable risks to the environment and/or to human health. Respondents who answered in the affirmative indicated that such an answer was dependent on:

- the level of any proposed emission limit values;
- an acceptable timescale to allow reformulation of products and completion of customer acceptance trials;
- any such agreement being applied consistently on an EU wide basis to ensure continued business competitiveness for UK based companies; and
- any such agreement applying to only those uses which pose a risk to the environment.

Other companies answered in the negative arguing that:

- with adequate IPPC in place, there should be no need to have to voluntarily discontinue the use of OP/Es;
- as OP/Es are most frequently used in contained applications, with minimal releases into the environment, there was no need for any voluntary agreement;
- the risk assessment does not depict realistic exposure scenarios for the main uses of OP/Es; and
- because OP/Es are primarily used in applications where suitable substitutes are not readily available, reformulation will pose a significant problem. For instance, it was argued that there are no comparable replacement products for OP-based tackifiers in rubber formulation. Any such VA would mean that tyre companies in Europe would not be able to produce tyres, since all global tyre makers use OP-based tackifiers to make tyres in all regions of the world. One respondent noted that some potential substitutes have more hazardous environmental profiles than OP or have not been tested to the extent that OP has and are, therefore, not technically proven.

In summary, this option may be considered as broadly unpractical and unlikely to achieve the reductions required.

8.4 Monitorability of Possible Risk Management Measures

8.4.1 Introduction

There are three sub-criteria against which the monitorability of risk management option may be assessed:

- *availability of appropriate indicators that could be used for the monitoring of the implementation of the option*: two types of indicators are needed,
  - those that allow monitoring of the presence of the chemical in the environment, biota and humans (for example, the concentration of the substance in specific environmental compartments or human tissue), and
  - those that allow monitoring of the manufacture, import and use of the substance across the Community (for example, import statistics from the Customs authorities in the Member States or the concentration of the substance in preparations placed on the market);
- *ease of monitoring*: the monitoring of a suitable option should be easy to set up and administer and its cost and administrative burden should be proportional to the levels of use of the chemical and the number of actors involved; and
- *availability of monitoring mechanisms*: effective monitoring mechanisms should be in place to monitor both use and releases, and the implementation and success of the

option. Monitoring should be capable of providing the necessary guarantees that Industry is complying and that the option is meeting its original objectives across the Community and within the required timeframe. Options capable of utilising existing monitoring mechanisms may have a relative advantage over options that require new ones. When the proposed risk management option requires new monitoring mechanisms, the proposal should include specific proposals for setting up and operating these.

8.4.2 Cessation or Phase-out of Use

Monitoring the implementation of restrictions on the use of 4-*tert*-octylphenol in the sectors of concern should be relatively straightforward, given that suitable systems have been established through previous restrictions. Experiences from NP may also prove to be useful in this regard.

8.4.3 Legislation to Reduce Emissions and Exposure

The legislative measures being considered will employ the existing monitoring networks that have been established (or are being put in place) as a result of Community-wide (IPPC and WFD) and national legislation on emissions control. Monitoring the effects of emissions controls should thus be straight-forward.

8.4.4 Economic Instruments

All of the economic instruments considered would require significant resource inputs to establish comprehensive monitoring of one or more of the following:

- consumption of OP/Es within the sectors and at individual sites;
- imports and exports of the substance: this type of approach would rely on declarations by importers, as it could be difficult for Customs Authorities to monitor imports otherwise. The potential for charge evasion will exist unless the producers are also willing to provide records of sales for cross-validation purposes; and
- trading in permits to ensure that adequate environmental controls were in place at sites buying the permits.

It is expected that the implications of undertaking this monitoring could make some of these instruments relatively less favourable compared to some of the other potential risk management measures being considered. However, we do not have sufficiently detailed information in this respect at the current time to further elaborate upon this.

8.4.5 Negotiated Voluntary Agreement

General monitoring of emissions may already be taking place due to companies' obligations under different frameworks (for instance, IPPC). Any further needs for monitoring of compliance should be discussed at the negotiation stage and will vary in accordance with the number of sites involved and the specific targets of the agreement.

8.5 Summary of Assessment of Possible Risk Management Options

Table 8.1 below summarises the main points from the assessment of the risk management options against the three key criteria.

Table 8.1: Summary of Assessment of Risk Management Options

Measure	Effectiveness	Practicality	Monitorability
Controls on Marketing and Use	Restrictions on all uses of octylphenol will provide certainty regarding the intended effect of the RRS; however, it is also likely to constitute an exaggerated response to the imminence/degree of risks identified as well as the scope/size of the OP/E problem in the UK.	Controls on marketing and use constitute a useful tool for addressing the risks identified in the RER. A blanket approach may, however, not be appropriate taking into account the extent and magnitude of risks.	Should be relatively straightforward, given that suitable systems have been established through previous restrictions.
Emissions and Exposure Control	Emissions control (using the WFD and IPPC) allow for the risks and emissions of each sector to be taken into account individually. There are, however, concerns relating to the ability of these regulatory frameworks to capture minor, unconfirmed and/or historic uses.	May not be the simplest option (compared with marketing and use restrictions), however, the frameworks under which these measures will be introduced have existed for some time (or are being developed). Sites should be familiar with negotiating their actions within these frameworks.	Should be straight-forward employing the existing monitoring networks that have been established (or will be put in place).
Economic Instruments	Economic instruments cannot guarantee the desired reduction of OP emissions to acceptable levels at site, local and national levels.	Economic instruments are not easy to set up or manage especially where a large number of SMEs are involved.	The economic instruments considered would require significant resource inputs to establish comprehensive monitoring.
Negotiated Voluntary Agreement	The nature of voluntary agreements cannot guarantee the absolute success of the measure and the reduction of risks to an acceptable level.	The level of support which would be garnered for a negotiated VA amongst the sectors of concern is unlikely to be significant and, as such, this measure may be considered as broadly impractical.	This should be discussed at the negotiation stage and will vary in accordance with the number of sites involved and the specific targets of the agreement.

Following from the Table, it is clear that in order to address the risks from OP/OPEs, the two main options which are of relevance are controls on marketing and use and emissions/exposure control. These will be taken forward into the proposed risk reduction strategy.

9. SOCIO-ECONOMIC IMPACTS OF POSSIBLE RISK MANAGEMENT OPTIONS

9.1 Introduction

Under REACH, a socio-economic assessment (SEA) may be made of the impact of any proposed restrictions; however, it is discretionary and is not a mandatory component of the restrictions dossier. Third parties may, however, wish to prepare a SEA that covers the benefits of a particular form of risk management option, or provide evidence to justify a restriction based on the health or environmental impacts of failing to restrict the substance of concern. In general, while the level of detail needed within the SEA may vary from case to case, it should provide a good basis for decision making.

The Section below examines the impact of the proposed risk management options on various parties who may be affected by them.

9.2 Cessation or Phase-out of Use

While considerably very little information has been received from industry on the possible cost implications of any risk management measures on OP/Es, a consideration of the sectors which will be affected by the proposed restrictions shows that the economic impacts can be expected to be minimal for all the affected sectors with the possible exception of the rubber industry and the paints and coatings industry. More specifically:

- **emulsion polymer manufacture**: consultation in this sector indicates that there are on-going plans to move to alternative substances within the next three years; hence, any restrictions after three years would be expected to have minimal impacts;

- **oil (offshore) industry**: there is no indicated use of OP/Es in this sector within the UK, hence minimal (if any) costs will be incurred;

- **textiles and leather**: while a few users may incur some costs as a result of any marketing and use restrictions, consultation indicates that the vast majority of users in these sectors have identified alternatives – which can be assumed provide sufficient benefits (even if unrelated to costs) to have prompted a shift. Costs are thus expected to be minimal and should be lower than the benefits accruing;

- **pesticides**: there are on-going plans to completely substitute OP/Es in all relevant products by 31 December 2006, hence, costs (if any) should be minimal; and

- **other uses**: most of the other uses are either historic or minor uses or uses which have re-appeared as replacements for NP/Es. For these uses, there is always the possibility that significant costs may be incurred by specific companies as a result of marketing and use restrictions; however, none of these companies or sectors has provided any information to suggest the scale of such costs or the criticality of OP/Es

to their products/applications. In any case, it is considered that the risk related justification for restrictions take precedence over socio-economic impacts.

There are a number of applications where 4-*tert*-octylphenol may be either 'technology-' or 'application-' critical (or both). These include the use of OP/Es in rubber formulation, insulating varnishes, printing inks and paints. In drawing up marketing and use restrictions, consideration would have to be given to such applications in terms of both the time it can take to develop and approve a suitable 'drop-in' substitute, but also whether the application represents an essential use, the risks of which can be eliminated or reduced to an acceptable level by the adoption of more rigorous emissions controls.

For the **rubber industry**, if OP-based resins are as critical to the tyre manufacture as indicated by industry, the impacts of restrictions may be expected to be significant. While no cost estimates have been provided by the rubber industry of the significance of OP to their business; it is noted that the EU rubber industry employs around 360,000 employees in 4,100 companies across the EU-25 and its turnover in 2005 was around €42 billion. The **insulation varnishes, printing inks and paints industry** (represented by CEPE) employs 125,000 people directly in the EU. There are more than 3,000 enterprises manufacturing around 5 million tonnes of paints and coatings per year in the EU and 100 printing ink manufacturers producing 1 million tons of printing inks per year. The market for the paints and coatings is around €16 billion/year while that for printing inks is around €4billion. In the UK, over €1.5 million worth of paints are sold per year and around €700,000 worth of printing inks (CEPE, 2006). It is not known what part of this market may be affected by marketing and use restrictions on OP/Es.

In general, any marketing and use restrictions will result in direct and indirect costs to companies and industry sectors, where these would typically include:

- costs of the alternative substance;
- capital and operating costs associated with the need to purchase any additional production or processing equipment;
- costs associated with machine downtime when substitution takes place;
- research and development costs; and
- marketing costs.

The estimated costs of the restrictions will vary depending on the size of company, the variety of operations/processes at each site, the existing level of knowledge of the alternative systems (what R&D each company has undertaken) and the type of alternative chosen. Some of the sectors (e.g. paints and printing inks) involved include a significant proportion of SMEs; in this respect, the impacts of marketing and use restrictions may be significant. For some of the sectors (e.g. emulsion polymer manufacture), the impact of an immediate ban (as opposed to a time-limited ban that accounts for the time required for technically suitable alternatives to be developed) could impact significantly on the short-term (and possibly long-term) competitiveness of the company at an EU and international level.

In addition to these direct costs, there may also be costs to other stakeholders, including changes in product performance to downstream users and the cost to the producers of OP related to the loss of part of their market. There would also be costs of developing and enforcing legislation at the Member State/Community level.

In terms of benefits, restrictions have the inherent advantage of spurring innovation; such innovation can make more environmentally friendly technologies less costly and more accessible to users. However, whilst there would be a financial benefit for the producers of substitutes (associated with an increased market for their products), there may be costs associated with research and development and marketing. There would also be environmental benefits based on the protection of the quality of the environment, as well as, meeting the objectives of the WFD.

Proportionality is an important issue in the introduction of marketing and use restrictions. In the context of an RRS, the proportionality of a risk management option relates to the scope of the measure and how able it is to take into account the different levels of risk for the different applications. In other words, a measure should ideally target the areas associated with unacceptable risks only and should not impose unnecessary burdens on any of the parties affected by the measure; although the primary consideration should be impact on society as a whole. For some of the sectors, the cost to be incurred from an immediate restriction may be considered to be disproportionate to the risks identified. For instance, risks associated with use of OP-based resins in rubber formulation in the RER are based on relatively low risk characterisation ratios for the terrestrial and aquatic compartments (1.49 and 4.05 respectively) based on generic scenarios. In this case, care has to be taken to ensure that the restrictions effectively target those sites where there is a need for limiting the risks. If directed at sites where the risks are already effectively managed, costs could be incurred with little environmental benefit.

Furthermore, there are also social impacts to be considered, for instance, safety considerations, which are the main factor considered by tyre manufacturers. Tyres placed on the market are expected to give maximum reliability being the sole component that links the vehicles with the road. Any measure (i.e. restriction) which compromises the ability to provide maximum safety to humans (and the overall economic movement of goods and services) can be considered to constitute a disproportionate cost. The same case applies to paints and coatings and printing inks.

9.3 Legislation to Reduce Emissions and Exposure

Clearly, in order to comply with the current or proposed EQS for OP, sites would incur some costs from the introduction of additional effluent treatment or changes to the processes involved. However, this would not be the case for all sites since, as described in previous sections, emissions at some sites may not pose an unacceptable risk to the environment. It is, however, unclear what proportion of the sites within the industry sectors of concern will need to invest in new technology and systems to allow them to achieve the required reduction in emissions and hence, the costs to industry cannot be calculated at present.

In any case, changes to be introduced and investments to be made in installations affected by any proposed risk management option will not be introduced solely for the control of OP emissions. Most likely they will take place as part of each installation's effort to meet the requirements placed on them by the regulator – in an attempt to meet the requirements of the WFD. Therefore, any such costs or part thereof should be attributed to the implementation of WFD rather than to this RRS.

A different situation would apply where an ELV is introduced to address OP which required the introduction of additional effluent treatment or changes to the processes involved at specific sites. The costs of this, while unknown, may be significant. However, it is considered that on the basis of the emissions profile for OP/Es (for instance, from the Pollution Inventory data), it is not expected there would be significant costs across the board associated with this measure.

Costs to consumers cannot be foreseen at present but they are expected to be lower compared to those resulting from restrictions on the marketing and use of the substance.

9.4 Economic Instruments

It is expected that all of the economic instruments considered here would result in lower costs than those that would be associated with direct regulation placing controls on uses and/or emissions of OP/E. Companies could respond to the measures either by ceasing use of OP/E for the applications in question; or by reducing emissions by upgrading their facilities; or by paying the charge and carrying on their processes as usual. The choice will depend on the current levels of emissions at each site and the financial capabilities and calculations each company would make. It should be assumed though that companies will adopt the least cost of action.

A product charge on the use of OP/E would have a detrimental financial effect upon producers of OP/E (or upon consumers if the charge were levied upon the product itself). An emissions charge upon OP/E would involve costs for the companies concerned including those companies for which the presence of OP/E is neither intentional nor particularly desired. With tradeable permits, economic instruments could also give rise to distributional concerns as only those with funds available would be able to bid for tradeable permits leaving the smaller player in the market in an even more disadvantageous position.

There would be significant resource (or cost) implications for the regulators in implementing the economic instruments considered here, where these would depend on:

- *the number of sectors and of companies involved*: the smaller the number, the easier to administer and monitor the emissions charge or tradeable permits system; and
- *the requirements for registration of emissions or tonnage*: emissions or tonnages would need to be registered on an annual basis. If such registers can be made available through the existing legislative framework (for instance, IPPC or other similar monitoring systems), the administrative costs would be lower.

Overall, it is unknown whether these impacts would be greater or lesser than those associated with direct regulation. In comparison to restrictions on marketing and use, economic instruments could offer a more proportional approach to the reduction of risks: in theory, those who pollute the most would also have to pay the most.

9.5 Negotiated Voluntary Agreement

Costs to industry (as well as consumers) will vary depending on the objectives and targets of the voluntary agreement (VA). While they could potentially be as high as those resulting from marketing and use restrictions, one of the perceived advantages of VAs is the ability of the contracting parties to choose the most cost-effective option in meeting their obligations under the agreement.

While it could be costly to 'police' compliance with the agreement (especially when dealing with a large number of SMEs), administrative costs could be reduced because the pursuit of information on which policy instruments are designed is reduced. Indeed, most VAs involve the volunteering of information to the regulator by regulated parties. At the same time, the running and management of the VA should be the responsibility of the industry and not the regulators. For instance, the identification of 'free-riders' and the allocation of fines or other penalties should be tasks to be performed by industry.

In general, monitoring costs will depend on the structure of the market, the frequency of monitoring and whether individual sites are capable of performing it on their own. General monitoring of emissions may already be taking place due to companies' obligations under different frameworks (for instance, IPPC). Any further needs for monitoring of compliance should be discussed at the negotiation stage and will vary in accordance with the number of sites involved and the specific targets of the agreement.

9.6 Summary of Assessment of Socio-Economic Impacts of Risk Management Options

Table 9.1 overleaf summarises the envisaged socio-economic impacts of the risk management options that have been considered under this RRS.

Table 9.1: Summary of Socio-Economic Impacts of Risk Management Options

Measures	**Socio-Economic Impacts**
Controls on Marketing and Use	The economic impacts can be expected to minimal for all the affected sectors with the possible exception of the rubber industry and the paints and coatings industry.
Emissions and Exposure Control	Significant costs are not expected as a result of emissions control under IPPC and WFD – as some of the requirements would have to be met in any case.
Economic Instruments	In comparison to restrictions on marketing and use, economic instruments could offer a more proportional approach to the reduction of risks; however, it is not clear that they would be greater or lesser than those associated with direct regulation.
Voluntary Agreement	Monitoring costs will depend on the structure of the market, the frequency of monitoring and whether individual sites are capable of performing it on their own.

10. DEROGATION ISSUES

10.1 Uses Requiring Derogations from Restrictions

As discussed in Section 8 and 9 above, although marketing and use restrictions are a useful tool for controlling the risks identified in the RER, a blanket approach may not be appropriate. On this basis, the following uses of OP/Es and OP-based resins have been considered for derogation under any proposed marketing and use restrictions (with the reasons provided):

- **use of OP/OP-based resins in rubber formulation**:
  - considering that the use of tyres is of major socio-economic importance to both the UK and the EU, it is believed that the use of OP should be allowed until the technical, environmental and economic aspects of OP substitution are clarified. Also, potential trade barrier issues may apply if any restrictions are placed on OP;
  - the imminence and degree of risk associated with OP use in rubber formulation has also been taken into account, in particular the relatively low risk characterisation ratios for the terrestrial and aquatic compartments (1.49 and 4.05 respectively) based on generic scenarios; and
  - existing regulatory frameworks and site-specific emissions control measures (taking into account the 'captive' use pattern of OP and possibility of the identifying and monitoring such users) provide options for addressing the risks from OP-based resins in rubber formulation.
- **use of OP/OP-based resins in insulating varnishes, printing inks and paints**:
  - as insulating varnishes, printing inks and paints and coatings are of socio-economic importance to both the UK and the EU, it is considered that the use of OP is allowed until the technical, environmental and economic aspects of OP substitution are clarified. Also, potential trade barrier issues may apply if any restrictions are placed on OP;
  - the imminence and degree of risk associated with OP use in insulating varnishes (risk characterisation ratio of 1.82 for the aquatic compartment) and paint application (risk characterisation ration of 1.03 for the terrestrial compartment) have also been taken into account; and
  - existing regulatory frameworks and site-specific emissions control measures provide options for addressing the risks from OP in these uses. Notably the risks associated with paints relate to industrial and not consumer use.
- **use of OPEs in emulsion polymer manufacture**:
  - information received for the RRS indicates that, although the introduction of alternative substances is considered in principle to be a feasible option, a timeframe of not more than three years may be required to move to suitable alternatives. This has been taken into account as well as the suitability of existing regulatory frameworks and site-specific emissions control measures to address the risks from OPEs in emulsion polymer manufacture.

10.2 Proposed Derogations

Taking into account the reasons given above, these critical applications should be included in marketing and use restrictions only under a conditional five-year derogation.

At the end of five years, the derogation for use of OP/OP-based resins in rubber formulation, insulation varnishes, printing inks and paints and coatings would be subject to review. Should industry seek an extension to the derogation, a review of progress would be carried out at the end of the five-year derogation. The review process would examine the progress made in the research and development (R&D) into substitute chemicals and technologies for the identified critical uses of octylphenol. It is proposed that industry should be required to provide evidence of research progress together with tangible evidence of continuing problems in substitution and of the need to continue using OP. Other issues to be considered might include quantities used, efficiency of emissions control, emissions monitoring data, substances/technologies researched, performance issues, worker health & safety considerations, time to market, etc. It is proposed that the detailed scope of issues to be covered in the review be agreed between the appropriate regulators (i.e. Defra and the Environment Agency in the UK, or the European Commission for the EU) and the relevant industry sectors. The level of detail required to justify any continuation of the derogation will also need to be agreed between the appropriate regulators and the relevant sectors. For instance, issues related to commercial confidentiality may form a necessary part of any such agreement.

For use of OPE in emulsion polymer manufacture, the five-year derogation will effectively represent a transitional period for the affected users to move to alternative substances and/or processes which should be available in three years time; hence, this use should not be subject to review at the end of the five-year period.

These derogations are consistent with the requirements which will be placed on OP under an authorisations procedure under the proposed REACH regulation. As set out in Part A of this RRS, authorisations may be granted for (specific) uses of a substance for which the applicant shows that the risks posed by a substance are adequately controlled or where the socio-economic benefits for those uses outweigh the risks and there are no alternative substances or technologies.

11. OVERVIEW OF JUSTIFICATION FOR THE PROPOSED RISK REDUCTION STRATEGY

11.1 Description of Proposed Risk Reduction Strategy

Preventing the re-occurrence of historical uses, the continuation of dispersive and uncontrolled uses, and the development of new uses with the potential to release OP to the environment is viewed as being essential to the success of this RRS in addressing the environmental risks associated with 4-*tert*-octylphenol. A reduction in releases of 4-*tert*-octylphenol from point sources which are responsible for significant releases into the environment, as well as curtailing unaccounted uses which may be unknown to manufacturers of OP (including the manufacturers of OP-based resins and OPEs) and regulatory authorities, is also considered crucial.

In determining the appropriate risk management measures, the assumptions within the RER, the use of generic (default) scenarios for some of the sectors and the possible exaggeration of risks has been taken into account. The relevance, performance and implementation of existing risk management measures have also been taken into account, particularly, the UK Voluntary Agreement on NP/Es and OP/Es, the full implementation of the IPPC Directive in 2007 and the future implementation of the Water Framework Directive over the next 20 years. Notably, the Water Framework Directive will require a progressive reduction in discharges, emissions and losses of OP to the environment and, as such, this RRS should, *inter alia*, support the achievement of this objective.

On the basis of the findings of the RER and the information collected for the purposes of this RRS, the following recommendations for a RRS are made:

Recommendation 1

It is recommended to consider at UK level, marketing and use restrictions under the Technical Standards Directive 98/34/EC (subject to clearance from EC authorities) for **all uses of octylphenol**, except in:

- manufacture and use of OP and OP-based resins in:
  - rubber formulation;
  - insulating varnishes;
  - printing inks;
  - paints and coatings; and
- manufacture and use of OPEs in emulsion polymer manufacture for use in paints.

These uses will be subject to a five-year derogation (subject to review at the end of this period) pending provision of information which shows that the risks posed by OP/Es are adequately controlled, the socio-economic benefits for these uses outweigh the risks and there are no alternative substances or technologies.

Recommendation 2

For these derogated uses and all uses of 4-*tert*-octylphenol in the EU[20], it is recommended that:

- emission limit values or equivalent parameters or technical measures regarding octylphenol are set out in the permits issued under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) in order to operate by the end of October 2007 according to the best available techniques taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions; and

- to facilitate permitting and monitoring under Council Directive 96/61/EC (Integrated Pollution Prevention and Control), the results of the octylphenol risk assessment should be taken into account in developing guidance on Best Available Techniques (BAT). Also, the results of the RER should be taken into account in the next revision of the relevant BREFs (where this includes the horizontal BREF on the chemical sector).

Recommendation 3

For possible releases of OP/E as an impurity in commercial NP/E, the uncertainties regarding the presence of 4-*tert*-octylphenol in specific NP/E isomers, the changes in NP/E tonnages in various industry sectors in the last ten years and the existing marketing and use restrictions on certain uses of NP/E have been taken into account. It is thus recommended that further sampling, monitoring and analysis is undertaken to confirm the presence and resulting risks of 4-*tert*-octylphenol in the NP/E processes at specific industrial sites and where these are found to be significant (i.e. the PEC is greater than the PNEC), IPPC controls are put in place, as appropriate. Information provided in Annex 2 on the critical loads of OP can also be taken into account by regulatory authorities in this regard.

Recommendation 4

Finally, with regard to possible releases of OP/Es from imported textiles, it is recommended that further analysis is undertaken to ascertain the scale of this problem at the UK and EU levels and a peer review of the available data is undertaken prior to any further recommendations. The aforementioned analysis would aim to clarify, *inter alia*, the amount of OP/Es present in finished textiles and the total amount (or proportion) of textiles imported into the UK/EU actually containing OP/Es.

[20] While all efforts were made during the development of this RRS to obtain information at an EU level for the uses of 4-*tert*-octylphenol, it is recognised that the information received, while significant, does not provide sufficient evidence on which to recommend marketing and use restrictions at an EU level. This would have to be the subject of a more detailed investigation which is strictly outside the scope of the terms of reference for this study.

11.2 Risk Related Justification for Risk Management Action

This RRS recommends measures that take into account the current (and foreseeable) controls/measures (including those which affect NP) that impact upon the levels of environmental risk from OP and effectively reduce risks to the environment, while imposing the minimum necessary burden on society as a whole.

The RER for 4-*tert*-octylphenol indicates the need to reduce the predicted risks for the freshwater and marine aquatic (including sediment) compartments, waste water treatment plants (WWTP) and the terrestrial compartment associated with a number of lifecycle stages (EA, 2005a).

4-*tert*-octylphenol has also been identified by the Oslo and Paris Convention for the Protection of the Marine Environment of the Northeast Atlantic (OSPAR) as a substance for priority action and has been included in the EU Water Framework Directive (2000/60/EC) list of priority substances (Annex X to the Directive). It is thus generally recognised as a hazardous substance in the environment and is now classified as 'dangerous to the environment' with the following risk phrase: *R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment*.

Octylphenol also exhibits endocrine disrupting properties and snails have been shown to be a potentially sensitive group of organisms. It has thus been included in the candidate list under the EC Community Strategy on Endocrine Disruptors as an endocrine disruptor of medium concern. The Environment Agency in the UK has also published a strategy for endocrine disrupting substances in the environment and OP/Es are included on the list of substances for which endocrine-disrupting effects have been reported (OSPAR, 2004).

11.3 Justification for Risk Management Action on a UK-wide basis

4-*tert*-octylphenol is a high production volume chemical and is the most likely immediate replacement for NP which was assessed for risks to the environment and human health under the Existing Substances Regulation (ESR) 793/93/EEC and is currently the subject of marketing and use restrictions under Council Directive 76/769/EEC. On this basis, the Environment Agency for England and Wales commissioned a detailed environmental risk evaluation to cover the current lifecycle of OP and to investigate whether its use as a NP substitute is likely to give rise to risks.

UK action to address the risks from 4-*tert*-octylphenol is justified on the basis that:

- despite the efforts made during the development of this RRS and the RER to obtain information at an EU level for the uses of 4-*tert*-octylphenol, the information received, while significant, does not provide sufficient evidence on which to recommend the most appropriate risk management measures at EU level; and

- there appear to be replacements of NP/Es with OP/Es in applications which are not historically significant uses of OP/Es and have been the subject of marketing and use

restrictions regarding NP use. The discovery of widespread, dispersive and unaccounted uses of OP in the UK has the potential to result in risks in both the UK and EU. In addition, it is recognised that some of the uses considered historical in the UK may not be historical in other Member States.

Also, an assessment of the UK voluntary action (See Annex 1) to reduce the risks from OP/Es shows that, while the tonnages used are reducing, there is a need for further action to limit the risks.

In general, the production and use pattern for OP/Es suggest that there may be potential problems in other EU Member States, in addition to the UK. The risks identified in the RER may be more prominent in Member States where production and use are at a level higher than the UK. On this basis, it may be useful for Member States or the European Commission to examine the RER and RRS in further detail and where required, further consultation at EU level is undertaken to provide the relevant information.

PART E

INFORMATION ON STAKEHOLDER CONSULTATION

12. CONSULTATION AND DATA COLLECTION

12.1 List of Stakeholders Consulted

Name	Country
Airbus	FR
Akzo Nobel	SE
Albion Chemicals	UK
American Chemistry Council	USA
Asahi Fluoropolymers UK Ltd	UK
Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien (AISE)	EU
Association of Plastic Manufacturers of Europe (APME)	EU
Association Technique de L'Industrie Européenne des Lubrifiants (ATIEL)	EU
Asutex	ES
BASF	DE
BIP	UK
Benjamin Vickers	UK
British Adhesives and Sealants Association (BASA)	UK
British Association for Chemical Specialities (BACS)	UK
British Chemical Distributors and Traders Association (BCDTA)	UK
British Coatings Federation (BCF)	UK
British Electrotechnical and Allied Manufacturers' Association (BEAMA)	UK
British Fragrance Association (BFA)	UK
British Leather Confederation (BLC)	UK
British Rubber Manufacturers Association (BRMA)	UK
British Tyre Manufacturers Association (BTMA)	UK
Buckman Chemicals	UK
Catomance	UK
Centre for Environment, Fisheries and Aquaculture Science (CEFAS)	UK
Chemetall	UK
Chromatech	UK
CHT	UK
Ciba Speciality Chemicals	UK
Comite Europeen des Agents de Surface et leurs Intermediaires Organiques (CESIO)	EU
Confederation of Paper Industries (CPI)	UK
Conseil Europeen des Phenols Alkyles et Derives (CEPAD)	EU
Cosmetic, Toiletry & Perfumery Association (CTPA)	UK
Cray Valley	UK
Crop Protection Association (CPA)	UK
Dick Peters	NL
Dow Europe GmbH	CH
Dr Petry	DE

Name	Country
Europacable	EU
European Adhesives Manufacturers Association (FEICA)	EU
European Adjuvants Association (EAA)	EU
European Council of the Paint, Printing Ink and Artists‘ Colours Industry (CEPE)	EU
European Crop Protection Association (ECPA)	EU
European Information, Communications and Consumer Electronics Technology Industry Association (EICTA)	EU
European Leather Association (COTANCE)	EU
European Oilfield Speciality Chemicals Association (EOSCA)	EU
European Phenolic Resins Association (EPRA)	EU
European Polymer Dispersion and Latex Association (EPDLA)	EU
European Rubber Chemicals Association (ERCA)	EU
European Stabiliser Producer Association (ESPA)	EU
European Synthetic Rubber Association (ESRA)	EU
European Tyre and Rubber Manufacturers Association (ETRMA)	EU
FC Limited	UK
Focus DIY	UK
Goodyear	USA
Group for Organic Surfactants and Intermediate Products (GOSIP)	UK
Huntsman Chemicals	UK
Independent Union of the European Lubricant Industry (UEIL)	EU
Kolb	CH
Lanxess	DE
Magna Colours	UK
M&J Polymers	UK
Mobile Rosin Oil Ltd	USA
Novartis Animal Health	UK
Noveon Inc.	UK
Omya	UK
Plastic Additives Group - CEFIC	EU
Polymeri Europa	IT
PPG Glass	UK
Protex Chemicals	UK-FR
Rhodia	FR
Rohm and Haas	UK
Rudolf Chemicals	DE
Sasol	DE
Schenectady	UK
Schill & Seilacher	DE
Stahl UK	UK
Stepan Europe	UK
Stevenson Group	UK
Sumitomo Bakelite	BE
Technical Committee of Petroleum Additive Manufacturers in Europe	EU

Name	Country
(ATC)	
Tegewa	DE
Texchem	UK
Textilcolor	CH
Textile Finishers Association (TFA)	UK
Thames Water	UK
Thor	UK
Total UK Ltd	UK
UK Cleaning Products Industry Association (UKCPI)	UK
UK Lubricants Association (UKLA)	UK
Union Chemicals	UK
University of Leeds	UK
White Sea & Baltic	UK
Pesticides Safety Directorate (PSD)	UK
Veterinary Medicines Directorate (VMD)	UK
Small Business Service (SBS)	UK

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ANNEX 1

ASSESSMENT OF THE UK VOLUNTARY AGREEMENT

ANNEX 1: ASSESSMENT OF THE UK VOLUNTARY AGREEMENT

A1.1 Background to the Voluntary Agreement

In 2001, the UK Chemicals Stakeholder Forum (CSF) undertook a review of the risks posed to the environment and to human health via the environment as a result of uses of nonylphenol (NP), nonylphenol ethoxylates (NPEs), octylphenol (OP) and octylphenol ethoxylates (OPEs). This review was based on the NP risk assessment report (RAR), the NP risk reduction strategy (RRS) and the draft RAR for OP - which suggested that similar risks (to those from NP) would occur if OP replaced NP.

Following this review, the CSF wrote to the UK Government in June 2002 advising that a formal voluntary agreement (VA) with industry should be established to speed up a reduction in the use of nonylphenol and its ethoxylates (NP/Es) in sectors likely to lead to the greatest environmental exposure and where costs are proportionate. This was done on the basis that it would take a considerable period of time (up to four years) for marketing and use controls to be agreed in the EU and implemented via UK legislation. The CSF also concluded that similar action should be taken for octylphenol and its ethoxylates (OP/Es) because, while they are much less widely used than NP/Es, they have similar properties and could potentially be used as substitutes, resulting in similar levels of risk.

On 18 October 2002, the Government announced its decision to accept the CSF's advice and at the same time called for industry to come forward with proposals for voluntary action. Following a series of meetings and discussions between Government departments and industry sectors, and between industry sectors themselves, proposals for voluntary action to reduce the risks from NP/Es and OP/Es were submitted by industry representatives on 1 August 2003. These proposals were converted into a formal agreement which took effect from April 2004.

The objectives of the voluntary proposals are to:

- rapidly reduce the risk from NP/Es to the environment by making early progress in replacing NP/Es in a number of uses and to minimise discharges into the environment in order to reduce existing risks to the environment;

- prevent the development of new risks from OP/Es by preventing the use of OP/Es as substitutes for NP/E for those uses to be phased out; and

- reduce the risks from OP/Es by phasing out uses of OP/E in targeted sectors.

Signatories to the VA include trade associations representing suppliers of NP/Es, OP/Es, industrial users of NP/Es and OP/Es and suppliers of alternatives to NP/Es and OP/Es. The trade associations propose to work with their members:

- to promote awareness among their customers of the VA and forthcoming legislation;
- to facilitate substitution of NP/Es by promoting safer alternatives;

- not to promote OP/Es as substitutes for NP/Es;
- to harmonise the environmental classification and labelling of NP/Es and OP/Es; and
- trade associations would report on annual sales of NP/Es and OP/Es by their members and on the results of a communication campaign by 31 December 2003.

The main features of the proposals from downstream users are to:

- stop using NP/E and OP/E in new formulations from the start of the VA;
- phase-out use in existing formulations as soon as possible or by December 2004 at the latest;
- promote and publicise the agreement widely within their sector; and
- provide monitoring data on use for up to five years.

The main signatories to the VA are as follows:

- British Association for Chemical Specialities (BACS);
- British Chemical Distributors and Traders Association (BCDTA);
- British Fragrances Association (BFA);
- Conseil Européen des Phénols Alkylés et Derivés (CEPAD);
- Crop Protection Association (CPA); and
- Cosmetic, Toiletry & Perfumery Industry (CTPA);
- Confederation of Paper Industries (CPI);
- UK and European Adjuvants Associations;
- Focus (DIY) Ltd;
- the CIA Sector Group for Organic Surfactants and Intermediate Products (GOSIP); and
- the UK Cleaning Products Industry Association (UKCPI).

The aim of the following sections is to review the effectiveness of the VA in reducing the risks from NP/Es and OP/Es. The Sections below thus:

- set out the trends in use and sales of NP/Es and OP/Es in the last four years;
- provide the views of industry (signatories) on the impact of the VA; and
- evaluate the effectiveness of the VA against some key criteria.

A1.2 Trends in the Use and/or Sales of NP/Es and OP/Es in the UK

Sales of NP/Es and OP/Es by Members of CEPAD

Table A1.1 below shows sales of NP, OP and APEs to the UK and Ireland by CEPAD members. According to CEPAD, while sales of NPEs and OPEs have declined significantly, sales of NP to the UK did not decline as the specific uses were outside the scope of the voluntary agreement (e.g. sales of NP to produce phenolic resins).

Table A1.1: Sales of NP, OP and APEs to the UK and Ireland by CEPAD Members (Indexed)						
	2000	**2001**	**2002**	**2003**	**2004**	**2005**
NP	100	107	121	102	125	?
OP	100	11	17	7	8	?
APEs	100	46	42	32	28	11
Source: CEPAD						

Use of NP/Es and OP/Es by Members of CTPA

Table A1.2 below provides the quantities of NP, NPE and OPE used in the UK by CTPA member companies from 2002 – 2005.

Table A1.2: Quantities of NP/Es and OPE Used by CTPA Member Companies in the UK				
Quantity in tonnes	**2002**	**2003**	**2004**	**2005**
NP	5	4.7	**0**	**0**
NPE	12.8	5.4	8.2	**0**
OPE	0.1	0.1	0.1	0.1
Source: CTPA				

Sales of NP/Es and OP/Es by Members of BACS

Table A1.3 below shows the trends in the sales/use of NP/Es and OP/Es by BACS members companies. In BACS' view, the voluntary scheme has worked well as uses of NP/Es and OP/Es in 2005 are significantly below those of the previous years and the number of companies with zero returns have increased steadily (in 2002, 1 company had zero returns, this increased to 8 companies in 2004 and 16 in 2005). In BACS' opinion, there is no evidence that OP/Es are being used as substitutes for NP/Es and risk management measures on OP/E would be unlikely to have more than a minimal impact on their members (as they do not use significant quantities of OP/Es).

Table A1.3: Sales/Use of NP/Es and OP/Es by BACS Member Companies (in tonnes)										
Use	**NPE**				**OPE**				**NP**	**OP**
	2002	**2003**	**2004**	**2005**	**2002**	**2003**	**2004**	**2005**	**2004/ 2005**	**2004/ 2005**
Sold as surfactant to blenders	983	1737	1100	**0**	146	139	100	**0**	**0**	**0**
Manufacture of phosphate esters	73	70	125	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Soldering fluxes/Oil industry	68	68	40	75*	5	6	**0**	3	**0**	**0**
Disinfectants	239	130	149	1**	**0**	**0**	**0**	**0**	**0**	**0**
Antifoams	16	16	12	**0**	1	2	**0**	**0**	**0**	**0**
Industrial Cleaners/Degreasers	170	188	117	**0**	**0**	**0**	**0**	**0**	7/**0**	**0**
Pesticides	6	3	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
** Use not covered by Controls on Nonylphenol and Nonylphenol Ethoxylate Regulations, Statutory Instrument 2004 No. 1816*										
*** Usage ceased on 12th January 2005*										
Source: BACS										

Use of NP/Es and OP/Es by Members of CPA

Table A1.4 below provides the quantities of NPE and OPE used in approved pesticides in the UK by CPA member companies from 2003 – 2005.

Table A1.4: Quantities of NPE and OPE Used in Approved Pesticides in the UK by CPA Members			
	2003 (M Tonnes)	**2004 (M Tonnes)**	**2005 (M Tonnes)**
Membership	23	23	22
Responses	9	16	17
NPE	104.44	177.958	98.93
OPE	21.42	37.32	0.161
Source: CPA			

CPA, however, notes that there may be companies who do not belong to the CPA and are not party to the agreement and as such, have not provided data for the VA. These are likely to be companies that do not manufacture themselves and as such, do not hold their own product registrations. The figures presented are, however, thought to be in accordance with the expected trend (by CPA) in which there would be little decline in use initially but with a sharp fall later, reaching zero in 2007.

Use of NP/Es and OP/Es by Members of GOSIP

Table A1.5 below provides the quantities of APEs sold by GOSIP members. Information received from GOSIP shows that since 2004, their membership has changed with a number of members discontinuing their membership such that there is only one member currently involved in the manufacture and sale of NPE. Due to commercial confidentiality rules, GOSIP cannot provide the figures for this company; however, it is understood that this company is also a member of another association which is also a signatory to the VA and will be providing their sales data through this association. GOSIP also notes that all companies that have left GOSIP still retain their membership of other signatory associations and, as such, are still complying with VA reporting commitment, albeit through a different route. In lieu of this, GOSIP believes that it is important that the coverage of the signatories be reviewed to ensure that annual data comparisons are still statistically meaningful.

Table A1.5: Quantities of APEs Used by GOSIP Member Companies in the UK (Indexed)	
Year	**Quantity in tonnes**
2000	100
2001	44
2002	24
2003	9
2004	7
2005	-
Source: GOSIP	

Sales of NP/Es and OP/Es by Members of BCDTA and Use of NP/Es and OP/Es by Members of BFA and UKCPI

According to the BCDTA, no sales of OP/Es or NP/Es were recorded in 2005. Similar information was received from the BFA, which states that none of their members uses NP/Es or OP/Es. The UKCPI also indicates that AP/Es have not been used in the UK cleaning products sector for a significant length of time.

It is of note that information collected for the purposes of the OP RRS suggests that some quantities of OPEs have been supplied to both the UK fragrance and cleaning products sectors.

Use of NP/Es and OP/Es by Focus DIY

Between April 2002 and June 2003, all Focus suppliers were asked to complete a questionnaire about the chemicals used in their products. The survey responses indicated that 16 of their suppliers were using NP/E and/or OP/E in their products – half of whom were already taking action to reduce or replace these chemicals in their products. In 2004, another survey was conducted in which 11 suppliers (out of 42 responses) were using NP/E and/or OP/E in their products or packaging. A review of the industrial sectors of these suppliers showed that no NP/Es were used in products or packaging manufactured in sectors restricted by the marketing and use controls on NP/Es that came into force on 17th January 2005. Only 2 of these suppliers did not have action plans in place to phase-out these chemicals due to the lack of cost effective alternative substances.

Focus has suggested that no further information has been requested from suppliers for the year 2005. The reason for this is that less than 30% of the suppliers in their survey were still using NP/Es and OP/Es at the end of 2004 and these substances were being used in products and packaging manufactured in sectors not restricted by the marketing and use controls that came into force in January 2005.

Sectors for which Tonnage Data for 2005 have not been Submitted

For the following sectors/signatories, data for the year 2005 were not submitted in time for inclusion to this assessment:

- Confederation of Paper Industries; and
- UK and European Adjuvants Associations.

It is not clear what implications this may have for the overall effectiveness and success of the VA. For instance, it has been suggested that larger quantities of NPE and OPE are used in adjuvants than in pesticides.

A1.3 Views of Industry (Signatories) on the VA

It is considered that the views and experiences of UK industry (in particular, the VA signatories) are an important aspect in assessing the efficacy of the VA. The discussion below centres on some key questions – relating to the content, implementation and impact (cost/benefits) of the VA – which were posed to industry and the responses received.

1. ***How do you believe the Voluntary Agreement influenced the relationships and the exchange of information between industry associations/companies and other actors in the supply chains of the sectors of concern?***

   Some companies/industry associations were of the opinion that the VA had an important role in bringing together a broad range of stakeholders (manufacturers of NP/Es and OP/Es, manufacturers of alternatives, downstream users, etc.) and made connections and communication along the supply chain possible.

   One company respondent noted that they and other actors in the supply chain collectively developed a template of communication to address issues pertaining to the marketing and use restrictions and the use of alternatives - and that was the first time this had taken place. They had to significantly improve their websites to provide new and more detailed information, particularly on alternatives and this is believed to have been a success judging from the increase in the number of hits on their web pages, particularly by people looking for information on alternatives.

   Other companies/industry associations did not experience any impact on the supply chain as there were already links across the supply chain (probably due to the very nature of the sector). One trade association was of the opinion that gathering responses or data collection would always be a problem.

2. ***Has the Voluntary Agreement acted as a forum where information on the availability and technical suitability/feasibility of alternatives to APEs could be disseminated and discussed? Also, has it helped in sending a single message across the supply chains that APEs need to be replaced with alternative chemicals?***

   None of the respondents felt that the VA acted as a forum for exchange of information on alternatives. While it may have brought manufacturers in contact with their downstream users, technical discussions on suitable alternatives are not considered to be attributable to the VA.

   As regards sending a single message, some industry sectors agree that the VA helped in setting clear deadlines for replacement of NP/Es and OP/Es, while in other sectors, the VA was of no consequence in this regard. It should, however, be borne in mind that due to the faster than expected progress in the development of legislation on NP/E, the VA ended up being a forerunner to the marketing and use restrictions so it could be argued that the single message (or deadline) related to both the VA and the restrictions. This is obviously not the case for OP/Es.

3. ***How do you think your consumption/sales would have evolved if there was no Voluntary Agreement, taking into account the introduction of Marketing and Use Restrictions on NPEs soon after the signing of the Agreement? More generally, what do you think the benefits of the Voluntary Agreement have been considering that the EU-wide restrictions were introduced soon after?***

   In general, most respondents were of the opinion that the VA did not make a significant difference in consumption/sales as (a) the marketing and restrictions which were already on the way (within a few months) would have caused consumption/sales to change regardless of the VA and (b) there was already minimal use of NP/Es and OP/Es in some of the sectors – especially those covered by other agreements which affected the use of NP/Es (e.g. cosmetic sector). In this case, the VA was considered in a number of sectors to be commercially neutral. As noted by one respondent, if by signing up to the VA, UK companies were disadvantaged in comparison to non-UK competitors, it is likely that things would have been different. Another respondent was of the opinion that without the looming restrictions, only companies interested in their public image would have signed up and the whole process would have been slower.

   More broadly, while the presence of a VA in the cosmetics sector since 1994 meant that NPE use was already low and the impact of the current VA on consumption/sales has been marginal; the UK VA helped reinforce the existing VA in the cosmetics industry. A similar situation applies to the cleaning products sectors, which according to UKCPI, had taken action on these substances long before the VA or restrictions came into force. However, it is now known (as a result of the OP RRS) that OPEs are still supplied to the cleaning products sector in the UK.

4. ***Do you believe that the Voluntary Agreement gave UK companies a significant relative advantage in preparing for the Marketing and Use restrictions on NPEs?***

   In general, most respondents were of the opinion that there were no clear-cut advantages to them from the VA in terms of preparing for the restrictions. However, the VA was clear and straightforward regarding what needed to be done before the marketing and use restrictions came into force. Hence, it had some benefit (albeit, unquantifiable and marginal) in helping UK companies pre-empt the EU action. On the other hand, one respondent noted that in some cases, the VA proved to be a disadvantage for UK companies as other companies in other EU Member States did not take any action until the restrictions came into force.

5. ***Were there any specific problems in implementing the Voluntary Agreement or involving your members in the process of implementation?***

   The answer to this question varied according to the sector. For cosmetic manufacturers, the main problem relates to (a) the large number of ingredients used (up to 2,000), (b) the large number of product ranges, (c) the formulation (modification/update) cycle which occurs over a two to three year cycle and (d) the world/EU market for their products. These reasons make it difficult to trace (or

correlate) products and formulations sold in previous years to various markets. In general, it appears that the cosmetic industry finds it easier to make decisions on future ingredient use compared with obtaining historical use data on ingredients used.

With regard to the global market for cosmetic products, a problem arises from the fact that companies use standard formulations in as many markets as possible. So, for instance, companies may find it difficult to convince the US parent company that manufactures a cosmetic product to revise a formulation containing NPEs when NPEs are not restricted in the US and the UK accounts for only a small market in sales terms. For this reason, EU-wide solutions (or agreements) are generally preferred by the cosmetic industry.

For crop protection, however, the CPA indicates that there are some problems experienced by their members in obtaining approvals (for NPE-free formulations) in time from the PSD.

The BCDTA did not experience any significant problems as their members were keen to enhance their public image (or assume the moral high ground) and, as such, signed up to the VA quickly. As noted earlier, a number of associations also considered the agreement to be commercially neutral and, as such, were happy to sign up.

6. ***Do you believe that the benefits from the Voluntary Agreement have been proportionate to the efforts by your members?***

Most responses indicated that the benefits from the VA had not been proportional to the effort put in. On the one hand, one respondent was of the opinion that the VA had performed well in the circumstances with regard to highlighting the upcoming marketing and use restrictions, the need for prompt action and by facilitating communication between interested parties – and as such, could be considered to have been proportional. Another respondent felt that the long drafting period of the VA meant that many members had already made changes by the time it came into force – and as, such, the VA was not disproportionate. More broadly, there were no concerns or complaints regarding the effort put into preparing and participating in the VA.

7. ***Has the request by the UK Government to industry to provide specific consumption/sales tonnages per sector played a significant role in helping to make the Voluntary Agreement successful?***

There were mixed views on this question. While some companies/industry associations answered in the affirmative; others were of the opinion that the collection of sales data had no impact on the success of the VA - as they were already collecting such data from their members/customers either due to marketing reasons or previous regulatory initiatives.

It was, however, highlighted that a VA on NP has been in place in Germany for several years but the statistical figures have not been published on the Internet like in

the UK. In this regard, the UK VA could be considered to encourage transparency and public accountability. A drawback (or slight complication) of collecting such data, however, is that, to comply with competition requirements and rules, indices assuming sales of 100 for the year 2000 and reporting the relative tonnages for each year thereafter have been used by some industry associations.

8. Do you consider that the Voluntary Agreement has spurred innovation in the UK?

In general, the response was that the VA cannot be credited entirely with spurring innovation in the UK, as the restrictions were scheduled to come into force and therefore companies would have had to stop using NPEs anyway; the agreement obviously brought this earlier and helped some companies to identify new suppliers or clients. For instance, in the cosmetics industry, the suppliers had alternatives available and the industry was generally well ahead in understanding what those alternatives were. In summary, the VA may perhaps be credited with speeding up the 'innovation' process but not necessarily with spurring innovation.

9. Do you believe that the Voluntary Agreement would be an appropriate tool for addressing the risks from other chemicals in the future? If yes, do you have any views on the scope of such an Agreement (national versus EU-wide) or parameters that might need to be different in different cases?

Only one respondent believed it was an appropriate tool while another believed that the relevance of a VA should be decided on a case by case basis. Others were keen to stress that any further agreements should be on an EU-wide basis particularly as today's industry does not operate on an isolated or national basis. At the UK level, it could be used to prepare the UK industry for forthcoming legislation (especially marketing and use restrictions) and to show that UK industry is aware of environmental issues.

A1.4 Effectiveness Analysis of the VA

In assessing the effectiveness of the VA for NP/Es and OP/Es, the key question to be answered is: *what were the aims and objectives of the VA and have these been met?*'

In practical terms, the aims/objectives of the VA can be simplified to the following:

1. Reinforcing the provisions of the marketing and use restrictions on certain uses of NP (with the focus on a speedier attainment of risk reduction in the UK).

2. Reducing the use tonnages of NP/Es and OP/Es in various sectors and consequently, the risks (with few fixed quantitative targets set).

3. Promoting awareness amongst UK industry of the environmental risks associated with NP/Es and OP/Es and the need to substitute these substances, where feasible and as soon as possible.

The VA contains few fixed quantifiable targets and focuses more on qualitative targets (i.e. promoting awareness, facilitating substitution, minimising discharges, etc.), it is thus difficult to provide a strictly quantitative assessment of whether it has achieved its goals. Instead, the assessment of the VA would have to be qualitative taking into account the known quantitative facts (such as the trends in use and sales of NP/Es and OP/Es in the UK - see Section A1.2).

Consultation with the signatories to the VA and with UK Government departments and subsequent analysis shows the following:

1. With regard to *Objective 1*, the faster than expected introduction of the marketing and use restrictions on certain uses of NP/Es - which left eight months between the VA and the restrictions coming into force - means that it is difficult to attribute any changes in environmental risks or market sales to the VA strictly; the impacts of the VA and the EU legislation are likely to be captured in the same industry reporting cycle, whether sales or emissions-related. There were also negotiations on the VA for over a year prior to April 2004 which may have alerted industry to start making changes to their formulations earlier. In addition to that, the ESR RAR and RRS for NP/Es (with the latter recommending marketing and use restrictions) had been concluded by 2001. As a result, industry was generally aware of the issues and hence it is not possible to attribute a speedier attainment of risk reduction from NP/Es in the UK to the VA. However, a parallel objective of highlighting the upcoming marketing and use restrictions, making clear to those involved the need for prompt action, and facilitating communication between interested parties could be said to have been some of the positive outcomes of the VA.

2. With regard to *Objective 2*, for NP/Es, the arguments above apply. While tonnages of NP/Es in the UK have reduced significantly, the exact contribution of the VA to this reduction cannot be stated with any certainty. For OP/Es, the situation is different - there were no impending restrictions on the use of OP/Es - and it is possible to attribute a significant part of any reductions in environmental levels or market sales (in the last two years) to the VA. For OP/Es, information collected from UK industry under the terms of the VA shows that there have been significant reductions in quantities of OP/Es used in some of the sectors which are covered by the VA. This is shown in Table A1.6 below. Again, the momentum of the marketing and use restrictions on NP/Es cannot be totally disregarded. The fact that measures were being taken on some substances in the APEs family could and should have alerted many parties in the relevant industry sectors to take a cautious approach and avoid swapping NP/Es with OP/Es, if not to consider a move away from APEs altogether.

   Overall, with regard to *Objective 2*, the VA achieved its objective with the support of the regulatory intervention of the marketing and use restrictions at the EU level. However, what still requires some thought is that the usage and sales figures provided in this review of the VA are applicable only to companies who are members of trade associations which are signatories to the VA. As with most such VAs, there exists the possibility that some companies will not participate in the agreement or will not comply with its requirements.

Table A1.6: Quantities of OP/Es (in Tonnes) used in various UK Industry Sectors as Declared Under the UK Voluntary Agreement						
Sector Representative	**Year**					
	2000	**2001**	**2002**	**2003**	**2004**	**2005**
Relative change in sales to the UK and Ireland by members of the Conseil Européen des Phénols Alkylés et Derivés (CEPAD) (Year 2000 = 100)	100	11	17	7	8	
Sales/use of OPEs by BACS member companies						
- Sold as surfactant to blenders			146	139	100	0
- Soldering fluxes/oil industry			5	6	0	3
- Antifoams			1	2	0	0
Relative change in the use of APEs by GOSIP (CIA) members in the UK (Year 2000 = 100)	100	44	24	9	7	
Quantities of OPE used by Cosmetic Toiletry & Perfumery Association (CTPA) members			0.1	0.1	0.1	0.1
Quantities of OPEs used by Crop Protection Association (CPA) members (16 companies in 2004 compared to 9 companies in 2003)				21.42	37.32	0.16
Source: Information downloaded from Defra website (CSI, 2004)						

Fundamentally, by their very nature, VAs cannot guarantee the absolute success of risk management action nor can they ensure that risks are reduced to an acceptable level. It may always be the case that individual companies do not wish to be involved in and bound by any such agreement or they may not be part of a wider organisation (an industry association) which can co-ordinate the actions of individual companies. An example of this potential shortcoming of VAs can be seen in the case of the UK fragrance company which continues to purchase OPEs (evidently to use in its formulations) even though this runs contrary to the terms of the voluntary agreement which the British Fragrance Association (BFA) signed up to (See OP RRS; Section 2). Naturally, the importance of this company's actions depends on whether or not it is a member of the BFA. If it is not a member, this shows that even where willingness for participation by trade associations exist, a VA may still fail to ensure overall participation and compliance.

3. With regard to *Objective 3*, it is rather difficult to provide an independent verification of whether industry has promoted awareness amongst UK industry of the environmental risks associated with NP/Es and OP/Es and the need to substitute these substances. These are 'soft targets' which are open to interpretation. Information received from industry, however, indicates that there has been dissemination of information and communication up and down the relevant supply chains, where signatories believed that this would be important for achieving the objectives of the VA. The level and quality of this communication cannot be strictly evaluated neither

is it possible to judge whether appropriate action was indeed taken wherever this was 'feasible' or 'as soon as possible'. However, solely on the basis of the quantifiable results of the VA (the documented decreases in tonnages), one could assume that communication and the raising of awareness have been successful in contributing to the positive outcomes of the VA.

In summary, the VA has broadly achieved its objectives, although this has been influenced (albeit, to an unknown extent) by the introduction of the marketing and use restrictions. The main positive points may be considered to have been the improvement of communication channels along the supply lines and the reduction in the use of OP/Es as a result of industry refraining from promoting these products as replacements to NP/Es. Nevertheless the following issues should be noted:

- the analysis for the OP RRS has identified market data suggesting that OP/Es are still used in sectors targeted by the VA;

- use of OPEs in sectors, such as cleaning products and fragrances, which are not currently associated with OP/Es, rather with NP/Es, has been confirmed. These were not identified as areas of application for OPEs in the RER and this could be interpreted as a switch from NPEs to OPEs; and

- there are still considerable levels of OPEs present in pesticide formulations that are supposed to be OPE-free by the end of the year (as stipulated by the provisions of the VA). While there is no indication that the sector will fail to meet its target, it raises questions regarding the desired speedier reduction in risks.

A1.5 Scope for Future use of Voluntary Agreements

Putting all this into perspective, it is useful for the purposes of future risk management to consider how, where and why a VA could be used again as a risk management option. The OP/Es RRS provided a 'case study' for gauging industry's willingness to participate in such an agreement in the future. Companies were asked whether they would be prepared to voluntarily discontinue the use of OP/Es over a specified period and/or agree to ensure that emissions to the environment are below specified levels to ensure no unacceptable risks to the environment and/or to human health. Respondents who answered in the affirmative indicated that such an answer was dependent on:

- the level of any proposed emission limit values;
- an acceptable timescale to allow reformulation of products and completion of customer acceptance trials;
- any such agreement being applied consistently on an EU wide basis to ensure continued business competitiveness for UK based companies; and
- any such agreement applying to only those uses which pose a risk to the environment.

Other companies answered in the negative arguing that:

- with adequate IPPC in place, there should be no need to have to voluntarily discontinue the use of OP/Es;
- as OPEs are most frequently used in contained applications, with minimal releases into the environment, there was no need for any VA;
- the OP RAR does not depict realistic exposure scenarios for the primary uses of OPEs; and
- because OP/Es are primarily used in applications where suitable substitutes are not readily available, reformulation will pose a significant problem. For instance, it was argued that there are no comparable replacement products for OP-based tackifiers in rubber formulation. Any such agreement would mean that tyre companies in Europe would not be able to produce tyres, since all global tyre makers use OP tackifiers to make tyres in all regions of the world. One respondent noted that some potential substitutes have more hazardous environmental profiles than OPE or have not been tested to the extent that OPEs have and are, therefore, not suitable.

Based on the above responses, it can be seen that the approach taken by industry for OP/Es (and assumingly for any other VA in the future) cannot be expected to be the same as for the NP/Es VA. The key issues are:

- *circumstances and willingness*: regarding NP/Es, there had been a long debate (for over 20 years) in Europe on the risks from NP/Es and the appropriate options for risk management. The fact that the marketing and use restrictions were unavoidable meant that companies and trade association may have had little hesitation about signing up. In fact, one could argue that companies and trade associations that signed up to the VA may have benefited in the long-term by promoting a more environment-conscious image to customers and the wider public. As discussed above, the willingness of companies to voluntarily phase-out OP/Es is low;
- *timing*: the marketing and use restrictions on NP/Es appear to have made a significant difference to industry's perception of the acceptability of a VA for NP/Es. This shows that a VA backed up by some sort of regulatory action is more likely to be taken up by industry. Moreover, the experience with the NP/Es VA suggests that the length of the period between introducing regulation and a VA may also influence the effectiveness of the VA;
- *scope*: generally, industry is very conscious about competitiveness issues and wants to ensure a level playing field. Therefore, an EU-wide VA is more likely to be supported by industry as opposed to one with a national focus. UK companies might not have had many competitiveness concerns with the NP/Es VA since it was known that the introduction of EU-wide legislation was imminent; and
- *costs and benefits*: industry will generally opt for a VA if it perceives it as the risk management option with the best balance of costs and benefits. In the case of the

NP/Es VA, the costs were expected to be neutral (while some sectors could have benefited from broadcasting a positive environment-conscious image).

In conclusion, VA is a risk management option, the success of which will depend on several parameters. Underpinning a VA with legislation perhaps offers the safest way of ensuring success. Notably, REACH will offer limited scope for VAs as an option for management of unacceptable chemical risks.

Finally, the design of the VA will play an important role in determining whether it achieves its aims (or not). Analysis and consultation suggests that the following parameters should be carefully considered and set out from the beginning in the case of any future VA:

- *the terminology used*: it is important have consistency in the understanding of the requirements of the VA and the action needed by the signatories and the authorities. For instance, in setting out the industry sectors or uses of a substance which should be reported by signatories, specificity and consistency of reporting among different trade associations or companies will ensure clarity and transparency;

- *the parameters to be measured:* for instance, the tonnages of the substance(s) in question should be reported using the same format. This will allow for an integrated analysis and comparison of data coming from different sources and will facilitate the assessment of whether the VA is succeeding or not. Also, where possible, the targets of the VA should be fully quantifiable as this allows for a more rigorous assessment of effectiveness (as compared with qualitative targets);

- *the creation of a detailed list of signatories and the allocation of companies to specific trade associations*: it is generally the case that most companies tend to be members of more than one association/signatory to the VA. It will be important to clearly list the companies under the representative industry associations as this would help avoid double-counting when information on progress is submitted; and

- *the responsibilities of all parties to the VA*: these should be clearly set out from the beginning, especially with regard to timescales, information collection and reporting.

ANNEX 2

CALCULATION OF CRITICAL EMISSION LOADS FOR OCTYLPHENOL

ANNEX 2: CALCULATION OF CRITICAL EMISSION LEVELS FOR OCTYLPHENOL

A2.1 Data Used

The data on the properties and behaviour of octylphenol are taken from the published risk evaluation report (EA, 2005a). All calculations have been performed using the methods of the TGD as implemented in EUSES 2.0.3 and the physicochemical property values are as follows:

Property	**Value and comment**
Physical state at ntp	White or light pink flakes
Molecular weight	206.33 g/mol
Vapour Pressure	0.21 Pa at 20ºC (no method specified)
Water solubility	19 mg/l at 22ºC (for an aquatic test water)
n-Octanol-water partition coefficient (K_{ow})	log K_{ow} 4.12 at 20.5ºC (OECD 107 shake flask method)
Henry's Law constant	0.52 $Pa.m^3/mol$ at 25°C (measured)
Acid dissociation constant (pKa)	> 9.9 and <12.19

The calculations of the fate of octylphenol in a waste water treatment plant (WWTP) assume that the substance is inherently biodegradable but not meeting the specific criteria for such tests in the TGD, hence there is no biodegradation in the WWTP. The sorption coefficients needed for the calculations were estimated from the log K_{ow} value of 4.12. The resulting distribution in the WWTP is:

- To air: 0.007
- To water: 0.74
- To sludge: 0.25

The fate of octylphenol ethoxylates (OPEs) is described in Appendix 1 of EA (2005a). The key assumptions are that the release of OPEs to WWTP leads to the release of 2.5% of the input as octylphenol to water, and 19.5% of the input as octylphenol to sludge.

Other products from the degradation of OPEs are also considered. From Appendix 1 of EA (2005a), the short chain ethoxylates and carboxylic acids (OP1EO, OP2EO, OP1EC, etc.) account for 25% of the input amount of OPE.

The level of background emissions on the regional and continental scales is taken to be the same as in EA (2005a) except where a hypothetical additional release is considered. The regional concentration of octylphenol in surface water is taken as 0.084 µg/l, the value calculated in EA (2005a). The calculated background concentration for soil is negligible in relation to the PNEC value.

The PNEC for surface water is 0.122 µg/l. The PNEC for soil is 0.00591 mg/kg wet weight.

A2.2 Local Calculations

A2.2.1 Water

The PNEC for water is 0.122 µg/l, and the regional background concentration is 0.084 µg/l. Hence the local contribution to the PEC which would lead to a PEC/PNEC of 1 is 0.038 µg/l.

Assuming the standard dilution of 10 for a WWTP effluent, the concentration in the effluent would be 0.38 µg/l.

The effluent flow for a standard wwtp is 2,000 m^3/day; at a concentration of 0.38 µg/l this corresponds to a load of 0.76 g/day in the effluent. From the data summarised above, the fraction of OP in the effluent is 0.74; therefore the influent load would be 1.03 g/day.

A similar approach can be used to estimate the loading of OPEs which would lead to a risk. The critical load in the effluent is 0.76 g/day as calculated above. The risk evaluation estimates a yield of 2.5% octylphenol from the degradation of ethoxylates in the WWTP. Hence the loading of ethoxylates leading to this level of octylphenol is 30.4 g/day.

This assumes that none of the other products from the breakdown of the ethoxylates have effects. If it is assumed that the short chain ethoxylate products (1-2 units) are equally as toxic as octylphenol, then the yield of OP equivalent would be 27.5%. Hence the critical release rate would be 2.76 g/day of OPE.

The critical emissions are therefore:

- **1.03 g/day (as octylphenol)**
- **30.4 g/day (as OPE, assuming only octylphenol is toxic)**
- 2.76 g/day (as OPE, assuming short chain products are of equivalent toxicity)

The calculations above assume a regional background concentration of 0.084 µg/l. If a negligible background concentration were assumed, so that the local source alone would give rise to a risk, the release rates would be:

- **3.3 g/day (as octylphenol)**
- **98 g/day (as OPE, assuming only octylphenol is toxic)**
- 8.9 g/day (as OPE, assuming short chain products are of equivalent toxicity)

A2.2.2 Soil

Risks are also identified for the terrestrial compartment, through the application of sludge containing octylphenol. For the use of paints containing octylphenol ethoxylates, the PEC/PNEC ratio is 1.04, so the release rate for this scenario corresponds to the critical rate (the background concentration for soil is negligible).

The critical release rate for OPEs to a WWTP is 10 g/day. This relates to the octylphenol produced from the OPEs which is found in the sludge. The other products of OPE degradation are assumed to be found in the water phase and not in sludge, so there is no calculation based on total degradation products for soil.

The yield of octylphenol in sludge from OPE degradation is assumed to be 19.5%. Hence the release of 10 g/day of OPE leads to 1.95 g/day octylphenol in sludge. This corresponds to a concentration of 2.5 mg/kg wet weight in sludge.

The distribution of octylphenol in the WWTP includes 25% to sludge. Hence the release of octylphenol to give 1.95 g/day in sludge is 7.8 g/day.

The critical release rates are therefore:

- **7.8 g/day (as octylphenol)**
- **10 g/day (as OPEs)**

A2.2.3 Regional

This section calculates the additional load of octylphenol required on a regional scale to increase the regional PEC for water to the PNEC value. It has been assumed that the additional releases take place to surface water via a waste water treatment plant.

The release to surface water giving rise to a risk is 23 kg/day, compared to the current value of 12.6 kg/day for regional emissions to surface water. This is an additional 10.4 kg/day.

- If this was due to the release of octylphenol, then the additional release to waste water needed would be 14 kg/day, or **5.1 tonnes per year**.

- If this was due to the release of OPEs, then based on a yield of 2.5% octylphenol from OPEs the additional release of OPEs would be 416 kg/day. This is equivalent to a release of **152 tonnes OPE per year to WWTP**.

Assuming that the sources of these releases are disperse, then the total EU releases would be 10 times higher than these values.