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Chemicals of emerging concern in household products: a case study on the disposal of cosmetics in the United Kingdom

A thesis submitted to Imperial College London for the degree of Doctor of Philosophy in the Faculty of Life Sciences

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DECLARATION OF OWN WORK

I declare that this thesis

‘Chemicals of emerging concern in household products: disposal of cosmetics in UK households as a case study’ is entirely my own work and that where any material could be construed as the work of others, it is fully cited and referenced, and/or with appropriate acknowledgement given.

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DEDICATION

This thesis is dedicated to my aunt, the late Angela Hosein for all her love, unfailing support and encouragement throughout the initial stage of my research. I miss you dearly.

Rest in Peace

"But there is suffering in life, and there are defeats. No one can avoid them. But it's better to lose some of the battles in the struggles for your dreams than to be defeated without ever knowing what you're fighting for."

— Paulo Coelho

ABSTRACT

Household products may contain chemicals of emerging concern (CECs) and their use and disposal can contribute to CECs being released to the environment with the potential to cause concern. Cosmetic products were used to exemplify the source-pathway-effect relationship for CECs, by investigating the use of cosmetics as a prospective pollutant source, their disposal, as a pathway for environmental contamination and, the potential need for effective management of CECs in products. Emphasis was placed on the Registration, Evaluation and Authorisation of Chemicals (REACH) legislation as a framework to consider the use of regulation to facilitate the assessment and management of CECs in household products.

The CECs present in cosmetic products were identified, validated and quantified and, their potential environmental risks were assessed using a methodology developed under the REACH legislation guidelines. Findings demonstrated that once released in the environment, nanomaterials and triclosan have the potential to affect both aquatic and terrestrial organisms. Multi-criteria analysis was used to assess alternative risk management options for the use and disposal of these CECs in cosmetic products.

The analysis indicated the need to manage some CECs in cosmetics to minimize the potential for environmental contamination. REACH has the potential to facilitate the management of these chemicals by shifting the legislative focus from disposal to prevention and minimization. The guidelines under REACH could be amended to improve the risk assessment and management process for CECs. This research demonstrated the efficacy of modifying the guidelines to produce sound assessments, whilst emphasising the need for effective management of CECs in cosmetic products.

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- 2007 ECOTECH-XXI Workshop, Russia: Presentation on the use of multi-criteria analysis for identification of chemicals of emerging concern

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$\boldsymbol{PECinitialmg/l = DOSEai \times FpenWASTEWinhab \times DILUTION}$ Equation 5-2 89

$\boldsymbol{DOSEai}$ $\mathbf{(mg/inh/d)} = \boldsymbol{TCcec365Pop}$ Equation 5-3 89

$\boldsymbol{Fpen}$ % $= \boldsymbol{PopcecPop \times 100365 \rightarrow Popcec = PopPt \times Pcec}$ Equation 5-4 89

$\boldsymbol{PECswmg/l = Clocalsw \times Temission365}$ Equation 6-1 114

$\boldsymbol{PECsed}\mathbf{(mg/kg)} = \boldsymbol{Ksusp - waterRHOsusp \times PECsw \times 1000}$ Equation 6-2 115

$\boldsymbol{PECsoil(mg/kg) = Clocalsoil = 1T \times 0TCsoiltdt \Rightarrow}$ Equation 6-3.....116

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ABBREVIATIONS

ACHS	Advisory Committee on Hazardous Substances
ACS	American chemical society
AF	Assessment factor
AHP	Analytic hierarchy process
APEOs	Alkylphenolpolyethoxylates
BCF	Bioconcentration factor
BFRs	Brominated flame retardants
BHA	Butylated hydroxylanisole
BHT	Butylated hydroxytoluene
BP	Butylparaben
BPA/F	Bisphenol A/F
BP3	Benzophenone-3
CAS	Chemical Abstracts Service
CEC	Chemical of emerging concern
CECs	Chemicals of emerging concern
CMRs	Carcinogenic, mutagenic and reproductive toxins
CSA	Chemical safety assessment
CSF	Chemicals Stakeholder Forum
CSR	Chemical safety report

CV	Consumer valuation
D5	Decamethylcyclopentasiloxane
DBPs	Disinfectant by-products
DDD	Defined daily dose
DDT	Dichlorodiphenyltrichloroethane
DEFRA	Department of Environment, Food and Rural Affairs
DEHP	Di(2-ethylhexyl)phthalate
DEP	Diethyl phthalate
DINP	Diisononyl phthalate
DNELs	Derived no effect levels
DNP	Dinitrophenol
DTPA	Diethylenetriaminepentaacetic acid
EC	European Commission
ECHA	European Chemicals Agency
ED	Endocrine disrupting
EDTA	Ethylenediaminetetraacetic acid
EINECS	European Inventory of Existing Commercial chemical **S**ubstances list
EMEA/CHMP	Committee for Medicinal Products for Human Use
EPA	Environmental Protection Agency

EPM	Equilibrium partitioning method
ERA	Environmental risk assessment
EU	European Union
EU/EEA	European Union/European Economic Area
EUSES	European Union system for the evaluation of substances
EWL	European waste list
HBCD	Hexabromocyclododecane
HHS	Health and human services
IPP	Integrated Product Policy
IRGC	International Risk Governance Council
MBC	Methylbenzylidene camphor
MBT	Mechanical biological treatment
MCA	Multiple-criteria analysis
MECs	Measured environmental concentrations
MSDS	Material Safety Data Sheets
MSW	Municipal solid waste
Nano TiO_2	Nano titanium dioxide
Nano ZnO	Nano zinc oxide
NMOs	Nano titanium dioxide and nano zinc oxide

NORMAN	Network of reference laboratories for the monitoring of emerging environmental pollutants
NPEs	Nonylphenolethoxylates
NP/NPEs	Nonylphenol/ethoxylates
NPV	Net present value
NTA	Nitrilotriacetic acid
OECD	Organisation for Economic Co-operation and Development
OMC	Octylmethoxycinnamate
OSPAR	Convention for the Protection of the Marine Environment of the North East Atlantic
PAEs	Phthalic acid esters
PBBs	Polybromonated biphenyls
PBDDs	Polybromonated dibenzo-p-dioxins
PBDEs	Polybrominated diphenylethers
PBDFs	Polybromonated dibenzofurans
PBT	Persistent, bioaccumulative and toxic
PCBs	Polychlorinated biphenyls
PCPs	Personal care products
PEC	Predicted environmental concentration

$PEC_{initial}$	Initial predicted environmental concentrations
PFCs	Perfluorinatedchemicals
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanesulfonate
PIC	Pesticides in International Trade
PNECs	Predicted no effect concentrations
$PNEC_{SW}$	The PNEC values for surface water
POPs	Persistent organic pollutants
PPCPs	Pharmaceuticals and Personal Care Products
PVC	Polyvinyl chloride
QSAR	Quantitative structure-activity relationship
RCRs	Risk characterization ratios
REACH	Registration, Evaluation, Authorisation and restrictions of Chemicals
RIPs	REACH implementation projects
RMOs	Risk management options
SDS	Sustainable Development Strategy
SEA	Socio economic analysis
SVHC	Substance of very high concern
TBBPA	Tetrabromobisphenol A

TCcec	Total consumption of CEC
TOXNET	Toxicology Data Network database
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
US EPA	United States Environmental Protection Agency
USGS	United States geological survey
UV	Ultra violet
vPvB	very Persistent and very Bioaccumulative
WWTWs	Wastewater treatment works

1 INTRODUCTION

Anthropogenic release of chemicals into the environment is widely recognised as carrying the potential for environmental damage. Since the early 1900s studies of the impacts of chemical pollution have focused almost exclusively on lists of conventional priority pollutants, especially those collectively referred to as 'persistent, bioaccumulative toxicants' (PBTs) or 'persistent organic pollutants' (POPs). Emissions of these priority pollutants have been substantially reduced in most developed countries through the adoption of appropriate legal measures and the regulation of dominant pollution sources, hence focus is now being switched to compounds present at lower concentrations that have only recently been thought of as potential pollutants and are of largely unknown scope, known as 'chemicals of emerging concern' (CECs) (Daughton and Ternes, 1999). The environment has been exposed to these chemicals for many years but their presence is often concealed or masked by properties of the environment that deter or foil their detection, being obscured by interferences and irreversible matrix sequestration. The environmental concentrations of these chemicals are indiscernible (below analytical limits of detection), unreadable due to interference and their mode of introduction into the environment is unknown or unidentifiable, so they have simply been overlooked, or reside in compartments that have previously escaped suspicion such as consumer products and degradates/transformation compounds (Daughton, 2006).

Recently, the appearance of sophisticated tests for monitoring environmental contamination has revealed the presence of such potential contaminants at low levels in the environment (Daughton and Ternes, 1999, Caliman and Gavrilescu, 2009, Field et al., 2006, Gros et al., 2006, Gonzalez et al., 2007, Richardson, 2007). Several extensive

national and multinational monitoring programmes have been launched in order to provide comprehensive reconnaissance of the occurrence of various CECs, with special emphasis placed on chemicals such as pharmaceuticals, hormones and other polar organic contaminants (Kolpin et al., 2003, Reemtsma et al., 2006, Ternes, 2007). The studies have confirmed the presence of complex mixtures of unregulated CECs of various origins, and raised concern about their potential interactive effects (Kuster et al., 2008, Terzic et al., 2008). These chemicals, produced on a large scale worldwide, are used in an expanding range of domestic household products and have the potential to reach the environment via household use and disposal (Trenholm et al., 2008, Kuster et al., 2008, Blundell, 2003). Tighter regulation has been proposed, and the European Commission has introduced the Regulation on the Registration, Evaluation and Authorisation of Chemicals (REACH) 2006, to address this concern (Glegg and Richards, 2007b). However, REACH is still being implemented and its effectiveness in managing CECs is unknown.

Cosmetics commonly known as personal care products (PCPs) are some of the most intensively and frequently used products in households, increasing annually due in part to increased consumer demand (Cosmetic Toiletry and Perfumery Association, 2009). These products contain CECs that can be persistent, bioactive and/or exhibit accumulation potential as well as cause endocrine disruptions (Daughton and Ternes, 1999, Caliman and Gavrilescu, 2009). The fact that PCPs can be introduced on a continual basis to the environment via treated and untreated waste essentially imparts a quality of ‘persistence’ to these compounds that may not otherwise possess any inherent environmental stability as their removal/transformation is continually countered by their replenishment (Daughton and Jones-Lepp, 2001). Although the acute toxicity of these chemicals is reportedly low, some of these chemicals show signs of being of environmental concern.

For example, parabens can act as weak endocrine disrupting substances (Taxvig et al., 2008, Darbre, 2006) and triclosan can be converted, under certain conditions, into more toxic and persistent compounds, such as chlorophenols, dioxins or methyl triclosan (Regueiro et al., 2009). Methylbenzylidene camphor (MBC), a sunscreen agent was also detected in aquatic fauna in a German lake. The bioaccumulation factor, was calculated as a quotient of the MBC concentration in whole fish (21 pg/kg) versus that in the water (0.004 pg/l) and exceeded 5,200, indicating high lipophilicity, hence a high tendency to bioaccumulate (Daughton and Ternes, 1999).

Despite this, the potential concerns arisen from CECs in cosmetics have been given limited attention in scientific work and have been assessed mostly under the umbrella of pharmaceuticals, since some of the active ingredients used in cosmetics are also present in pharmaceuticals. These CECs from cosmetics are unwittingly introduced to the environment as complex mixtures via a number of routes, both direct (disposal and wastage from external application) and indirect (excretion, washing, and swimming), primarily via treated and untreated sewage effluent (Daughton and Jones-Lepp, 2001). However, limited or insufficient physicochemical and toxicological data for some of these bioactive chemicals have made it difficult to predict the levels and/or combinations of chemicals that may cause environmental harm and to comprehensively and systematically analyze these substances in household products that may ultimately end up in the environment (Gendebien et al., 2002). Research on these CECs in cosmetics has so far produced a large but incomplete patchwork of disconnected environmental studies, hence an inability to give sound answers to questions regarding the true risks of CECs for the preparation of strategies to prevent or minimize risks.

The uncertainties associated with the use and disposal of CECs in cosmetics also highlight major challenges for the management and indeed the evaluation of the need for managing cosmetic products. In the context of REACH, chemical safety assessments (CSA) are used to analyse environmental risks of chemicals and socio economic analyses (SEAs) describe and analyse all relevant impacts (both positive and negative effects) of imposing restrictions compared to the continued use of chemicals. However, the shortcomings of REACH could influence the decision making process for assessing and managing these CECs. REACH does not apply to the use of CECs in finished products, therefore cosmetics such as decorative make up, hair and skin care products made outside the EU could contain chemicals that are not registered under REACH. The process is costly and involves in-depth data collection and analysis to ensure data reliability. As a result, there are substantial numbers of chemicals awaiting assessment under REACH and this very lengthy process creates difficulties for assessing the full impacts of this regulation. Another key consideration under REACH is whether risk assessment should always be a prerequisite to a decision on whether or not a chemical should be marketed and whether the outputs from standard risk assessments could be used for socioeconomic assessment inputs. These uncertainties create difficulty in forming coordinated and coherent management opinions. This study therefore analyses the questions of "What are the relative risks to the environment from CEC exposure due to the use and disposal of cosmetics? Is there a need to manage CECs present in cosmetic products? Could REACH legislation be an effective tool for managing these CECs?"

1.1 Thesis Outline

Understanding the sources and pathways for CECs in the environment is a crucial step in addressing and reducing the uncertainty associated with estimating the likelihood of

environmental exposure of CECs from products. More importantly, understanding the sources and pathways of CECs strengthens the ability to quantify effects to predict the likelihood of effects. This provides critical information required to render decisions regarding regulatory initiatives, monitoring, and management (Ritter et. al., 2002). The structure of the thesis reflects a source-pathway-effects approach to the research in order to:

- consider the exposure of the environment to CECs and to determine whether consumption of cosmetics can be a possible source of environmental contamination, hence the need for further assessment of the use and disposal of cosmetic products;
- analyse the significance of household disposal of CECs in cosmetics as a pathway for environmental contamination, illustrating the effectiveness of REACH legislation to assess environmental concerns;
- assess the potential environmental effects, economic importance and stakeholder preferences associated with these CECs to determine the best management option for the use and disposal of cosmetics containing CECs.

Chapter 1 of the thesis introduces an overview of the research topic and puts into perspective the rationale for the research. The thesis structure is outlined, emphasising the flow pattern of the research from source to effect. In **Chapter 2** different groups of CECs, their pathways to the environment, current legislation as well as the contemporary methodologies for managing their associated risks are reviewed. The aim, objectives and research boundaries for this study are then defined in **Chapter 3**. **Chapter 4** identifies different groups of household products containing CECs and uses these as indicators to demonstrate the potential of these chemicals to reach the environment via treated effluent,

sewage sludge, incineration ash and landfill leachate, facilitating the understanding of the problems associated with use and disposal of household products. In addition, the use and disposal of cosmetics are assessed and the importance of further investigation of CECs in these products is highlighted.

Chapter 5 investigates the first stage of the tiered approach used to develop the methodology to specifically identify, quantify and evaluate the CECs used in cosmetic formulations. Tier 1 consists of screening and scoping of the chemicals in cosmetics, followed by an initial exposure assessment. Potential CECs extracted from product ingredient listings are identified, validated and quantified based on guidelines from existing legislation. Their initial predicted environmental concentrations ($PEC_{initial}$) are estimated to determine the exposure of the environment to the CECs. The second stage of the research methodology, Tier 2, (**Chapter 6**) gives detailed calculations and analysis of the predicted environmental concentrations of these CECs in different environmental compartments (surface water, sediment and soil). These values are compared to the predicted no effect concentrations for the selected CECs to determine the potential of these chemicals to cause harm to aquatic and terrestrial organisms. This chapter further illustrates the effectiveness of the EU legislation as a screening tool for environmental contamination.

A multi criteria analysis framework was used to rank the best risk management options for the use and disposal of cosmetic products containing CECs **(Chapter 7)**. The environmental effects, economic importance and stakeholder preferences were the main criteria used to determine the best management option. Environmental effects were estimated from the environmental risk assessments, economic evaluation from market competition and an estimation of market value added by products containing CECs.

Stakeholder and political preferences were estimated from existing surveys on CECs. An overall discussion is provided in **Chapter 8**. The need for the assessment and management of CECs in cosmetics is discussed and the implications of REACH legislation to facilitate this are assessed. Mitigation measures to reduce the quantities of CECs disposed are also addressed. A summary of the findings from the work and recommendations for further research are discussed in **Chapter 9**

2 BACKGROUND

In this chapter, the issues surrounding CECs and their presence in household products are introduced. Their environmental pathways and occurrences within the environment are reviewed together with current legislation. The existing guidelines used for assessing risks are also summarised briefly.

2.1 Chemicals of emerging concern

The study of chemicals of emerging concern (CECs) has been the focus of a number of scientific and news journals within the last few years. The United States geological Survey (USGS) defines these chemicals as 'any synthetic or naturally occurring chemicals that is not commonly monitored in the environment but has the potential to enter the environment and cause known or suspected adverse ecological and (or) human health effects' and, Wong, (2006) defines '*emerging contaminants'* as chemicals that currently are being used and released into the environment and are of special concern due to widespread occurrence and potential for toxic effects. It also includes in this category metabolites (break down products produced as chemicals or other organic compounds are metabolized) of past-use chemicals and mixtures, both of which are poorly understood. There are currently no precise definitions for any of these chemicals in the UK and European legislation.

Unfortunately, over the years, the expansion of these terms has become so broad that at times they seem to encompass all chemical pollutants not regulated, and, paradoxically, even some whose environmental presence is sufficiently understood that some actions are already underway regarding their regulation or control (Daughton, 2006). Potential pollutants such as some brominated flame retardants, perfluorinated compounds and plasticizers are still categorised as 'emerging' despite having been identified as problematic several decades ago (Jansson et al., 1987, Urbansky and Schock, 1999, Thuren, 1986). To distinguish certain 'novel' unregulated pollutants from those that are regulated, environmental chemists quite often use the terminology 'emerging contaminants' or 'emerging chemicals of concern' in scientific research (Daughton, 2004, Pal et al., 2010). However, it may be more scientifically accurate to refer to these

'emerging' substances as 'chemicals of emerging concern' (CECs) since many of these substances, such as hexavalent chromium and 1, 4-dioxane have not been newly introduced to the environment, but have only recently gained attention with the revelation of new aspects of their environmental occurrence, fate and effects, often because of improved analytical detection levels.

Research has demonstrated potential hazardous properties such as the toxicological and endocrine-disrupting effects of some of these new chemicals and, as such, these CECs are now under increased scrutiny (Birnbaum and Staskal, 2004). Concerns also remain about several groups of unmonitored chemicals including nanoparticles, ethoxylates, phthalates, disinfectant by-products (DBPs) and endocrine disrupting chemicals, given their persistence, potential biodegradability and bioaccumulation (Anderson and MacRae, 2006, Richardson, 2007, Blaise et al., 2008).

Once a substance is deemed emerging, the longevity of its emerging status, in the view of scientists and the public, is largely determined by whether the chemical agent of concern is persistent and/or has potentially deleterious human or eco-toxicological effects. Alternatively, new observations or information (e.g., endocrine disruption) on chemicals can spur the reincarnation of a well-known contaminant as a (re)emerging chemical. Unfortunately, the same analytical advances that bring chemicals to the public's attention do not often offer knowledge about whether the newly detected chemicals are of eco-toxicological interest (Field et al., 2006).

Assessments of these CECs in the environment remain a major time and resource-intensive challenge (Field et al., 2006). This may be a result of their sheer number and diversity, as well as the lack of sufficient information about their inherent properties for proper analysis and evaluation (Bawden, 2004, Hemmett, 2008). Classifying them

according to their presence in products (e.g. medicine; cleaning agents; textiles) and product uses presents a feasible option for characterization of these CECs. These products, during use and/or at the end of their life cycle, are typically disposed of into waste systems where there is the potential for these chemicals to enter the receiving environment if not properly immobilized or degraded.

2.2 Presence of CECs in household products

Chemicals of emerging concern (CECs) are used as ingredients in a wide range of household products, including cosmetics, pharmaceutical drugs, cleaning products, household pesticides, and do-it-yourself home maintenance, e.g., paints and glues, all of which are marketed throughout the world and frequently discharged during or after use despite concerns about the control and use of chemicals in such products and the extent of their impacts on humans and wildlife (Glegg and Richards, 2007a). A study of the contents of common Danish households by Eriksson et al., (2003) illustrated that approximately 900 different substances or groups of substances were found to be potentially present in grey wastewater from household products. The CECs found to be present included major groups of compounds such as fragrances and flavours, preservatives, solvents and surfactants (amphoteric and cationic surfactants) as well as softeners and emulsifiers. Another study by the Environment Agency illustrated that 90 tonnes of triclosan (an antimicrobial agent) are released annually into the environment of the United Kingdom, most of it directly to sewer, from its use in products such as toothpastes, soaps, and washing liquids (Glegg and Richards, 2007a). Some of the CECs commonly used in household products are listed in Table 2-1, providing a non-exhaustive list of some of these emerging chemicals.

In recent years, concerns regarding the use of CECs within households have increased (Blundell, 2003). In the UK, the national press frequently publishes articles about substances that occur in household products and hence there is a growing public awareness of the issues and concern over the potential risks posed to human health as well as the environment (Guardian, 2004, Newling, 2006). Campaigns by environmental organizations have also highlighted the potential hazards from a range of commonly used household chemicals, from household cleaners to the very fabric of the home and its contents (Glegg and Richards, 2007a, Friends of the Earth, 2004, Greenpeace, 2005). The US Department of Health and Human Services (HHS) has launched the Household Products Database which contains consumer product information and links over 10,000 consumer brands to the health effects listed in Material Safety Data Sheets (MSDS) provided by manufacturers and allows scientists and consumers to research products based on their chemical ingredients. The database is designed to increase public awareness on the chemical ingredients and their percentage in specific brands.

Table 2-1: Commonly used CECs in household products

Chemicals of emerging concern	Examples	Function/Use in Households	References
Antioxidants	Butylated hydroxylanisole (BHA) and butylated hydroxytoluene (BHT)	Pesticide formulations and in petroleum products, waxes, rubbers, paints, inks, plastics and elastomers to protect these materials from oxidation during prolonged storage. Food products and animal feeds to retard rancidification, soaps, cosmetics and food packaging material such as waxed paper, paperboard and polyethylene.	(Soliman et al., 2004) (Fries and Püttmann, 2002)
	4-tert-Butylphenol	An intermediate for varnish and lacquer resins and fragrances	(OECD SIDS, 2000)
Biocides	Dichlofluanide	Common fungicide in glazing paints, varnishes and paints.	(Nakashima and Miyano, 1995)
	Triclosan, Methyl triclosan,	As a material preservative in adhesives, fabrics, vinyl, plastics (toys, toothbrushes), polyethylene, polyurethane, polypropylene, floor wax emulsions, textiles (footwear, clothing), sealants, rubber, carpeting and hygienic products such as toothpaste, shampoos, deodorants, skin lotions and hand soaps.	(Capdevielle et al., 2008)

Chemicals of emerging concern	Examples	Function/Use in Households	References
Brominated Flame retardants (BFRs)	Polybrominated diphenyl ethers (PBDEs) and impurities: Polybromonated biphenyls (PBBs) Polybromonated dibenzo-*p*-dioxins (PBDDs) Polybromonated dibenzofurans (PBDFs)	Furniture applications, foam padding under carpets, polypropylene fabric and other textiles but primarily for hard plastics casings of electronic equipment such as computers, household electrical appliances, cell phones, electronic games, televisions, adhesives and coatings in circuit boards, wire and cable insulation and electrical connectors.	(Chen et al., 2008) (Alaee et al., 2003) (Hoenicke et al., 2007)
	Hexabromocyclododecane (HBCD)	Polystyrene foam used in building construction	
	Tetrabromobisphenol A (TBBPA)	Reactive intermediate in the production of epoxy and polycarbonate resins which is used to manufacture printed circuit boards	
Complexing agents	Ethylenediaminetetraacetic acid (EDTA)	Scum and grind cleaners to remove lime scale and as a preservative in cosmetics and car axes	(DeLima Associates, 2001)
	Diethylenetriaminepentaacetic acid (DTPA)	Soaps as a water softener and to protect dyes and perfumes from combining with metals in solution.	
	Nitrilotriacetic acid (NTA)	Chelating agent in laundry detergent.	
	Benzotriazole	Silver protection in dishwashing detergent	(Richardson, 2007)
Detergents	Nonylphenolethoxylates (NPEs)	Surfactants in domestic detergent formulations and as inert ingredients in pesticides and spray adjuvants.	(Fernandes et al., 2008) (Mihaich et al., 2001)

Chemicals of emerging concern	Examples	Function/Use in Households	References
	Alkylphenolpolyethoxylates (APEOs)	Dispersing or stabilizing agents in food-packaging plastics, rubber and papers	(Montgomery-Brown and Reinhard, 2003)
Fragrance	Musk xylene	Group of fragrance ingredients widely used in a range of personal care products such as perfumes, cosmetics, shampoos, lotions, washing and cleaning agents, and fabric softeners	(Lu et al., 2011) (Carballa et al., 2005)
	Galaxolide		
Nanomaterials	Carbon nanotubes	Potential applications include reinforced composites, plastics, conductive materials, fabrics, sensors, sports equipment, and microelectronics.	(Kennedy et al., 2008) (Fiorito et al., 2006)
	Nano titanium dioxide and zinc oxide	UV filters in cosmetics.	(Gottschalk et al., 2009) (Brayner et al., 2010)
Perfluorinated Chemicals (PFCs)	Perfluorooctanesulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)	Water/oil/grease repellent for textile, fabric, carpets, plates and food containers, bags, wraps and folding cartons. Cleaning agents in shampoos, denture cleaners, carpet spot cleaners and mold release agent. Emulsifier in wax and floor polishes as well as promotes wetting, dispersion and colour development in paints.	(Higgins et al., 2005) (Schultz et al., 2006) (Skutlarek et al., 2006) (Hoehn et al., 2007) (Jensen and Leffers, 2008) (Ericson et al., 2007) (Wererniuk et al., 2006)
Pharmaceuticals	Ibuprofen	Non-steroidal anti-inflammatory drug used in	(Carballa et al., 2005)

Chemicals of emerging concern	Examples	Function/Use in Households	References
(active ingredient)		pharmaceuticals	(Hyder et al., 1999)
	Codeine	Opiate used for its analgesic antitussive and antidiarrheal properties in pharmaceuticals	
	Sulfamethoxazole	Antibiotics used to treat a wide variety of bacterial infections in drugs	
	Diclofenac	Non-steroidal anti-inflammatory drug taken to reduce inflammation and as an analgesic for reducing pain	
	17-alpha-Ethinylestradiol	Oestrogens used as a pharmaceutical agent for hormone replacement therapy of post menopause and as components of combination oral contraceptives	
Plastisizers	Diethylphthalate (DEP)	Housings for portable electronics such as telephones, lighting fixtures, kitchen appliances, fans, radio cabinets, coffee makers, computers, and clocks. Magnetic swipe cards; water hose; hairspray, insect repellent, cosmetics; textiles; baby toys.	(Mersiowsky et al., 2001) (Fromme et al., 2002) (Bauer and Herrmann, 1997) (Oie et al., 1997) (Osemwengie et al., 2006)
	Di(2-ethylhexyl)phthalate (DEHP)	Component of articles made of .polyvinyl chloride (PVC) such as vinyl sidings, pipes, plumbing & conduit fixtures, electrical cable insulations, roofing membranes and paints.	(Green et al., 2005)

Chemicals of emerging concern	Examples	Function/Use in Households	References
	Bisphenol A,	Component of epoxy resins and polycarbonate plastics which are used in food and drink packaging applications such as food containers, cling film, bottles, carrier bags and bin liners. Lacquers to coat metal products such as food cans and bottle tops.	(Furhacker et al., 2000) (von Goetz et al., 2010)
Cosmetics or Personal Care Products (PCPs) (active ingredient)	Benzophenone	Hair care products such as conditioners and 2 in 1 shampoos	(Xia et al., 2005) (Pedersen et al., 2005) (Zhang et al., 2007) (Daughton and Ternes, 1999) (Ingerslev et al., 2003) (Buser et al., 2006)
	Decamethylcyclopentasiloxane (D5)	Emollient in facial and skin care products	
	Parabens	Stain removers and facial make up products	
	Octocrylene	UV filter in sunscreens and other PCPs	
	Musk ketone and xylene ;	Used in fragrances, candles and air fresheners	
Wood preservatives	Chlorophenol	Inhibits microbial growth in a wide array of wooden products used in homes	(DeLima Associates, 2001)
	2,4-Dinitrophenol (DNP)	To make dyes, organic chemicals, wood preservatives and pesticides.	

2.3 Pathways and occurrences in the environment

CECs have been recently discovered in both aquatic and terrestrial environments at environmentally relevant concentrations with the potential to harm both aquatic and terrestrial organisms. A recent U.S. Geological Survey reconnaissance study provides an example of the prevalence of a wide range of CECs in U.S. streams (Kolpin et al., 2003), whilst findings reported by Reemtsma et al., (2006) illustrated the same for the European Union (EU). Studies have also shown that some of these chemicals can act as endocrine disruptors, disrupting normal hormone function, and can produce effects at the parts per billion or parts per trillion levels (Richardson, 2007, Newbold et al., 2007, Giudice and Young, 2010, Barcelo and Petrovic, 2006). Also, the effects of some CECs can be transgenerational so that when animals are exposed *in utero*, effects are transmitted not only to the offspring, but can be inherited for many generations (Lawson et al., 2011, Uzumcu and Zachow, 2007).

The continuous use and disposal of a range of household products including paints and solvents, electronics, cleaners (household and laundry), clothing, lawn and garden care, automotive products, food storage and kitchenware, furniture, children's products, pharmaceuticals and personal care products, can contribute to the possible release of CECs to the environment. However, some of the chemicals used in pesticides, electrical and electronic equipment, batteries and fluorescent tubes are already well established in scientific literature and legislation exists that governs the use and disposal of products containing these chemicals (Slack et al., 2004). By contrast, certain chemicals used in households are newly synthesized chemical agents and the risks they pose to the environment are unknown due to lack of sufficient information about their inherent properties such as persistence, accumulation and toxicity, in addition to having no

regulatory standards (Hemmett, 2008, Bawden, 2004).The environmental significance of these chemicals remains poorly understood and there is a paucity of information about their fate in the environment. The potential environmental impacts associated with these chemicals have been inadequately analysed, hampering evaluation and assessment of these emerging chemicals as potential threats to the environment (Hemmett, 2008, Bawden, 2004). Therefore, understanding the use and disposal routes for household products containing these chemicals could assist in the determination of the potential for these chemicals to enter the environment, be it direct disposal to landfills from municipal solid waste or via wastewater treatment to the aquatic environment (Figure 2-1). Evidence is given below to illustrate the pathways by which selected CECs reach the receiving environment.

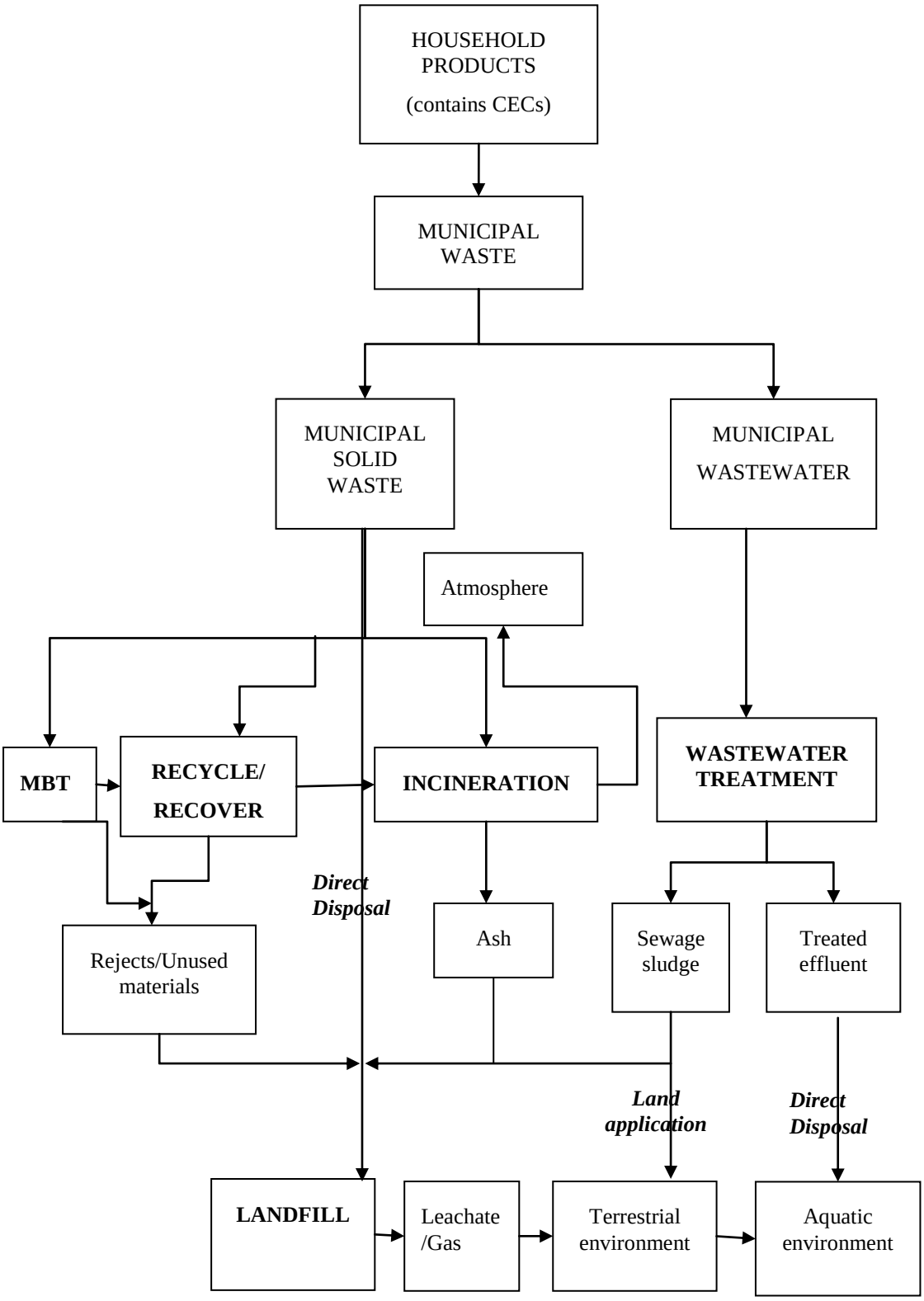


Figure 2-1: Pathways for CECs from households to the environment

2.3.1 Brominated Flame Retardants (BFRs)

BFRs are a diverse group of chemicals, whose common points are that they all contain bromine and are all used to retard the combustibility of goods (Soderstrom and Marklund, 2002). They include compounds such as polybrominated diphenylethers (PBDEs), polybromonated biphenyls (PBBs), polybrominated dibenzo-p-dioxins/dibenzofurans (PBDD/Fs) and hexabromocyclododecane (HBCD), of which PBDE is the most common class (Hemmett, 2008). PBDEs are transformed into PBDD/Fs when they are incinerated at temperatures up to 900°C forming potentially harmful by-products (Hemmett, 2008, North, 2004, Soderstrom and Marklund, 2002).

Although the exposure and fate of BFRs in the environment are not fully understood (Anderson and MacRae, 2006, Osako et al., 2004), these compounds can potentially enter the environment via direct disposal of waste material containing BFRs to municipal solid waste (MSW), sludge disposal from municipal wastewater treatment works (WWTWs) and disposal of incineration residue or volatilization into the atmosphere (Hale et al., 2002, North, 2004, Osako et al., 2004).Various studies, as reported below, have illustrated significant concentrations of BFR from MSW entering the environment through a variety of exposure pathways.

Huang et al., (1992) analyzed several fly ash samples for DBDD/Fs from municipal waste incinerators in the USA and Canada and found concentrations ranging from 4-981 ng/g in the USA and 12-894 ng/g in Canada. Another study by ter Schure et al., (2004) also analyzed combusted residue at a MSW incineration plant in Sweden, where PBDE concentrations reached a high of 63.8ng/g. Leung et al., (2007) investigated the combusted residue from an e-waste recycling plant in China for levels of PDBE and PBDD/F. Findings illustrated that up to 33000-97 400 ng/g of these compounds are found

in the residue which is normally landfilled. Another study by Morf et al., (2005) found PBDE concentrations ranging from 34 to 530mg/kg in combusted residue from an e-waste recycling plant whose e-waste comprised small household appliances and personal electrical equipment. These findings indicated that electronics recycling is a potential source of PBDEs from MSW to the environment.

E-waste comprising used electronics may also enter household refuse and go directly to landfills after crushing and compacting. This is not a common practice throughout Europe because of the Waste Electrical and Electronic Equipment (WEEE) Directive, but still exists in other countries. Osako et al., (2004) investigated leachate samples from 6 MSW landfills in Japan for PBDEs and TBBPA concentrations. The results showed PBDE levels reached 4ng/l and TBBPA levels 620ng/l. In particular, extremely high concentrations of PBDEs were observed at the site with a large amount of organics suggesting that there exists the possibility that leachability of PBDEs could be influenced by the presence of dissolved humic matter in leachate. PBDEs also have the ability to adsorb to suspended solids and sediment and have been detected in soil samples at levels reaching 789ng/g at an e-waste recycling site in China (Liu et al., 2008).

A range of studies have reported significant concentrations of PBDEs in sewage sludge from municipal WWTWs. This has the potential to be spread on land or to end up at landfill sites (Anderson and MacRae, 2006, Knoth et al., 2007, North, 2004, Nylund et al., 1992, Öberg et al., 2002, Song et al., 2006). The main source of these chemicals could be the result of human exposure to BFR-products, through consumption of foods, inhalation of contaminated particles or direct contact with materials that have been treated with flame retardants (Vos et al., 2003). Indoor dust and air have both been shown to have measurable PBDE concentrations with inhalation accounting for up to one quarter of

total exposure (Wilford et al., 2004, Rudel et al., 2003, Hites, 2004, Harrad et al., 2004). A domestic survey conducted by Chen et al., (2008) further illustrated that PBDE levels were highest in homes with greatest amounts in electronics, reaching concentrations of up to 2877 and 2061 pg/m^3. This further supports the idea that BFR can enter municipal WWTWs in human excretory products from food consumption as well as inhaled particles, suggesting that waste management may not be the cause of the problem but that these substances are ubiquitous.

2.3.2 Plasticizers

Plasticizers are organic esters added to polymers to impart properties such as flexibility, toughness and workability to plastics for effective processing and tailoring of a final plastic product (Barnabe et al., 2008, Gimeno et al., 2003, Mersiowsky et al., 2001). They include phthalates: di(2-ethylhexyl)phthalate (DEHP), diethyl phthalate (DEP) and diisononyl phthalate (DINP) which are generally high-boiling esters of dicarboxylic acids, and bisphenol A/F (BPA/F) (do Nascimento et al., 2003, Fromme et al., 2002, Ogunfowokan et al., 2006, Oie et al., 1997).

Plasticizers are ubiquitous in environmental samples due to their release during both use and disposal of consumer products (Hoenicke et al., 2007, Jobling et al., 1995). These compounds enter MSW mainly from disposal of used household products and hence quite often are sent directly to landfills in household refuse (Bauer and Herrmann, 1997, Jonsson et al., 2003). Although other management options such as mechanical, biological treatment (MBT) and recycling may be common for plastisizers (Agamuthu and Faizura, 2005, Kale et al., 2007, Simoneit et al., 2005, Trois et al., 2007), the rejects and unused materials are eventually landfilled. No published data are available on the evaluation of these CECs in refuse before landfill disposal.

The occurrence of plasticizers in landfill leachate has been widely reported. An assessment of 3 landfill sites in Ireland showed maximum values of 7.05mg/l DBP, 7.37 mg/l DEHP and 5.56 mg/l DINP in sampled leachates (Reid et al., 2007). These values are comparable to contaminant levels found in a European study by Jonsson et al., (2003), who quantified leachates from 17 different landfills in Europe with respect to phthalic acid esters (PAEs). PAEs were observed in 11 leachates with a maximum concentration of 19 mg/l hence suggesting the ubiquitousness of phthalates in the environment. Phthalic acid levels in leachate are also high, reaching 14 mg/l (Kjeldsen and Christensen, 2001). Asakura et al., (2004) studied the seasonal and yearly variations of the behaviour of BPA and PAEs in landfill leachate at 2 MSW landfills in Japan. This report illustrated levels of BPA ranging from 0.07 to 228µg/l and PAEs from 0.7 to 49µg/l. Concentration of BPA in leachate reduced over time except when the leachate temperature was low, but the concentration of DEHP remained constant. Further studies by Barnes et al., (2004), Bauer and Herrmann, (1997), Deng et al., (2005), Marttinen et al., (2003), Mersiowsky et al., (2001) and Paxeus, (2000) also demonstrated the presence of phthalates in municipal landfill leachate.

Unfortunately, because these chemicals are not chemically bound to the polymers, plasticizers can migrate from plastic products during normal use and following their disposal (Fromme et al., 2002). In 1990, it was estimated that 7740 tonnes/year of phthalates were leached in Western Europe into the environment from PVC products (Oliver et al., 2005). Thus, as many studies have shown, they have become widely distributed in the environment and are frequently present in MSW. Microbial decomposition of plasticizers is slow and no treatment is usually applied to eliminate

them from landfill leachate, allowing plasticizers to persist and contaminate the environment (do Nascimento et al., 2003).

2.3.3 Perfluorinated Compounds (PFCs)

PFCs are a group of chemicals with surface-active properties that have been produced in high volumes for over 50 years and have a wide range of applications in the domestic market (Ericson et al., 2007, Plant et al., 2005).Among the different classes of PFCs, perfluorooctanylsulphonic acid (PFOS) and **p**erfluorooctanoic acid (PFOA) have received worldwide attention, being the cause of potential environmental contamination (Ericson et al., 2007, Wilhelm et al., 2008). PFOS and PFOA are the end metabolic products of the two most common perfluorooctane surfactant classes: perfluorooctane sulfonamides and fluorotelomer alcohols (Boulanger et al., 2005).

Usage of fluorinated surfactants has led to the observed accumulation of PFOS and PFOA across environmental matrices but despite their global environmental presence, little is understood about the major environmental pathways of these compounds (Boulanger et al., 2005) and there is insufficient knowledge to assess their full environmental consequences (Jensen and Leffers, 2008).

Work carried out by Loganathan et al., (2007) in the USA gave evidence for the presence of perfluoroalkyl sulfonates and carboxylates in sewage sludge at a municipal WWTWs with levels ranging from less than 2.5 to 219ng/g. The sludge along with other unwanted by-products from wastewater treatment goes directly for landfilling, hence potentially contributing to levels of PFCs in the environment. A study conducted by Schultz et al., (2006) further exemplifies the presence of PFCs in sewage sludge from a municipal wastewater treatment facility. A quantitative determination of PFCs in sewage sludge

illustrated that levels of PFCs in domestic sludge ranged from 5 to 152 ng/g for total perfluorocarboxylates and 55 to 3370 ng/g for total perfluoroalkyl sulfonyl based chemicals (Higgins et al., 2005).

PFCs may also go directly to landfills from the disposal of end products that contain them. However, there is no published research on the PFC content of municipal landfill leachate and its reactions in landfill, although a study by Bossi et al., (2008) evaluated the PFOS and PFOA levels in industrial landfill leachate. The study determined that leachate collected in Denmark had PFCs concentration ranges from 0.3 to 5.8ng/l.

2.3.4 Pharmaceuticals and Personal Care Products (PPCPs)

PPCPs encompass two diverse, widely used groups of products comprising all human and veterinary drugs as well as cosmetics which contains bioactive ingredients. Sewage sludge and municipal waste are considered to be the predominant sources of PPCPs to the environment through the inevitable usage of personal care products for personal hygiene and the excretion of used medicinal products from the body (Bound et al., 2006, Bound and Voulvoulis, 2005, Jones et al., 2001). These products enter the environment either as unchanged compounds or after metabolism in the human body via WWTWs where they may also be degraded (Dussault et al., 2008). Unlike the numerous studies that have been conducted to investigate PPCPs at WWTWs (Boyd et al., 2004, Chang et al., 2006, Gagnon and Lajeunesse, 2008, Sacher et al., 2008, Ternes et al., 2003, Ying et al., 2008), investigations into environmental contamination from PPCPs via landfill leachate have received little attention and hence the overall contribution of PPCPs from MSW is difficult to evaluate.

The occurrence of pharmaceutical products in landfill leachate has been reported by Slack et al., (2005). Propyphenazone, ibuprofen and clofibic acid were identified in leachate leaking through the faulty bottom seal of a domestic landfill in Germany (Schwarzbauer et al., 2002). Holm et al., (1995) described the rapid methanogenic degradation of a group of pharmaceuticals in groundwater contaminated by landfill leachate including propyphenazone, sulphonamides and barbiturates. Phenazone, an analgesic similar to propyphenazone, was also identified in soil and groundwater below a MSW landfill in Croatia by Ahel and Jelicic, (2001).

Sewage sludge from MSW treatment plants contributes to the levels of PPCPs in the environment (Diaz-Cruz et al., 2009; Lee et al., 2005). A semi quantitative analysis of amphetamine in sewage sludge samples from municipal sewage treatment plants revealed concentrations of up to 300 µg/kg in sewage sludge (Kaleta et al., 2006). Chang et al., (2008) and Kot-Wasik et al., (2007) demonstrated the presence of 17β-ethynylestradiol, 17β-estradiol and oestrone in sludge from a municipal sewage system in Germany. Giger et al., (2003) and Osemwengie, (2006) also gave evidence for the presence of antibiotics in sewage sludge in China.

2.4 Current legislation for managing CECs

The growing number of CECs released in association with the normal use and disposal of household consumer products are particularly difficult to estimate and regulate because of the myriad of chemicals in products, which may end up in the environment (Richards et al., 2000, Richards et al., 2002, Jones et al., 2005). Although a list of recognized dangerous substances could be obtained from the European Union (EU) regulation on the Classification, Labelling and Packaging of Substances and Mixtures (EC) No 1272/2008 (CLP regulation), the constituents of waste which render them hazardous under the Waste

Framework Directive 2008/98/EC and the priority hazardous substances identified under the Water Framework Directive 2000/60/EC as well as other Directives dealing with air pollution, there still exist a lack of precise evaluation and legislation for CECs.

The management of CECs reflects limitations in the chemicals regulatory systems at both the international and national levels. These chemicals are often regulated under different aspects of environmental legislation based mainly on consumer safety or control of emissions for specific chemicals or chemical groups. The following sections outline the international agreements, EU and national legislation, and the associated administrative agreements for regulating the assessment and management of chemicals, under which CECs may be considered.

International Agreements

Three main international bodies have developed agreements or conventions on aspects of chemicals risk management. These include the harmonisation of information requirements and test methods by the Organisation for Economic Co-operation and Development (OECD), United Nations Environment Programme (UNEP) instruments for addressing global problems caused by the production and use of chemicals and the Convention for the Protection of the Marine Environment of the North East Atlantic (OSPAR Convention).

OECD

The Organisation for Economic Co-operation and Development established a programme in 1971 to undertake work at the international level on the safety of chemicals such as the organochlorine pesticides, PCBs, lead, mercury and cadmium. They influenced the development of common approaches to safety testing and risk assessment of chemicals to

avoid barriers to trade and multiple testing of chemicals. Such activities include: harmonisation of chemical testing and hazard assessment procedures and of classification and labelling; development of principles for good laboratory practice; co-operation on the investigation of existing high production volume chemicals; work on pollutant release and transfer registers; and sharing and exploration of possible co-operative activities on risk management from chemicals. An OECD hazard assessment programme was developed to investigate the hazards of chemicals produced in quantities of at least 1,000 tonnes per year in at least one OECD country. The chemicals programme has also co-ordinated the development of a set of test guidelines, which are widely used across the world to measure and evaluate the toxicity and other properties of chemicals.

OECD has also stipulated a minimum data package required to determine whether or not a chemical requires further investigation. Member countries work together to provide this data set for a particular chemical. Information is collected from government, public and industry sources and, where necessary, by additional testing. Once all the necessary information has been collected on a chemical, a lead country makes an evaluation that includes conclusions on potential risks and, if appropriate, recommendations for further action. The results are co-ordinated by the international organisations and made widely available to all countries through the United Nations International Programme on Chemical Safety (as Concise International Chemical Assessment Documents or CICADs). The mutual acceptance of data generated to internationally accepted standards prevents unnecessary duplication of testing. The test data are used within a number of national and international risk assessment programmes, including that under the Existing Substances Regulation (Royal Commision on Environmental Pollution, 2003).

United Nations International Programme (UNEP)

The UNEP programme on chemicals covers a number of activities. It has developed the international register of potentially toxic chemicals and, initiates and coordinates many capacity-building initiatives in the developing world as part of this the programme on chemicals to ensure that expertise on chemicals safety, and resources to manage risks from chemicals, are enhanced in recipient countries. Primarily, UNEP is the forum for the negotiation of multilateral environmental agreements– conventions that, once in force, are legally binding on ratifying parties. Two conventions that directly relate to chemicals risk management are the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (PIC Convention) and the Stockholm Convention on Persistent Organic Pollutants (POPs Convention).

The PIC Convention establishes a procedure for obtaining and disseminating the decisions of importing countries as to whether they wish to import specified chemicals, and for ensuring compliance with these decisions by exporting countries. The aim is to promote shared responsibility between exporting and importing countries in protecting human health and the environment from the harmful effects of such chemicals. Decisions taken by the importing party must be trade neutral: if the party decides it does not consent to accepting imports of a specific chemical, it must also stop domestic production of the chemical for domestic use or imports from any non-party.

The POPs Convention is an agreement to phase out the production, use and emissions of chemicals that are capable of moving long distances through the environment from their point of release, and causing environmental effects in countries other than those where they are used. Twelve substances were initially included in the Convention, though limited derogations were provided for dichlorodiphenyltrichloroethane (DDT) (synthetic

pesticide) when used as a malaria vector control, and for polychlorinated biphenyls (PCBs) because of their widespread use in electrical equipment. The Convention is broadly based on the United Nations Economic Commission for Europe (UNECE) Convention on Long-Range Transboundary Air Pollution Protocol on Persistent Organic Pollutants, agreed in 1998, although its scope extends beyond atmospheric dispersion to include other global transport modes. Other measures that establish global risk management regimes for chemicals under the UNEP include the Montreal Protocol on Substances that Deplete the Ozone Layer (a protocol to the Vienna Convention for the Protection of the Ozone Layer), which introduces measures to restrict the production and use of chemicals that damage the ozone layer and the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, which, *inter alia*, defines which wastes are to be considered hazardous and the criteria to be taken into account in so defining them.

OSPAR Convention

The OSPAR Convention introduces controls on the use of certain hazardous chemicals and, in particular, a system for identifying chemicals that meet certain hazard criteria. The convention aims to prevent pollution of the sea by continuously reducing discharges, emissions and losses of hazardous substances (substances which are toxic, persistent and liable to bioaccumulate or which give rise to an equivalent level of concern) with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close to zero for man-made synthetic substances. A progressive strategy will be implemented by making every endeavour to move towards the target of the cessation of discharges, emissions and losses of hazardous substances by the year 2020.

Under the OSPAR convention an initial selection procedure and a ranking procedure was developed and applied to identify priority substances that should be added to the OSPAR List of Chemicals identified for Priority Action, which was first established in 1998. Currently some 50 substances have been identified for priority action under the Convention's revised list 2010. For example, CECs such as PFOs and its salts, BFRs, clotrimazole (pharmaceutical) and nonylphenol/ethoxylates (NP/NPEs) are in OSPAR's list for priority action. In 2002, OSPAR's List of Substances of Possible Concern was adopted. It is a dynamic working list and is regularly revised as new information becomes available. There are currently 315 substances that might merit action by OSPAR due to their persistence, liability to bioaccumulate and toxicity or other equivalent concern. The cut-off values for persistence, bioaccumulation and toxicity agreed by the OSPAR Commission in 2001 are used as criteria to select substances for inclusion in the List of Substances of Possible Concern. Substances that do not meet the criteria but for which there are other reasons for concern may also be listed via the 'Safety Net Procedure', provided that suitable monitoring data and associated information are presented which demonstrate the presence of the substances in the marine environment.

In 2005, the Network of reference laboratories for the monitoring of emerging environmental pollutants (NORMAN) in collaboration with the European Commission launched a 3 year project to improve the exchange of information and data on emerging environmental contaminants between monitoring institutes, research centres and end-users (modelling experts, risk assessors and risk managers) as well as to encourage the validation and harmonisation of common measurement methods and monitoring tools so that the demands of risk assessors and risk managers can be better met. This marks the first time an international programme has tackled this rather ill-defined aspect of

environmental science, fostering more attention on CECs that have been ignored as a result of the design of environmental monitoring programs or because of the limitations of analytical chemistry. At the end of the project a new permanent NORMAN network was established as a non-profit organization to encourage information sharing and exchange, data collection and EU wide monitoring of emerging contaminants.

EU Legislation

The CLP regulation as well as the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 (REACH) represent the major pieces of legislation assessing and managing of risks from chemicals in the EU and by extension, the UK. A number of other directives deal with special purpose chemicals or activities such as sale to consumers. The principal concern of early chemicals policy was to avoid fragmentation of the internal market within Europe.

CLP Regulation

The CLP regulation entered into force on 20 January 2009. It replaced certain provisions of the directives related to the classification, packaging and labelling of dangerous substances (Directive 67/548/EEC) in addition to classifying chemicals according to their hazards and prescribing packaging and labelling regimes and requiring all 'new' chemicals to be notified and assessed. The CLP regulation harmonises national measures on classification, packaging and labelling of dangerous substances, to facilitate the establishment of a single market and to provide protection for public health and the environment. This represented the first harmonising legislation in the field of chemical products but does not affect provisions relating to medicinal products, cosmetic products, mixtures of substances in the form of waste, food and animal feed, pesticides, radioactive substances, other substances or preparations for which notification or approval procedures

exist, the carriage of dangerous substances and unrefined substances which are in transit and are subject to customs inspection.

The classification element of the directive categories substances based on the degree of hazard and the specific nature of the risks they pose. This includes physicochemical properties (explosive, oxidising, or flammable) and/or the health hazards it presents (toxic, carcinogenic or harmful) and/or the environmental hazards. The main requirements relating to packaging ensures that products are designed and manufactured in such a way that its contents are secured and the packaging materials must be strong Any package must be clearly and indelibly marked with certain specific information such as the trade name of the preparation, name and contact details of the person responsible for placing it on the market, the chemical name of the substance or substances present in the preparation which have given rise to the classification of the preparation with regard to health hazards and the danger symbols and indications of danger, the risk phrases and the safety advice.

REACH Legislation

In the late nineties and causing considerable debate, new horizontal chemicals legislation was developed, and in 2007, REACH entered into force. It streamlines and improves the former legislative framework on chemicals of the EU. The main aims of REACH are to ensure a high level of protection of human health and the environment from the risks that can be posed by chemicals, the promotion of alternative test methods, and free circulation of substances on the internal market and the enhancement of competitiveness and innovation. REACH places the burden of proof on industry, to collect or generate data necessary to ensure the safe use of chemicals. This data is publicly available through the

central database held at the European Chemicals Agency (ECHA) and will help to close the current information gap on chemicals. REACH also provides rules for phasing out and substitution of the most dangerous chemicals. REACH is complemented by the new CLP Regulation (2009), as described above.

This piece of legislation ensures manufacturers and importers of chemicals are responsible for assessing and managing the risks posed by their chemicals and for providing appropriate safety information to their users. For substances manufactured or imported in quantities of 1 tonne or more per year per company, manufacturers and importers need to appropriately demonstrate their chemical safety by means of a registration dossier, which must be submitted to ECHA. The Agency may then check that the registration dossier complies with the Regulation and must evaluate testing proposals to ensure that the assessment of the chemical substances will not result in unnecessary testing, especially on animals, but also that adequate information is provided.

Where appropriate, authorities may also select substances for a broader substance evaluation to further investigate substances of concern. REACH also foresees an authorisation system aiming to ensure that substances of very high concern are properly controlled, and progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. Where this is not possible, the use of substances may only be authorised where there is an overall benefit for society of using the substance. In addition, EU authorities may impose restrictions on the manufacture, use or placing on the market of substances causing an unacceptable risk to human health or the environment. The Member States authorities are responsible for enforcing REACH through inspections as well as penalties in case of non-compliance.

Other EU Environmental Legislation relevant to Chemicals

The legislation described so far has been specifically directed towards securing the environmental safety of chemicals and products containing those chemicals. There is, however, a much larger block of legislation related to the control of emissions, the management of waste, and securing the quality or safety of various environmental media, which has a bearing on chemicals in products (Royal Commision on Environmental Pollution, 2003). This section briefly describes the more relevant of these European instruments.

Water Framework Directive

The Water Framework Directive 2000/60/EC contains a legal framework and methodological basis for the prioritisation of substances of concern in water. The European Commission has proposed a list of 32 substances based on a review of 658 substances using a combined monitoring-based and modelling based priority setting procedure. Under the scheme, it is suggested that the proposed substances should be subject to emission controls and quality standards at European Community level in order to achieve a 'progressive reduction of discharges, emissions and losses'. Within the list of priority substances, a proposed list of priority hazardous substances that are of particular concern for the freshwater, coastal and marine environment has been identified. The Directive also contains requirements to monitor water quality, including detection of the presence and levels of these priority substances. These lists replace the previous Lists I (black list) and II (grey list) provided in Directive Dangerous Substances Directive (76/464/EEC) and its daughter directives.

Waste

EU waste policy contains a specific Directive dealing with the management of hazardous waste. The hazardous waste stream will include by-products of chemical production, chemical substances, and products incorporating such substances. Annex III of the Waste Directive lists the properties of wastes that render them hazardous, derived from the definitions in the Basel Convention.

Integrated Product Policy

In 2001, the European Commission published a Green Paper on Integrated Product Policy that proposed a strategy to strengthen and refocus product-related environmental policies, and to promote the development of a market for greener products. Part of the purpose of the Green Paper was to improve environmental performance of a range of products and services throughout their life cycles. It was noted that as a result of this life cycle approach, there could be no single instrument to deliver Integrated Product Policy. The success of the approach depended upon successful design and consumer uptake of greener products. The European Commission noted that pricing mechanisms would be important in the adoption of Integrated Product Policy, including fuller reflection of life cycle external costs in the price of goods and services. They also proposed that Community level measures, such as reductions in VAT for eco-labelled goods should be explored. Part of Integrated Product Policy also relates to producer responsibility which means that producers take responsibility for the recovery of goods once they have reached the end of their service life. Such schemes have been introduced in the Directive on End of Life Vehicles and the Directive on Waste Electrical and Electronic Equipment and several others.

EU Legislation on Chemicals in Products

Several other Directives govern the use of chemicals in products. These different regimes have arisen for a number of specific reasons. Some of the products come into direct contact with sensitive parts of the human body or are directly ingested (cosmetics and food additives), others are deliberately designed to be toxic and are released widely in the environment (plant protection products and biocides), while others are designed to be biologically active in small doses (pharmaceuticals and veterinary medicines)(Royal Commision on Environmental Pollution, 2003).Table 2-2 lists schemes that operate on a positive approval system, under which a chemical substance may not be used unless specifically approved for a particular use.

Table 2-2: Summary of Legislation governing chemicals in products

Chemicals group Directive	Description/function
Plant protection Regulation (EC) 1107/2009	Forms part of the EU Thematic Strategy, along with the Sustainable Use Directive (2009/128/EC) and Statistics Regulation (1185/2009/EC). It has established agreed criteria for considering the safety of active substances, the safety and effectiveness of formulated products based on hazard based criteria, assessment of cumulative and synergistic effects and comparative assessment.
Biocidal products 98/8/EC	Harmonise the European market for biocidal products and their active substances such that product authorisation in one Member State can be recognised in other Member States. This provides high level of protection for people, animals and the environment from the use of biocidal products through risk assessment and ensure products are sufficiently effective against the target species
Veterinary medicine 81/852/EEC	Ensure veterinary medicines are approved in the UK by the Veterinary Medicines Directorate or centrally by the European Medicines Evaluation Agency and assesses risk associated with animals, people handling the medicines, the consumer and natural environment
Cosmetics 76/768/EEC	Include a series of annexes listing banned substances and ingredients permitted for specific uses. This legislation ensures that cosmetic products can move freely within the Community market, protects public

	health and lays down rules on the composition, labelling and packaging of products. It also introduces a ban on animal testing and on the marketing of products that have been tested on animals.
Directive 2001/83/EC relating to medicinal products for human use	Establishes a Community code which brings together all the provisions in force governing the placing on the market, production, labelling, classification, distribution and advertising of medicinal products for human use. No medicinal product (with the exception, under certain conditions, of radiopharmaceuticals prepared at the time of use) may be placed on the market of a Member State unless an authorisation has been issued by the competent authorities of that Member State or by the European Medicines Agency.
Food Additive 894/34/EEC	Prohibits the use of certain additives in foodstuffs produced using traditional methods on their territories, provided the prohibition existed on 1 January 1992 and that the free movement of goods is not affected. This examines all additives which are already authorised and any new ones to show that the product is safe, technologically necessary, of benefit to the consumer via risk assessments on these products.

UK Chemicals Strategy

In 1999 the UK Government set out its proposals for a Chemical Strategy on the Sustainable Production and Use of Chemicals. It aimed to avoid harm to the environment and human health via environmental exposure to chemicals. The strategy was designed to make information about the environmental risks of chemicals publicly available and to continue to reduce the risks to the environment from chemicals while maintaining the competitiveness of industry and to phase out those chemicals that pose an unacceptable risk to the environment and human health. A key feature of the strategy was the establishment of the UK Chemicals Stakeholder Forum (CSF) in 2000 to promote better understanding between stakeholders on issues of chemicals and the environment and to provide advice to government about chemicals in the environment to guide the development of policy. The work of the CSF has been carried out in conjunction with technical support from the Environment Agency and the UK Advisory Committee on Hazardous Substances (ACHS), which provide technical support to the CSF (Department for Environment Food and Rural Affairs, 2008).

2.5 Assessing risks for management of CECs

To effectively manage the use of CECs in household products it is imperative to manage activities in a way that minimises the risks of environmental damage, while at the same time ensuring economic growth and social progress. The interaction between human activity and the environment however, is complicated and difficult to quantify, and it is not easy to judge where the balance should lie between environmental protection and economic and technological progress. The current regulatory approach to the management of chemicals is based almost entirely on risk assessment. Risk assessment is presented as a structured approach to determining the consequences of an event and the probability of it happening as well as a means of informing judgements about the need for, and ways of, managing the consequences of the event (Figure 2-2) (National Research Council, 1983). As a result, this approach emerges as a key element to ensure that the harm caused by synthetic chemicals is contained within acceptable limits and to adequately manage the risks of chemicals from products, thereby transparent and equitable policy, regulatory or other decisions can be taken.

However, within Europe and even the US there has been a multiplicity of drawbacks affecting the implementation of environmental risk assessment, especially for CECs. These include deficiencies of toxicity and exposure information on chemicals in commerce, unequal treatment of new versus existing chemicals, slow chemical and/or risk assessment processes due to existing regulations where government is responsible for these assessments, a dearth of incentives to stimulate development and implementation of safer substitutes, and lack of an integrated and comprehensive approach to chemicals management.

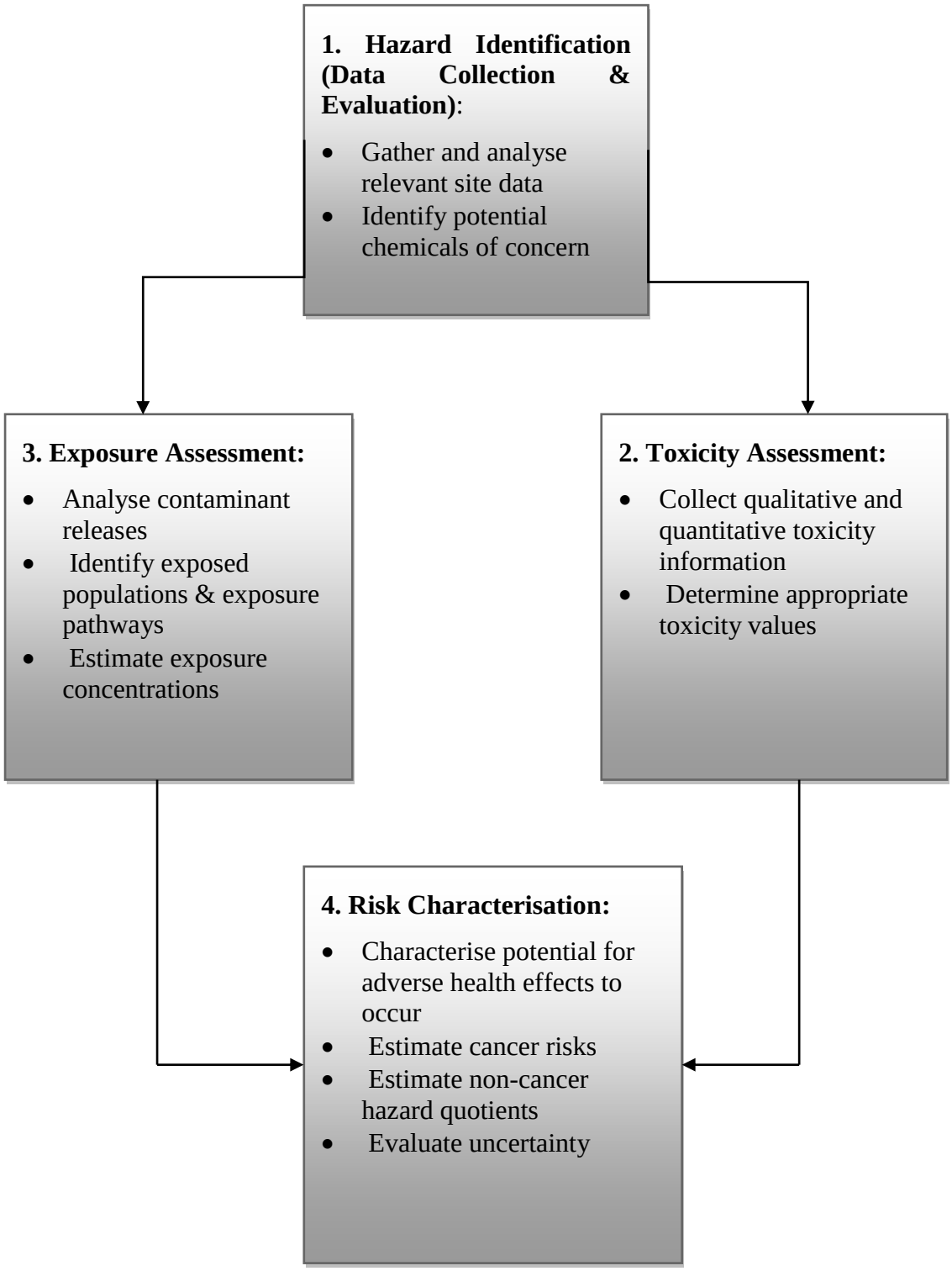


Figure 2-2: Baseline Risk Assessment Framework Proposed by the National Research Council (1983).

The implementation of REACH Regulation (EC) No 1907/2006 Annex XV attempts to minimise these shortcomings and assesses environmental risk by means of a chemical safety assessment (CSA) (Figure 2-3). The CSA, submitted as part of the registration dossier, is performed by registrants for substances manufactured and imported in quantities starting at 10 tonnes per annum and by downstream users if their uses are not addressed by their supplier. Risks arising from the manufacture and/or use of a substance are assessed to ensure that they are adequately controlled by:

- human health hazard assessment: determination of the classification and labelling of the substance, derived no effect levels (DNELs);
- physicochemical hazard assessment: determination of the classification and labelling of the substance;
- environmental hazard assessment: determination of the classification and labelling of the substance, derivation of predicted no effect concentrations (PNECs);
- persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment (or substances of similar concern): comparison of the data on degradation, bioaccumulation and toxicity with the criteria available in Annex XIII of the REACH Regulation.

If the substance meets the criteria for classification as dangerous, or meets the PBT/vPvB criteria, the CSA should also include the following:

- An **exposure assessment** for all identified and relevant uses of the substance and resulting life cycle steps, including the generation of exposure scenario(s). An exposure estimation for humans and the environmental compartments to the

substance should be performed from the conditions defined in the exposure scenarios.

- A **risk characterization** which is the final step in the chemical safety assessment. The risk characterisation identifies whether the risks arising from manufacture/import and uses of a substance are adequately controlled. It consists of a comparison of DNELs and PNECs with calculated exposure concentrations respectively to human and the environment.

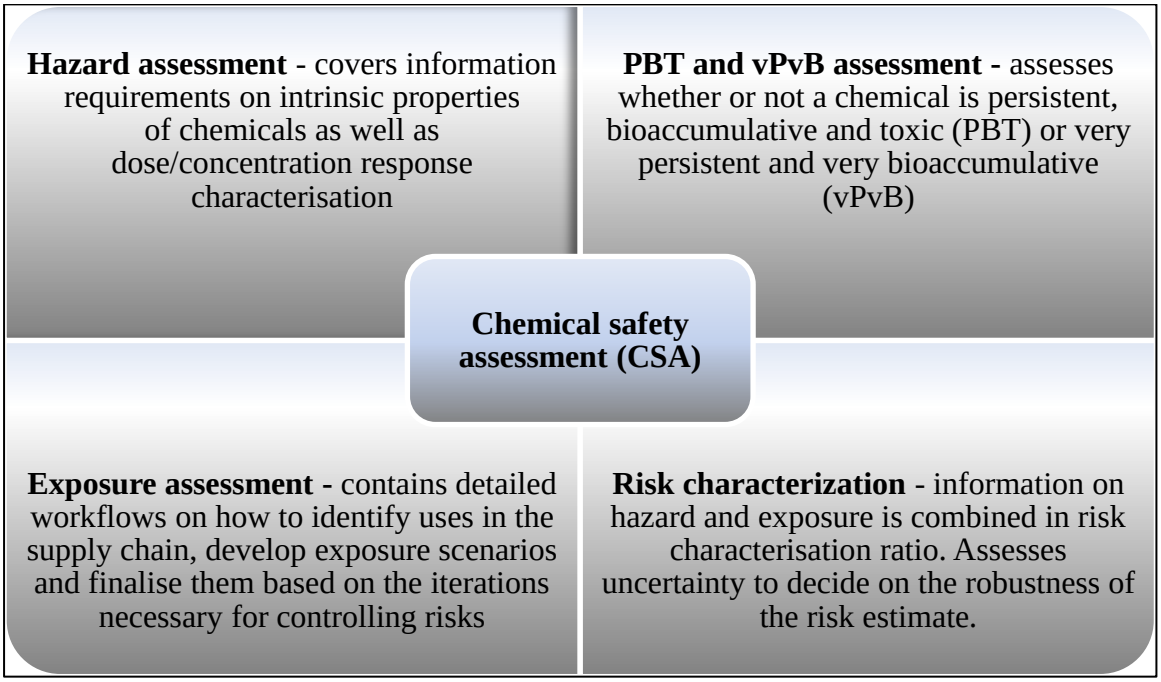


Figure 2-3: Overall process related to information requirements and chemical safety assessment under REACH

The output of the CSA is exposure scenarios with operational conditions and risk management measures for adequate risk control. However, the application of CSA under REACH has been the subject of much debate, particularly because of the following:

- *Concerns about concealed uncertainties and assumptions* - Limited or incomplete data sets or data that may be subject to random errors as is common with CECs together with real world uncertainty where the predicted risk may not necessarily be realised in the environment because of uncertainty in both environmental and effects estimates contribute to the ambiguity of using the guidelines under REACH for risk assessments. For partially unknown substances such as CECs, prediction models are a first step for assessing risk, although they are not fully designed to be used for site specific risk assessments (they do not account for spatial and temporal variability) (Keller, 2006). The EUSES model however, is considered legally acceptable for the use in predicting environmental concentrations for risk assessment in Europe, although uncertainties of modelling can arise from a lack of knowledge of decisions made by the analysts during the modelling process (bias) and from assumptions used in models (Keller, 2006).
- *Paucity of opportunities to incorporate public values into the process* - Under REACH, a socio economic assessment is only conducted when arguments are made in relation to the decision of whether or not to grant an authorisation for the use(s) of a substance and in relation to the decision whether or not to introduce a restriction. When adequate control of risks cannot be demonstrated and when no suitable alternatives exist, the Commission decision on whether or not to grant an authorisation for uses of a substance will take into account whether the socio-economic net benefits (taking into account all benefits and drawbacks) from continuing these uses outweigh the risks to human health and the environment. Additionally, the outputs from environmental risk assessments are not the same as the impact assessment inputs required for socioeconomic analysis, hence the two

different 'currencies' need to be aggregated when forming an opinion, making it complicated to develop coordinated and coherent opinions for proper management of chemicals.

2.6 Decision making for risk assessment

During the past two decades decision making methods have shifted from simple single-objective modelling and optimisation to multi-objective modelling and optimisation. Multiple objectives in modelling and decision-making have increased in importance leading to the emergence of a new discipline known as multi-criteria analysis (MCA). This decision-making tool has been applied together with conventional risk assessment procedures to drive the improvement of hazard and risk management outcomes and provides a structured, transparent, and justifiable tool to quantify both scientific, economic and decision makers' values, as well as to develop a system of performance metrics consistent with regulatory requirements.

Multi-criteria Analysis (MCA) is a methodology for ranking risk management alternatives based on evaluation criteria weighted by the user (Belton and Stewart, 2002). MCA provides a rational methodology for decision making in the face of uncertainty (Mahmoud and Garcia, 2000). The ability to mix quantitative and qualitative data is a feature of some MCA methods that is particularly useful where all impacts cannot be measured in the same way (Buckley, 1988, Voogd, 1988). Another advantage of MCA is its accommodation of multiple criteria, which permits the evaluation of various effects through the scientific methods by which they are normally measured. This in turn facilitates the inclusion of wider impacts in the appraisal of management options. This type of decision making has emerged as a philosophy capable of integrating common sense with empirical, quantitative, normative, descriptive and value-judgment-based

analysis (Balasubramaniam and Voulvoulis, 2005). It is an approach that is supported by advanced systems concepts (previously used for data management procedures and modelling for example) that draws on both the arts and sciences to improve the decision-making process and ensure it is as reproducible as possible. MCA is incorporated into most modelling and optimisation of technological systems today including risk management, particularly in linking scientific risk assessment and value based risk management.

3 AIM AND OBJECTIVES

The thesis aims to investigate and understand the need for management of chemicals of emerging concern (CECs) in household products in the UK, particularly cosmetics. The research was carried out using survey data to quantify CECs in cosmetics and used prediction models to estimate the levels of environmental contamination as well as the economic valuation of CECs in cosmetics. Multi-criteria analysis (MCA) was used to assess the need for management of the use and disposal of CECs in products.

To achieve this aim, the following objectives were set:

- To establish and evaluate the regulatory framework for CECs in cosmetics and to assess whether REACH regulation has the capacity to effectively manage CECs in these products;
- To consider whether the use and disposal of cosmetics can be a possible source of CECs in the environment by implementing a research methodology to identify, quantify and estimate initial predicted environmental concentrations for CECs used in cosmetics;
- To assess the significance of the different environmental pathways for cosmetics by estimating the environmental risks associated with the disposal of CECs used in cosmetic formulations. The guidelines under REACH legislation were used to demonstrate its effectiveness for managing CECs;
- To compare and rank the alternative risk management options for reducing the risks associated with the use and disposal of CECs in cosmetics, using MCA;
- To understand the need for management for cosmetics to ensure sustainability of product use and disposal in the UK.

4 MANAGING CHEMICALS OF EMERGING CONCERN IN COSMETICS: IMPLICATIONS OF REACH

The household disposal of cosmetics containing chemicals of emerging concern (CECs) could eventually expose the environment to a wide range of chemicals with the potential to cause concern. Traditionally, chemicals have been mainly assessed and quantified on the basis of emissions levels but policymakers are now moving away from this "command-and control" type of regulation towards an approach that relies more on co-operation and incentivisation such as the REACH legislation. This chapter explains the applications of REACH as well as the challenges encountered for the implementation of this legislation with respect to cosmetic products containing CECs. It also emphasises the differences between the traditional concepts of chemical legislation and REACH regulation and discusses how this regulation could be effectively and efficiently implemented to manage CECs in cosmetic products.

4.1 Why manage CECs in cosmetic products?

The growing number of CECs released from everyday use and disposal of consumer products are particularly difficult to estimate and regulate because of the myriad of items in the household disposed of daily with the potential to reach the environment (Richards et al., 2000, Richards et al., 2002, Jones et al. 2005). Evidence already exists illustrating the presence of potentially harmful CECs such as brominated flame retardants, plasticizers, and active ingredients from pharmaceuticals and personal care products in the environment at concentrations of mg/l, readily exceeding the µg/l detection limits of these contaminants (Kjeldsen and Christensen 2001; Jonsson et al. 2003; Osako et al. 2004; Morf et al. 2005; Slack et al. 2005; Glegg and Richards 2007; Reid et al. 2007; Liu et al. 2008).

Cosmetics referred to as 'personal care products' (PCPs) under the European Union Cosmetics Directive (76/768/EEC) as amended which governs their manufacture, are defined as any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition. Hence, it is not surprising that these products cover everything from soap, shower gel, shampoo, shaving cream and toothpaste to make-up, skin cream and perfume. This directive is implemented in each member state via national legislation which, in the UK, is the Cosmetic Products (Safety) Regulations 2004.

Cosmetics represent an extraordinarily diverse group of products containing multiple chemical ingredients, some of which may be CECs and the group is one of the most

frequently used in households (Daughton and Ternes, 1999). For example, 2.6 billion units of PCPs were sold in the UK in 2008 as compared to other regulated household products such as fluorescent light bulbs (1.1 billion units sold) and batteries (3.8 billion sold) (Slack et. al. 2005). The sheer size of the cosmetic industry indicates the substantial usage and disposal of these products.

As previously stated, CECs present in cosmetics can be continually introduced into the environment and many of these CECs as well as their metabolites are ubiquitous, displaying persistence in, and bioconcentration from surface waters on par with those of the widely recognized organochlorine pollutants (Daughton and Ternes, 1999). Additionally, by way of continual infusion into the aquatic environment, those PCPs that might have low persistence can display the same exposure potential as truly persistent pollutants since their transformation/removal rates can be compensated by their replacement rates (Daughton and Ternes, 1999). This can cause unwanted long term environmental effects even at low parts per trillion/parts per billion concentrations (ng-µg/l), suggesting that a major concern of PCPs reaching the environment is not necessarily the acute effects but the manifestation of imperceptible effects that can accumulate over time.

Several of the chemicals used intensively in cosmetics can be persistent, bioactive and exhibit accumulation potential as well as cause endocrine disruptions (Daughton and Ternes, 1999, Caliman and Gavrilescu, 2009). Although the acute toxicity of these chemicals is supposed to be low, some of these chemicals still show signs of being of environmental concern. For example, parabens, benzophenone-3, octyl-methoxycinnamte and musk xylol/ketone can act as weak endocrine disrupting substances (Darbre, 2006, Taxvig et al., 2008, Caliman and Gavrilescu, 2009). However, for many CECs, data on

physicochemical and toxicological characteristics are insufficient making it difficult to accurately predict the levels and/or combination of chemicals that may cause environmental harm. Few of these CECs are inventoried or regulated worldwide, and no legal requirements exist to assess the impact of long-term exposure to low concentrations of these chemicals (Caliman and Gavrilescu 2009, Kummerer, 2010).

Cosmetics have also been given limited attention in scientific work as these products are frequently assessed under the umbrella of pharmaceuticals and personal care products, where the focus has been mainly on pharmaceuticals. Cosmetics differ from pharmaceuticals in that large amounts can be directly introduced to the environment. For example, these products can be released directly into recreational waters or volatilized into the air (e.g., musks), bypassing possible degradation processes. Also, in contrast to pharmaceuticals, less is known about the effects of this broad and diverse class of chemicals on non-target organisms, especially aquatic organisms (Daughton and Ternes, 1999). The quantities of PCPs produced and used daily by consumers for hygienic purposes, are very large, as compared to drugs which are administered on the basis of need.

Although work in academia, public research institutes and industry has undoubtedly led to improved practices, there is still a dearth of knowledge with respect to understanding the potential long-term and subtle harm from the burden of these CECs entering the environment. Chemical legislation specific to CECs does not exist and regulations are focused on addressing general groups of chemicals which may include CECs. CECs reaching the environment have been mainly assessed and quantified based on concentrations in surface water, sediment, soil and air using ‘command and control’ regulations. Due to the complexity of the supply chain and the diffuse nature of emissions

of chemicals released from products, the problems of products containing chemicals are not addressed in legislation, making management of individual products difficult (Royal Commision on Environmental Pollution, 2003).

4.2 REACH versus traditional concepts of chemical legislation

The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation has the ability to revolutionise the concept of chemical legislation by bringing products containing CECs into focus, placing emphasis on the source management of CECs rather than emission levels. REACH legislation is being implemented to standardize and simplify chemical laws throughout Europe, creating the foundation for effective and efficient use of both existing and new chemicals. All chemicals greater than 1 tonne per annum being manufactured in or imported to Europe must be registered under the REACH legislation, hence the potential to characterise CECs and enforce legislation. Products showing evidence of unacceptable levels of CECs can then be dealt with by regulatory authorities to minimise the production of these products.

Common products containing CECs can therefore be managed under the new REACH legislation, allowing the opportunity for management at source rather than at the point of disposal. It puts the onus on businesses to show that the chemicals they use are safe. It also encourages the replacement of hazardous chemicals with safer ones and spurs the chemicals sector to carry out research and development into more environmentally safe products. This legislation replaces approximately 40 pieces of European chemical legislation such as directives on chemicals control concerning classification and labelling, marketing and use, risk assessment, protection of workers, consumers and the environment. It overhauls the previous system and introduces key elements for a sustainable management scheme of chemicals (European Commission, 2006). Table 4-1

illustrates the potential changes the implementation of REACH legislation introduces versus traditional chemical legislation.

Table 4-1: Potential changes on implementing REACH legislation

Issues with chemicals in products	Current Legislation	REACH Regulation	Reference
Safety	Thousands of chemicals used in products that have not been tested for their effect on human health and the environment (only 140 chemicals have been selected for risk assessment since 1993, and even fewer have completed the process)	Any chemical produced or imported in significant quantities of over 1 tonne per year has to be tested unless sufficient safety information already exists.	(Foth and Hayes, 2008)
Replacement of hazardous chemicals	While some hazardous chemicals, such as DDT and PCBs, are banned by the Stockholm Convention on persistent organic pollutants, others are still widely used, despite evidence that they may affect human health and the environment.	The use of "substances of very high concern" can only occur if they are authorised. This will be granted under specific conditions, and will have to be regularly renewed, encouraging companies to seek safer alternatives.	(Foth and Hayes, 2008) (Lokke, 2006)
Encouragement of innovation	Although existing rules oblige companies to test new chemicals (even if they only produce 10kg), the 100,000 "old" chemicals that were on the market before 1981 are exempt, hence easier and cheaper to stick with the old, untested chemicals than to develop new ones. Only 3,000 chemicals have been introduced since 1981	All chemicals products in quantities greater than 1 tonne/year will have to be tested so innovation in product design would become more worthwhile. Manufacturers can incur negative publicity if a substance fails to be authorized or is authorized with heavy restrictions.	(Lahl and Hawxwell, 2006)

Issues with chemicals in products	Current Legislation	REACH Regulation	Reference
Burden of proof	Member States are responsible to ensure the safety of product on the market.	Chemical manufacturers and suppliers have the responsibility to ensure that their products do not constitute a risk to either human health or the environment.	(Glegg and Richards 2007) (Money et al., 2007)
Lack of Information	There is lack of knowledge about the environmental pathways, fate, and effects of many of chemicals routinely introduced to the environment.	All chemicals used in significant quantities to be evaluated for health and environmental effects. There will be information exchange across the supply chain, and therefore actors within the supply chain will be aware of the uses of their chemicals	(Heidorn et al., 2003) (Lahl and Hawxwell 2006) (Glegg and Richards 2007)
Public access to chemical information	Although classification and labeling of chemicals and preparations and provision of safety data sheets exist, the extent to which useful advice is specifically provided for users of chemicals to evaluate risks remains somewhat ad hoc	Obligations for sharing of information about chemical properties and risk management measures throughout supply chains are mandatory. Suppliers of a chemical or a preparation must provide their customers with a pertinent safety data sheet if the	(Glegg and Richards 2007) (Money, Jacobi et al. 2007)

Issues with chemicals in products	Current Legislation	REACH Regulation	Reference
		chemical or preparation is classified as PBT.This will enable informed choices concerning use of products to be made.	
Consumer exposure to chemicals in products	Consumer exposure is primarily estimated by the use of models based on source, the exposed population, the time frame of exposure, microenvironments, and activities	Consumer exposure must also present exposure scenarios. This requires information on how a chemical or product can be used in a safe way by use of risk management options and life cycle analysis.	(Lahl and Hawxwell 2006) (Van Engelen et al., 2007)

4.3 Cosmetic products under REACH legislation

The implementation of REACH regulation imposes comprehensive new requirements on producers of cosmetic products and will jeopardize the continued viability of many critical chemicals used in such products. The regulations will require producers of cosmetic products, or their chemical suppliers, to research and disclose the characteristics of the substances they use, permanently defend the continued use of substances that are dangerous to the environment, and in some cases even face an outright ban on them. Over time, cosmetic producers could also face more a limited choice as chemical suppliers seek to reduce the number of substances on offer, thus reducing cost of compliance with REACH.

Cosmetic products are generally defined as 'preparations' under REACH (preparations are defined as mixtures or solutions of two or more substances such as sun creams, toothpastes, and shampoos) and they are regulated depending on whether the chemicals used in products are manufactured in, or imported into, the European Union/European Economic Area (EU/EEA). EU/EEA manufacturers of cosmetic products are required to inform their suppliers of any new information they have available on the hazardous properties of the substances they use, and any information affecting the risk management measures indicated in the safety data sheets that affect identified uses. This information must also be supplied to national authorities or the ECHA. Importers of cosmetic products are required to report the chemical classification of all substances contained in their cosmetic products that are subject to registration (chemicals imported in quantities of one ton or more per importer per year) unless such classification has already been reported as part of the substances' registration. EU/EEA manufacturers of cosmetic products importing substances in bulk will also be subject to this reporting requirement.

Both new and old chemicals used in cosmetic formulations, including those that were listed in the EU's European Inventory of Existing Commercial chemical Substances list (EINECS), are subject to the registration requirement under REACH. Natural substances used in cosmetics that are not chemically modified and are not classified as dangerous and a limited number of other substances and groups of substances that are listed in Annexes IV and V to the Regulation will be exempted from registration. Registration will be chemical specific and require the submission of a technical dossier with extensive data on the toxic and eco-toxic characteristics of the chemical, which will entail substantial testing and data gathering as well as a chemical safety report (CSR) assessing the hazards, exposure, and risks of use during the entire life cycle for chemicals manufactured or imported in quantities of 10 tons or more per chemical manufacturer or importer per year.

Where suppliers register their chemicals, cosmetic manufacturers will be required to check whether their specific use of the substance is covered by their supplier's CSR as reflected in the safety data sheet provided by their supplier. If their specific use of the substance is not covered, manufacturers of cosmetic products may be required to report to the ECHA and prepare a CSR of their particular uses if the substances or the preparations containing them are classified as 'dangerous,' bioaccumulative and toxic substances (PBTs), very persistent and very bioaccumulative toxic substances (vPvBs) or substances raising an equivalent level of concern and they use the substance in quantities of one ton or more per year and in concentrations above specified thresholds. The CSR must assess the environmental and health risks of use of the substance during the manufacture of the cosmetic product, and the environmental risks resulting from the use of the substance in the cosmetic product.

Manufacturers and importers of cosmetic products can apply for prior authorization of substances of very high concern that they use in the manufacture of, or are contained in, their cosmetic products. Substances of very high concern may include Category 1 and 2 carcinogenic, mutagenic and reproductive toxins (CMRs), persistent, PBTs, vPvBs and other substances giving rise to an equivalent level of concern. Cosmetic producers using these substances will have to choose between withdrawing such substances or actively engaging in their regulatory defence. The dates by which cosmetic manufacturers and importers must ensure that they or their suppliers have applied for an authorization to use the substance in cosmetic products, or in their manufacture, and the date after which non-authorization applicants or holders must no longer market or use the substance are specified.

Authorization applicants will be required to show that the risks resulting from the use of their substances are adequately controlled or that the socio-economic benefits of the use outweigh the risks and there are no suitable alternative technologies. Applicants will also have to search for substitutes and present a substitution plan where substitutes are available. The REACH Regulation makes clear that the use of Category 1 and 2 CMRs in cosmetic products may never be authorized, and that the authorization requirement does not apply to substances used in cosmetic products if such substances are identified as substances raising "an equivalent level of concern" for health reasons. Applicants who do not obtain an authorization will be banned from using listed substances, unless their supplier or downstream user has obtained such authorization. All cosmetic products marketed in the EU/EEA and containing substances that have been authorized will have to be labelled with the number of the authorization that EU/EEA cosmetic manufacturers or importers, or their suppliers, have obtained.

The REACH Regulation also establishes a procedure through which the Commission may ban the marketing and use of substances that pose an 'unacceptable' risk, and envisions the use of this procedure to address the environmental risks from the use of a substance in cosmetic products (European Commission, 2006). The Commission could also issue a ban under REACH for the use of substances in order to address the human health and environmental risks from the use of such substances in the manufacture of cosmetic products in the EU/EEA, and the environmental risks from the use of such substances in cosmetic products.

4.4 Can REACH effectively manage CECs in cosmetic products?

REACH legislation follows a unified system for management of all chemicals produced at annual volumes greater than 1 tonne not covered by specific, more demanding regulations and Directives. A key element of REACH is the stepwise increase in data requirements as a chemical's market or production volume increases. As a result, REACH is having a major impact on chemical risk assessment practices in Europe, in particular with respect to abolition of the difference in approach to 'existing' and 'new' chemicals as well as the change from the current system where government authorities are responsible for risk assessment, to the producer or importer of a chemical becoming responsible for ensuring the adequacy of risk assessment undertaken. The producer/importer is obliged to make toxicity and exposure data and safe-handling advice available to the authorities, customers along the entire supply chain, and the public.

Overall, REACH aims to protect human health and promote a nontoxic environment while maintaining the competitiveness and innovative capability of the EU's chemicals industry. The strategy however calls for increased transparency in the regulatory system and provision of full information for the public about chemicals to enable them to make

informed choices and to avoid products containing harmful chemicals, which will in turn create pressure on industry to develop safer substitutes (Glegg and Richards 2007). Despite the potential opportunities that REACH offers for the safe use and management of chemicals, this legislation still has shortcomings and legal uncertainties which need to be addressed in its on-going implementation. The following section discusses the pros and cons of specific aspects of this legislation that can influence its effectiveness.

4.4.1 Chemicals in products

The REACH regulation aims to control the use of CECs so that exposure to every chemical can be demonstrated to be safe for consumers, workers, and the environment when considered separately, but also when considered in an integrated way. This integration will be another substantial challenge for the future as the legislation focuses on chemicals, but is weak with respect to the chemical makeup of complex products such as cosmetics and the issue of toxic chemicals and their possible synergistic effects in these products. REACH only applies to chemicals manufactured in or imported into the EU. It does not apply to the use of chemicals in finished products. Products such as decorative make up, hair and skin care products made outside the EU could contain chemicals that are not registered under REACH providing they are not banned under specific safety regulations. Hence, currently it is not possible to predict whether the expected benefits of the REACH legislation will materialise for the environment, for the health of consumers and at the work place (Gundert-Remy, 2008)

Additionally, REACH only applies to chemicals manufactured or imported in greater than 1 tonne per annum, hence some chemicals used in cosmetics due to the small concentrations and quantities involved might not trigger REACH at all. These chemicals

despite the potential to cause environmental harm will still be able to enter the environment if they are not degraded during disposal.

4.4.2 Consumer awareness

Consumer-demand patterns, attitudes and awareness of product ingredients and informed purchasing behaviour could be effective in decreasing environmental contamination from cosmetic products (Glegg and Richards 2007). Retailers are often afforded more credibility by consumers than producers or advertisers and are therefore in a strong position to influence their customers through the provision of information. However, there is a perceived lack of relevant and accessible information relating to cosmetic products and their constituent chemicals, which could be addressed by retailers so that consumers could make informed purchasing decisions. This strategy could complement the objectives of REACH, which is supposed to provide the public with greater protection from chemical exposure.

However, REACH relies on the public making appropriate choices to drive the changes through public engagement toward less harmful chemicals. Although REACH will make knowledge publicly available, the newly created knowledge refers mostly to substances. No central database containing information about products on the market, in particular their compositions, is planned. It is therefore unreasonable to expect the public to be able to make such choices without clear information about products and their constituents. The retailers of cosmetics may have to play a key role in the achievement of REACH's aspirations and through this contribute to the implementation of a sustainable chemicals policy (Glegg and Richards 2007). However, this may require the major parts of risk assessments and identifications of harmful chemicals to be performed by industry. The

industry will have to take this major responsibility on board and hence the success of REACH therefore depends on the way the private sector manages this important safety system and whether consumers and other stakeholders can build up trust and confidence in data generated by the industry (Bormann et al., 2006)

4.4.3 Hazard and PBT awareness

REACH legislation uses a 'no data, no market' principle and hence for the hazard and PBT assessment under the CSA process detailed information and data sharing is required. This means that detailed data need to be submitted at a number of separate stages of the assessment process. The screening process carried out based on REACH base data set is as follows:

a. **For substances in the range 1-10 tonnes per year**, testing for registration purposes should be confined to *in vitro* methods only (and *Daphnia*). Toxicity testing should only be on *Daphnia*, with valid quantitative structure-activity relationships (QSARs) being used to fill any data gaps. For human health, some information is needed on the following endpoints: acute toxicity, skin sensitisation, corrosivity, mutagenicity and reproductive toxicity (teratogenicity).
b. **For substances in the range 10-100 tonnes per year**, additional environmental data include information on analytical methods for environmental monitoring, pKa data for ionisable compounds, and consideration of the identity of any hydrolysis products. For human health, additional data are needed on repeated dose toxicity and on fertility. This may be obtained from one study (such as OECD Test Guideline 422, the Combined Repeat Dose and Reproductive/Developmental Toxicity Screening Test, or by investigating these end-points separately. Validated *in vitro* test methods for endocrine disrupters

should be introduced into the basic information package for substances over 10 tonnes (for screening purposes) as soon as they are available.

c. **For substances over 100 tonnes per year**, intelligent information gathering strategies need to be developed for both environment and human health impacts. These should concentrate on end-points of concern and be based on data already acquired and be augmented by existing non-standard information (QSARs or other techniques).
d. The outcome of the registration scheme results in the allocation of the substance to one of three categories: those of no immediate concern, those where accelerated risk management is necessary, and the remainder, which proceed to the next stage of risk assessment.

However, this process is costly and involves in depth data collection and analysis to ensure the data reliability. There are substantial numbers of chemicals awaiting assessment under REACH and this very lengthy process creates difficulties for assessing the full impacts of this regulation.

4.4.4 Exposure assessment

In order to perform a CSA under REACH, aggregation of exposure scenarios from all relevant identified chemicals is required. In this way, it is expected that the chemical supplier will be informed about all the relevant/reasonable foreseeable uses of the supplied substances and the information collected up the supply chain will play an important part in developing these exposure scenarios to ensure safe conditions for product and substance use when a substance is manufactured or imported in quantities of 10 tonnes per year and above, and classified as dangerous or as PBT/vPvB (De Bruin et

al., 2007). The development of appropriate methodology for realistic aggregation of exposure creates a challenge and is likely to require probabilistic approaches and comprehensive databases on populations' habits, practices and behaviours. The REACH regulation focuses exclusively on substances and to ensure proper functioning of REACH system, unambiguous substance identification and use is essential, especially for generating exposure scenarios. For consumer use of chemicals, one of the challenges will be to identify all of the consumer uses of a given chemical and then quantify the exposure derived from each of them for the exposure scenarios to be developed under REACH. Consumers are not part of the communication chain, and therefore manufacturers may have difficulties in defining the variation in use patterns.

Additionally, REACH classifies some chemicals as 'those of no immediate concern' given that the risks are already adequately controlled. However, an exposure evaluation might result in the reallocation of this substance to a different category of concern. This may result in leaving many existing substances on the market without any evaluation for a considerable amount of time. Therefore, REACH also has the potential to favour substances that have already 'been through REACH' regardless of whether they are safe or dangerous. In the worst cases, this could lead to the cessation of the use of certain safe substances and their replacement by substances that have been though REACH but are actually more hazardous.

4.4.5 Authorization

The 'adequate control' route for authorization allows the use of chemicals if the applicant can demonstrate a 'safe threshold' below which no serious adverse effects occur and the risk from the use of the substance is adequately controlled. This authorization route

requires regulators, together with industry, to assess and determine acceptable levels of exposure from risk calculations. However, this may be difficult as much recent scientific research has shown that the 'low dose' effect of EDCs makes it impossible to set a safe threshold for these chemicals and the no effect levels used in risk assessments are time-dependent properties, hence there is a lack of understanding of how these chemicals interact with biological systems, which leads to regular revisions of the threat posed (Bertanza et al., 2011; Caliman and Gavrilescu, 2009; Diaz-Cruz and Barcelo, 2009). Furthermore, risk assessments are not designed to take into account the interacting effect of chemicals to which we are commonly exposed. The inadequacy of this regulatory approach might lead to the continued use of CECs in products with the potential to increase environmental contamination.

A key consideration under REACH is, therefore, whether risk assessment should always be a prerequisite to a decision on whether or not a chemical should be marketed. This raises the issue of some fundamental flaws in the basic assessment procedure of REACH. It not only contravenes the precautionary principle by being based on arbitrary risk assessment decisions, but it also allows for dangerous chemicals to remain on the market even if safer alternatives exist. The precautionary principle states that where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation, thereby permitting a lower level of proof of harm to be used in policy making whenever the consequences of waiting for higher levels of proof maybe very costly and/or irreversible (Scheringer, 1997).

4.4.6 Restriction

REACH has the ability to restrict specific chemicals for use pending risk and hazard assessment of these chemicals, presenting a much clearer, more robust and protective approach to the management of chemicals. While it will not prevent all substances of concern from entering the market, it will ensure that their uses will only be permitted when no safer alternatives are available and the socio-economic benefits outweigh the risks to human health and the environment. However, the decision to restrict the use of a chemical is only finalized when an opinion is formed on the proportionality of a proposed risk reduction measure and the measure's adequacy at reducing the risk. Unfortunately, the outputs from standard risk assessments are not the same as the impact assessment inputs required for socioeconomic analysis, hence difficulty in forming coordinated and coherent opinions about restrictions. Similar translation challenges are also to be expected under the authorization processes of REACH, where socio economic assessment can be undertaken under certain circumstances. For example, outputs from environmental risk assessments are usually in the form of risk characterization ratios (RCRs), in which the predicted environmental concentration (PEC) is divided by a predicted no effect concentration (PNEC). If the RCR is >1 then a potential risk is assumed, although the predicted risk may not necessarily be realised in the environment because of uncertainty in both environmental and effects estimates. In addition, a higher RCR does not necessarily correspond to higher risk as the slope of the dose response relationship between exposure and effect (either for an individual species or a while community) is not considered in the calculations of RCRs. However, socioeconomic impacts assessment requires the translation of an RCR or its underpinning data unto a 'value'. For example, there may be an environmental risk that a substance causes long term adverse effects on

an aquatic ecosystem because of an RCR >1. Translating this rather vague risk assessment outcome into an assessment of impacts requires further, ideally quantitative information on how severe and extensive these effects are likely to be in the real world, and how different risk management measures might alter this.

4.5 The way forward with REACH

Existing chemical legislation has brought about substantial environmental benefits, but a more sustained effort is now needed to develop a consistent framework in order to break the link between economic growth and potentially harmful CECs in products. REACH legislation introduces the foundation for effective management schemes for CECs in products creating the opportunity for future reduction of CECs reaching the environment, through the establishment of more environmentally sustainable products. REACH addresses chemicals at its source thereby preventing the use of any potential CECs as ingredients in product formulations. This eliminates the concern about the release of CECs from products during the use phase as well as the testing of finished products for their detailed chemical composition (Royal Commision on Environmental Pollution, 2003, Bormann et al., 2006, Muir and Howard, 2007). CECs also have highly variable physical and chemical properties and it is not realistic to monitor environmental matrices for all of these chemicals that could be potentially damaging to the environment, hence source management of CECs can provide an opportunity for alternate management options for CECs.

The implementation of REACH complements the Sustainable Development Strategy (SDS) and Integrated Product Policy (IPP) in the UK. SDS introduces the concept of sustainable consumption and production in the future which aims to deliver new products

and services with lower environmental impacts across their life cycle, while boosting competitiveness. REACH can build on people's growing awareness of social and environmental concerns, and their roles as citizens and consumers through the influence of manufacturers and retailers on both consumers and supply chains. The IPP looks at all phases of a product's life-cycle and attempts to stimulate each part of these individual phases to improve the environmental performance of products. This is conducted through the use of a variety of tools both voluntary and mandatory, inclusive of economic instruments, substance bans, voluntary agreements, environmental labeling and product design guidelines.

REACH legislation adopts this principle by ensuring product sustainability in the future due to the sustainable use of chemicals through product intervention (Figure 4-1). This should be used as the basis for economic instruments to provide fiscal incentives for industry to move towards lower hazard products and processes. Better information flow through the supply chain, better understanding of and access to redress through liability law and greater transparency for the whole process will also drive this trend.

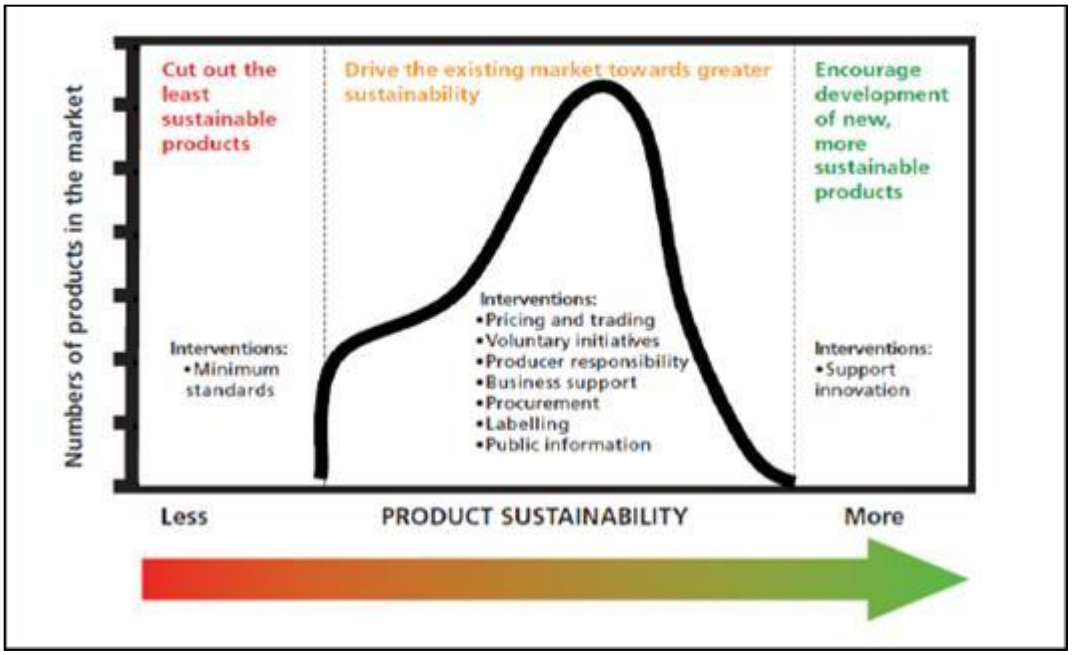


Figure 4-1: Product intervention for sustainable use

Although REACH sets the foundation for future regulation of CECs aiming for the sustainable use of chemicals, problems still exist with regards to the current levels and proper management of these CECs. As discussed earlier, the bulk data set required by REACH for conducting exposure assessments and characterising risks (physicochemical properties, PBT characteristics and ecotoxicological end points for CECs) are scarce and the processes to obtain this data are slow and costly. This creates a current system overload because of the difficulty of applying for cumbersome and expensive testing and assessment regime to the very large number of chemicals already on the market. Prioritisation schemes, an integral part of REACH, have reduced the number of chemicals under active consideration by a substantial factor, but even so, progress is slow. The acceleration of the initial stage of assessment under REACH can therefore minimize the collection of data considered unnecessary. Not only will this fast track the environmental risk assessment process but it will also create an efficient screening process for prioritizing CECs for further assessment.

Exposure scenarios will also have to be developed, covering a wide range of products and their use to speed up the risk assessment process under REACH. Product use categories can be established to identify in a systematic fashion how products are used. These product categories comprise products that are used similarly (such as facial moisturizers, anti-aging creams and wash). They can deliver information about product use characteristics, and provide an easy-to-handle tool for exchanging standardized information. The challenge will be to define them broadly, but in a way that does not provide such an overestimation of exposure that a next iteration or a more complex model is always needed. Scenarios can therefore be built up based on ‘worst case’ for estimation

of exposure and risk characterization. This gives a quick definite decision on whether CECs should be considered as potential risks or not.

A further critical distinction necessary for REACH is the systematic linking of information and assessments to instruments for risk management options. Although both the EU and the UK government have recognised the potential for economic instruments to drive chemicals policies, neither REACH nor the government's response include explicit discussion of how these or other potential drivers for managing chemicals might be incorporated into REACH. To determine whether CECs should or should not be used in cosmetic formulations therefore requires a means of transforming data analysed from CSA into a format that can be used for SEA assessment.

In the coming chapters the thesis illustrates how REACH can be applied to manage CECs in products, using cosmetics as a case study. The issues brought forward in this section will be addressed, demonstrating plausible solutions whilst considering the need for management of CECs in cosmetic products.

4.6 Conclusion

REACH legislation, adopts a new approach for regulating chemicals in the environment, and has the potential to facilitate the management of CECs by shifting the legislative focus from disposal to prevention and minimization. Chemicals in products, in particular CECs must be registered and authorised for use in cosmetic formulations under REACH to ensure safe use to humans and the environment. The responsibility is on manufacturers and retailers to show that the chemicals they use are safe, encouraging the replacement of hazardous chemicals with safer ones and spurring the chemicals sector into researching and developing more environmentally safe products. Although REACH is currently being

implemented and the success of this piece of regulation is still unknown, the CSA guidelines under REACH can be implemented, allowing for its shortcomings to effectively demonstrate the need for management of CECs in products.

5 COSMETICS AS A POTENTIAL SOURCE OF ENVIRONMENTAL CONTAMINATION IN THE UK

A methodology was developed to assess over 100 chemicals taken from product ingredient listings to identify and validate potential chemicals of emerging concern (CECs) in cosmetics. Ten CECs were identified and quantified based on their consumption and concentrations in cosmetics and percentage market penetration. Their initial predicted environmental concentrations were estimated to determine the exposure of the environment to the CECs. The selected CECs were linked to cosmetic products to highlight the products with the potential to cause the most environmental harm.

5.1 Introduction to cosmetics in the UK

The European Cosmetics and Toiletries market is estimated to have increased by 3.1 % over the past 4 years (COLIPA, 2008), with the UK having the third fastest growth rates among its European counterparts. Annual sales figures (2008) in the UK for cosmetics and toiletries are estimated at approximately £7.3 billion with over 2.6 billion units of PCPs sold (COLIPA, 2008, Brouwer et al., 1998, Euromonitor International, 2009a). Toiletries dominate the UK market, being the largest sales category for 2008, whilst skin care products and decorative cosmetics have shown the most growth (Table 5-1). Cosmetics are a diverse group of products containing multiple chemical ingredients, some of which may be CECs (Daughton and Ternes, 1999). The frequency of demand and use for these products as illustrated by the market figures, suggest that PCPs have become an essential part of our daily lives and hence the chemicals present in these products should be assessed and adequately managed to avoid environmental contamination.

Table 5-1: Cosmetics and Toiletries Statistics for UK for December 2008

UK data	Fragrances	Decorative cosmetics	Skin care products	Hair care products	Toiletries	Total
Sales (£billion)	0.978	1.202	1.644	1.536	1.916	7.277
Share of total market (%)	13	18	21	22	26	100

Contribution to growth (%)	0.2	1.2	1.3	0.1	0.2	2.8

The sheer number of potentially unsafe chemicals and combination of chemicals used in cosmetics makes it difficult to analyse these compounds in products (Jones et al. 2005). The environmental fate and behaviour of these chemicals cocktails are unknown as each product may contain different combination and concentrations of CECs, hence making it difficult to analyse potential risks associated with chemicals from products. Toxicity tests are usually carried out on a single chemical, but exposure in the environment is rarely to a single substance. If and when effects are observed, it is also complicated to establish statistically significant causal links with particular chemicals and specific organisms. Additionally, scientific literature has shown that the minimal research conducted on cosmetics in the past has traditionally been on the effects from intended cosmetic use on human health but the potential environmental effects have been overlooked (Daughton and Jones-Lepp, 2001).

Legislation such as the European Union (EU) Cosmetic Directive (76/768/EEC) as amended, has been the principal driver promoting the safe use of cosmetics by issuing precautionary bans on the use of certain chemicals in products. Its primary purpose is to protect human safety by controlling what may or may not be put in cosmetics. However, legislation governing the possible environmental consequences arising from the use of these products has been disregarded until recently. The Registration, Evaluation, Authorization and restriction of Chemicals (REACH) initiative addresses both the safety and long term environmental impacts of the ingredients used in cosmetics by controlling the use of chemicals so exposure to every chemical can be demonstrated as safe for the

environment (European Comission, 2006, Gundert-Remy, 2008). However, the guidelines under REACH for assessing these CECs are extremely complex and entail a lengthy process.

Additionally, relaxed legislation governing the proper labelling of cosmetics (Contaminants Hazard Information and Packaging for Supply Regulations 2009) as well as marketing strategies by manufactures to avoid listing the dangers/hazards of chemicals used and passing this information to their customers, have resulted in and can further result in numerous products containing chemicals of concern being placed on the market for use and ultimate disposal (Iles, 2007). For example, current EU law does not require full disclosure of cosmetic ingredients, hence chemicals of concern such as diethyl phthalate (DEP) are currently masked under the name 'parfum' or not included in ingredient lists on labels. Further research also illustrated that none of the 34 products tested positive for phthalates listed them as an ingredient on the label; this was even true for some products containing more than 10g DEP/kg (DiGangi et al., 2002).

This chapter describes aspects of a novel study to develop a methodology to identify, quantify and assess CECs in cosmetics. This is an essential initial step to considering the exposure of the environment to these chemicals, in order to determine whether consumption of cosmetics can be a possible source for CECs to reach the environment and hence the need for further assessment. Gaps in data to facilitate an understanding of why some of these chemicals are emerging and can be potential contaminants are also highlighted.

5.2 Methodology for the identification of CECs in cosmetics

Cosmetics comprise a huge range of products and to facilitate their study these products were grouped using the European Cosmetic, Toiletry and Perfumery (COPLIA) market's product categorization. The five product categories used in this study were chosen, based on their use on or application to the body; they included decorative cosmetics, skin care products, hair care products, toiletries and fragrances. These were subdivided into product groups using an illustrative list of cosmetic products outlined in the EU Cosmetics Directive (76/768/EEC) and its amendments (Table 5-2).

Table 5-2: Cosmetic classification based on the Cosmetics Directive 76/768/EEC and COPLIA product groups

Product category	Product group	Product examples
Decorative cosmetics (Products used for making up the face, eyes and lips)	Facial make up products	Foundation/concealer, bronzer/ blusher/highlighter & powder
	Lip products	Lip moisturiser, lip gloss, lipstick & lip pencil
	Nail products	Nail polish, nail treatment/strengthener& nail polish remover
	Eye products	Mascara, eye shadow & eye liners
Skin care (Creams, lotions, gels and oils for the skin (hands, face, body & feet)	Face care products	Day creams, night creams, masks, exfoliation, anti-wrinkle and anti-ageing creams for men and women, treatment series & anti-blackhead creams
	Face cleanser & toners	Liquid/cream/gel/bar cleansers& toners
	Body creams and lotion	General purpose body creams including hand lotion, baby care creams, lotion and milks, and firming/anti-cellulite body care;
	Sun care products	Sun blocks, before or after sun care sticks/lotions, sun tanning & baby sun care

Product category	Product group	Product examples
		products
Hair care (Products used for cleansing, treating, conditioning and styling of hair)	Shampoos and conditioners	Shampoos, conditioners, two-in-one (shampoo/conditioner),body shampoos& baby shampoos
	Hair styling agents	Hair sprays, Setting lotions and setting mousses, Hair creams, brilliantine & hair gels
	Hair treatment agents	Colouring shampoos, bleaches and hair dyes, Perms and relaxants
Toiletries	Toilet soaps	Liquid hand wash lotions, bar soaps, dermatological soaps & baby soaps
	Oral care products	Toothpastes, mouth washes (before and after brushing)& other dental products which are in contact with the mouth (sprays etc.)
	Shaving products	Foams, creams, gels, soaps for pre and post shaving
	Talcum powders	After bath powders and baby powders
	Bath and shower products	Bath foams, salts, bath oils, bath and shower gels
	Deodorants and antiperspirants	Roll-ons, sprays, creams & sticks
	Depilatories	Creams and waxes for hair removal
Fragrance	Perfume, toilet waters and eau de cologne	Extracts, perfumes, Eau de parfum, eau de toilette, eau de cologne, eau de lavande, parfum de toilette

A list of chemicals used in cosmetics was compiled from Euromonitor's International Passport database on 'Cosmetics and Toiletries' (Table 5-3). These chemicals were screened and sorted using the methodology developed (Figure 5-1) to identify CECs with the potential to affect the environment. This methodology was developed based on REACH Annex XIII of Regulation No. 1907/2006 (Euromonitor International, 2009a).

Annex XIII sets out the criteria for the identification of persistent, bioaccumulative and toxic (PBT) substances based on a technical guidance document on Information Requirements and Chemical Safety Assessment under Regulation (EC) No 793/93 and Directive 67/548/EEC, and on the Regulation 850/2004 on Persistent Organic Pollutants.

Table 5-3: Representative classification and listing of chemicals in cosmetics

Therapeutic class	Function/Use	Examples of Chemicals
Abrasives/Inorganics	Aids the removal of a variety of soils/stains through mechanical action.	Alumina
		Bentonites
		Hectorites
		Kaolins
		Magnesium aluminium silicate
		Mica
		Polythene beads
		Pumica
		Silica
		Talc
Acidulants	Combats the visible signs of ageing, linear dull complexion and blemishes, and for eliminating blackheads caused by acne.	Citric acid
		Lactic acid
Antifoams	Suppresses the formation of excess foam during production and/or consumer use.	Mineral oil
		Phosphate ester
		Silicone
Antifungals	Added to cosmetic products to help reduce the activities of fungal pathogens on the skin or body.	Piroctoneolamine
		Pyrithione

Therapeutic class	Function/Use	Examples of Chemicals
Antimicrobials	Added to cosmetic products to help reduce the activities of micro-organisms on the skin or body.	Polychlorophenol
		Quaternary salts
		Salicylic acid and its salts
		Triclosan
Antiperspirants	Active component that reduces perspiration.	Aluminium zirconium chlorhydrates
		Aluminum chlorhydrates
		Zinc phenolsulphonate
Bleaching agents	An agent used in the modification or removal of colour in the skin, hair and/or teeth.	Hydrogen peroxide
		Sodium hypochlorite
Colouring agents	An agent used for colouring the skin and/or hair.	Synthetic product colours
		Nano titanium dioxide
Conditioning agents	Enhances the appearance and texture of the hair and facilitates styling.	Dialkylquats
		Monalkylquats
		PCA dimethicone
		Phospholipids
		Decamethyl-cyclopenta-siloxane (D5)
Emollients	Softens or lubricates the skin.	Polydimethylsiloxane
		Dimethicone
		Hydrocarbon waxes
		Lanolin & derivatives
		Paraffins
		Petrolatum
Emulsifiers	Used in small quantities that help to	Alkoxylated fatty esters

Therapeutic class	Function/Use	Examples of Chemicals
	form or stabilize immiscible liquids in an emulsion.	Citric acid esters of monoglycerides
		Ethoxylated oils
		Fatty alcohols
		Mono- and diglycerides of fatty acids
		PEG esters
		Polyglycerol esters
		Sorbitan esters of fatty acids
Fragrance	Natural or synthetic substance used solely to impart an odour to a cosmetic product	Diethyl phthalate
Humectants	Holds/retains water in the product, and/or increases the moisture content in the top layers of the skin.	Butylene glycol
		Glycerol
		Propylene glycol
		Sorbitol
		Urea
Lacquers	A glossy, resinous material used as a surface coating in nail polish. Prevents chipping and peeling of nails.	Nitrocellulose
pH Control/salts	Adjusts the acidity/alkalinity of products.	Alkanolamines
		Ammonia
		Carbonates
		Citrates
		Hydroxides
		Lactates

Therapeutic class	Function/Use	Examples of Chemicals
		Magnesium sulphate
		Potassium chloride
		Silicates
		Sodium chloride
Preservatives/ antioxidants	Preservatives protect products from microbial growth and spoilage from accidental contamination by the consumer during use. Antioxidants inhibit the product reacting with oxygen, which can cause product spoilage.	Benzoic acid/benzoate
		Benzophenone-3 (BP3)
		Bronopol
		Butylatedhydroxylanisole (Xia et al.)
		Butylatedhydroxyltoluene (BHT)
		DMDM Hydantoin
		Formaldehyde
		Isothiazolinones
		Parabens
		Phenoxyethanol
		Sorbic acid/sorbate
Propellants	Delivers the product from an aerosol.	Dimethyl ether
		Fluorocarbons
		Hydrocarbons
Reducing agents	Changes the chemical nature of another substance by adding hydrogen or removing oxygen.	Thioglycollates
Skin tanning agents	Applied to the skin to enhance colour.	Dihydroxy acetone
Solvents	Dissolves other ingredients/materials.	Acetone
		Alcohol

Therapeutic class	Function/Use	Examples of Chemicals
		Butyrolactone
		Esters
Sunscreen agents	Filters out harmful UV rays.	Bis-ethylhexyloxyphenolmethoxyphenyltriazine
		Butylmethoxydibenzoylmethane
		Diethylhexylbutamidotriazone
		Ethylhexylmethoxycinnamate
		Ethylhexyltriazone
		Octocryelenes
		Phenyl benzimidazolesulphonic acid
		Terepthalylidenedicamphor sulphonic acid
		Nano titanium dioxide (nano TiO_2)
		Nano zinc oxide (nano ZnO)
Surfactant cleansers & adjuvants	Function as cleaning agents to dissolve dirt, suspend agents to keep solid particles from separating out of a liquid product, boost foaming and acts as an emulsifiers, enabling oil and water to mix.	Alkoxylated fatty alcohols
		Alkyl amido alkyl betaines
		Alkyl ether sulphates
		Alkyl isethionates
		Alkyl poly glucosides
		Alkyl sulphates
		Amphodiacetates

Therapeutic class	Function/Use	Examples of Chemicals
		Amphodiacetates
		Ethanolamides
		Linear alkylbenzenesulphonate
		Phosphate esters
		Polyalkylene glycols
		Sarcosinates/sarcosines
		Taurates
Synthetic polymers	Aid in creating specific textures of products, binding and moisture retention for products.	Acrylamides
		Copolymers
		Polyalkylene glycols
		Polycarboxylates
		Vinylpyrollidones/acetates
Thickeners/ structurants	Aids in emulsion stability.	Carbomers
Oral care agents	Provides cleansing, deodorising and protection to the oral cavity.	Pyrophosphates
		Sodium fluoride
		Sodium flurophosphate
		Strontium salts
Water softeners/chelators	Reduces or removes unwanted dissolved minerals in water used for the manufacture of products.	Carboxylates
		Ethylenediaminetetraacetic acid
		Phosphates

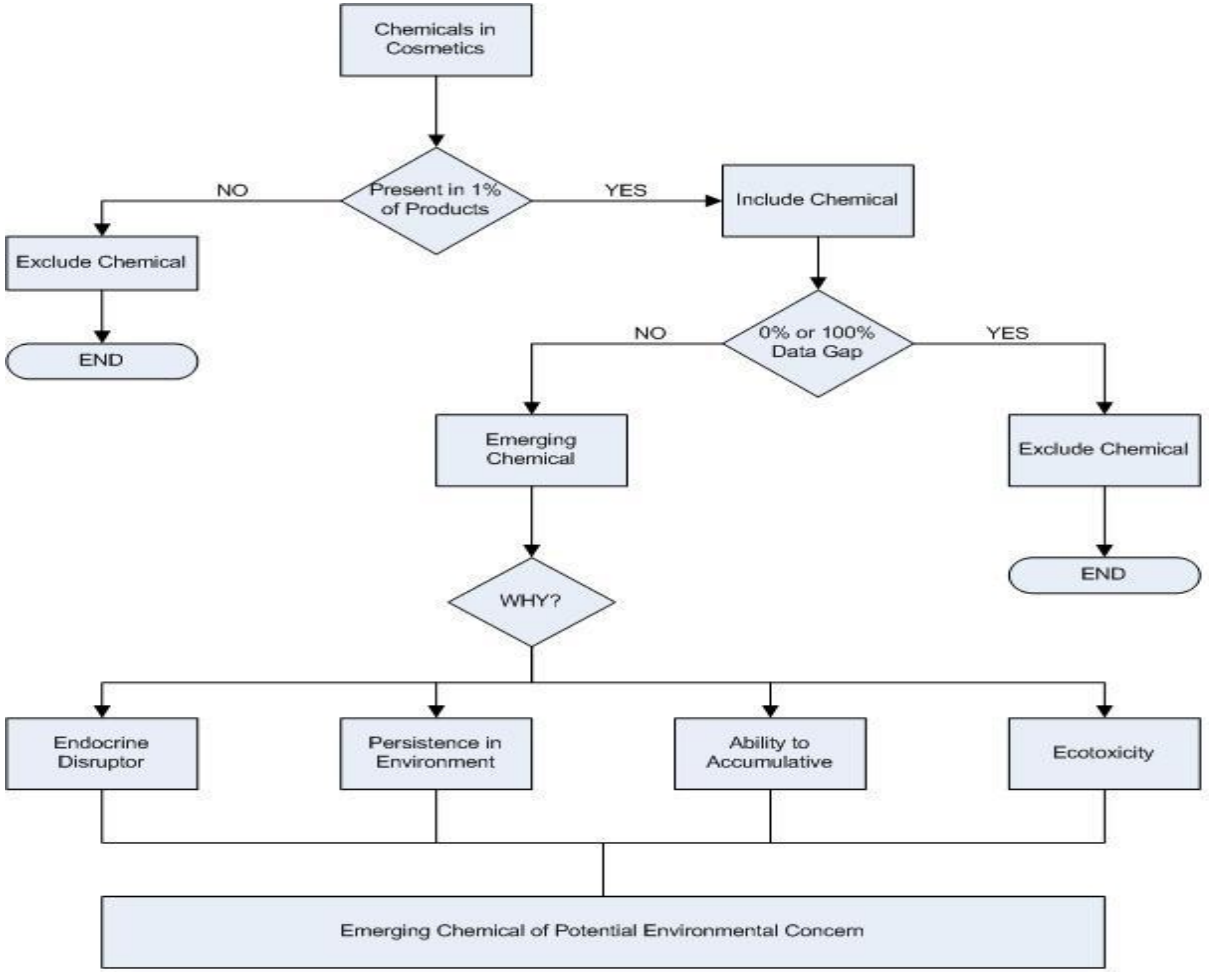


Figure 5-1: Screening and sorting of chemicals in cosmetics

The screening process eliminated chemicals present in 1% of the products sampled (500 products) from the study because of the insufficient use of these chemicals in PCPs. Also, if there was either a 0% or 100% gap of data on their physicochemical properties they were removed from the data set. Zero percent data gap meant that all information with respect to environmental concerns for the chemical is known and the chemical can be assessed effectively in terms of safety. Chemicals with 100% data gap meant that data on this chemical were unknown and hence it is impossible to adequately analyse this chemical in terms of potential environmental concerns (Appendix A). All other chemicals were assessed on the assumption that an existing data gap meant that the chemical is still in its emerging phase.

The chemicals were then sorted using PBT in full criteria outlined in Annex XIII of the REACH Regulation, 2006 (Table 5-4). Data were obtained from published journal articles, the Toxicology Data Network (TOXNET) database, approved under REACH and the United States Environmental Protection Agency (US EPA), as well as the Danish quantitative structure-activity relationship (QSAR) database using Syracuse Research EPIWIN software. Data were collected for over 100 chemicals found to be present in cosmetics to characterise these chemicals based on their PBT properties to determine potential environmental concerns.

Table 5-4: PBT criteria according to Annex XIII of REACH Legislation

Property	Description	PBT criteria
Persistence	resistant to biological/chemical breakdown in the environment	Half-life (T1/2) > 40 days in fresh- or estuarine water, or T1/2 > 120 days in fresh- or estuarine sediment, or T1/2 > 120 days in soil OR Not readily or inherently

		biodegradable OR Predicted biodegradability in a time frame of weeks-months
Bioaccumulation	Bioconcentrate in food chain, wildlife and humans	BCF > 2000 L/kg OR Log K_{ow}> 4.5
Toxicity	Toxicity of flora, fauna and ecosystems, toxicity of humans and/or interference with the body's natural hormonal system	Acute L(E)C < 0.1mg/L OR Chronic NOEC < 0.01 mg/L OR Substance is CMR : carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2 or 3) OR Endocrine disrupting (ED) effects

All chemicals meeting the EU's PBT criteria for at least one property were considered to be chemicals of emerging concern (CECs). Each chemical was quantified based on its consumption (per annum) in 53 different cosmetic products, using equation 5.1. Appendix B details the methodology used for quantification of CECs in cosmetics and provides comprehensive calculations for estimating the total CECs used in cosmetics (TCcec).

$$\boldsymbol{TCcec}^{1}(\boldsymbol{mg/yr}) = \sum_{i=1}^{53} \boldsymbol{Ccec}^{2} = \sum_{i=1}^{53} \left(\boldsymbol{P_{cec}}^{3} \times \boldsymbol{Conc_{cec}}^{4}\right) \textbf{ Equation 5-1}$$

[1] **TCcec** (mg/yr) = total consumption of CEC in cosmetics

[2] **Ccec** (ml)= consumption of CEC in cosmetic product

[3] $\mathbf{P_{cec}}$ (no. of products sold containing the CEC) (mu) = % of products sampled containing CEC * no. of products sold

[4] $\mathbf{Conc_{cec}}$ (concentration of CEC per unit of product) (µg/l) = CEC concentration in product * volume of product per unit

Initial exposures of the environment to these chemicals were then estimated by calculating the initial predicted environmental concentrations ($PEC_{initial}$) for the CECs in surface water. These values represented an initial assessment to estimate the potential of these CECs to affect the environment. If the $PEC_{initial}$ value was below an action limit (0.01µg/l) as derived from the Environmental Risk Assessment of medicinal products for human use, since no methodologies exist for assessing the environmental exposure of chemicals/contaminants in cosmetics (EMEA/CHMP, 2005), and no other environmental concerns were apparent, it was assumed that the CEC was unlikely to represent a risk for the environment following its usage in PCPs. If the $PEC_{initial}$ value was equal to or above the action limit, it was assumed that the chemical could pose a potential risk to the environment and further analysis (environmental fate and effects) would be required. The $PEC_{initial}$ was calculated for each chemical with the potential to cause environmental harm, irrespective of its route of exposure and environmental fate. This initial calculation was restricted to the aquatic compartment and assumed the following.

- The predicted amount of PCPs used per year is evenly distributed over the year and throughout the geographic area (UK).
- The sewerage system is the main route of entry of the chemicals from PCPs into the surface water.
- There is no biodegradation or retention of the contaminant in the sewage treatment plant.
- Dermal exposure to contaminant is not taken into account.

$$PEC_{initial}(mg/l) = \frac{DOSEai^{5} \times Fpen^{6}}{WASTEWinhab^{7} \times DILUTION^{8}}$$ **Equation 5-2**

DOSEai and Fpen were estimated using equations 5.3 and 5.4. DOSEai (maximum amount of CEC consumed daily per inhabitant) was calculated based on raw data collected from Euromonitor International on ingredients in cosmetics and quantities sold in the UK, and data collected from ingredient listings of products and material safety data sheets to determine concentrations of chemical used in PCPs. Maximum percentage concentrations of the emerging chemicals were used to predict a worst case scenario of environmental exposure to these potential contaminants. Fpen is defined as a percentage of market penetration and was calculated based on proportion of the population using a specific CEC on a daily basis. Calculations for DOSEai, Fpen and $Pec_{initial}$ are detailed in Appendix C.

$$DOSEai\ (\mathbf{mg/inh/d}) = \frac{TCcec}{(365Pop)}$$ **Equation 5-3**

$$Fpen\ (\%) = \frac{\left[\left(\frac{Pop_{cec}^{9}}{Pop^{10}}\right) \times 100\right]}{365} \rightarrow Pop_{cec} = \left(\frac{Pop}{P_t^{11}}\right) \times Pcec$$ **Equation 5-4**

CECs with the potential for environmental concern were linked back to products to determine the distribution and quantities of these emerging chemicals within products, to

[5] **DOSEai** (mg/inh/d) = maximum amount of CEC consumed daily per inhabitant

[6] **Fpen** (%) = percentage of market penetration

[7] **WASTEWinhab** (L/inh/d) = amount of wastewater per inhabitant per day = 200 (European Chemicals Agency, 2008b)

[8] **DILUTION** = dilution factor for consumer products = 10 (European Chemicals Agency, 2008b)

[9] $\mathbf{Pop_{cec}}$= population using PCPs containing CEC

[10] **Pop** = total population in the UK for 2008 (60 943912)

[11] $\mathbf{P_t}$= total number of PCPs sold in the UK (2.6 billion units)

assess whether cosmetics could be a potential source of environmental contamination. All data were analysed using Excel spread sheets.

5.3 Identification and assessment of CECs in cosmetics

Over 2.6 billion cosmetic products are sold in the UK per annum and the potential for environmental persistence, accumulation, toxicity and endocrine disruption of these chemicals means that there is a possibility for environmental contamination. The screening and sorting process identified two classes of CECs namely preservatives and sunscreen agents, and 10 candidates from these with the potential to cause environmental concerns based on their physicochemical characteristics and behaviour in the environment (PBT characteristics). These included benzophenone (BP3), butylated hydroxylanisole (BHA), butylated hydroxytoluene (BHT), diethyl phthalate (DEP), octyl methoxycinnamate (OMC), butylparaben (BP), decamethylcyclopentasiloxane (D5), nano titanium dioxide (nano TiO_2), triclosan and nano zinc oxide (nano ZnO) (Table 5-5). Although the acute toxicity of these CECs did not meet the EU criterion of L(E)C50<0.1mg/l, the toxicity levels were still moderate, ranging between 0.1-1.0mg/l, for most chemicals. The CECs were all linked to carcinogenic and/or mutagenic properties, and/or reproductive disorders in aquatic and terrestrial organisms. With the exception of nano TiO_2, nano ZnO and BHT, all other chemicals showed endocrine disrupting properties. Studies assessing the endocrine disrupting properties of the nanomaterials and BHT were either non-existent or non-conclusive, hence restricting the assessment of these potential contaminants.

Based on the calculated quantities of CECs present in cosmetics, the estimated per capita use for these chemicals ranged from a minimum of 0.081 mg/d/inh for BHA to a maximum for nanomaterials (81.85mg/d/inh for nano ZnO and 134.28 mg/d/inh for nano

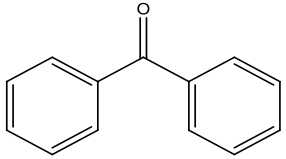
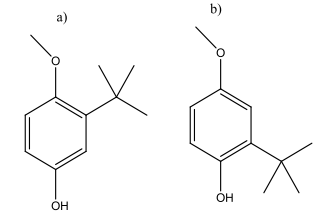
TiO_2) (Table 5-6). Although by weight the average per capita use of nanomaterials from cosmetics was greatest from among the CECs investigated, only about 42% of the products surveyed contained these potential contaminants. By contrast, over 70% of cosmetics contained DEP and BP, but estimated weights used of these products on a daily basis were much lower (2.80mg and 10.30mg respectively) (Table 5-6). DEP is a main ingredient in synthetic fragrance which is used in numerous products for odour enhancement whereas UV filters (nano ZnO and TiO_2), are used only in selected products for the specific function of UV protection. The market penetration for products further emphasised this, as DEP showed market penetration at 0.23%, greater than products containing nano TiO_2 (0.11%) and nano ZnO (0.05%) (Table 5-6).

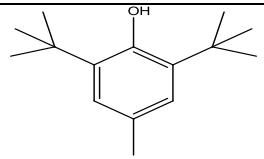
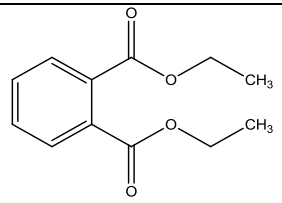
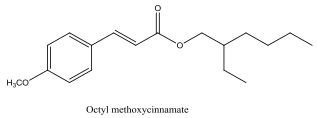
The initial exposure of the environment to CECs used in cosmetics was analysed by comparing the amounts of products consumed, the concentrations of CECs in each product and the frequency of use. This estimation was based on an amended model derived by the Committee for Medicinal Products for Human Use (EMEA/CHMP) for Environmental Risk Assessment of medicinal products for human use, since no methodologies exist for assessing the environmental exposure of chemicals/contaminants in cosmetics (EMEA/CHMP, 2005). The percentage market penetration (F_{pen} value) as determined by the EMEA/CHMP represents the proportion of a population being treated daily with a specific drug substance. It is usually a default value (0.01) based on the defined daily dose (DDD) values for drug substances derived by the World Health Organization. This DDD value cannot be derived for some of the CECs, as not all of the chemicals used in cosmetics have therapeutic uses, hence Fpen was corrected and calculated based on the proportion of the population using a specific chemical of emerging concern on a daily basis. Similar use and disposal patterns between medicinal

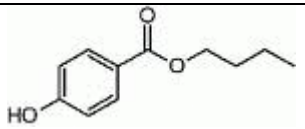
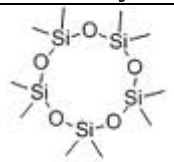
products and cosmetics validate the use of this model for estimating the exposure of the environment to CECs in PCPs. As in the case with pharmaceuticals, surface water receives the largest amount of PCPs via sewage and treated wastewater after use or disposal, hence the initial assessment of environmental exposure to these chemicals was directed to the aquatic environment (Daughton and Ternes, 1999, Heath et al., 2006).

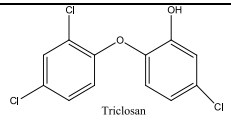
Findings demonstrated that $PEC_{initial}$ exceeded the action limit (0.01µg/l) for 9 out of the 10 CECs identified in this study. Nano TiO_2 (7.621 µg/l), D5 (4.285µg/l) and nano ZnO (1.95 µg/l) were significantly greater than the action limit, whilst BHA was the only chemical selected whose $PEC_{initial}$ was below the action limit (Table 5-6). Cosmetics can therefore represent a potential source for environmental contamination based on the quantities of the CECs used in cosmetic formulations and the frequency of use and disposal of these products. However, detailed environmental risk assessments are needed to assess whether these CECs are reaching the environment at sufficient concentrations to pose potential risks to aquatic and terrestrial organisms. This is dependent on refining the $PEC_{initial}$ values and comparing them to PNECs based on toxicity assessments. Physicochemical data for these CECs, especially nanomaterials, are scarce, posing a challenge for further evaluation of these chemicals. There is also a lack of information regarding the potential impacts associated with occurrence, fate and ecotoxicological effects in the environment, since few of the chemicals investigated are inventoried or regulated worldwide, and no legal requirements exist to assess the impact of long-term exposure to low concentrations of these CECs (Caliman and Gavrilescu, 2009).

Table 5-5: CECs commonly used in cosmetics based on the European Union PBT criteria

CEC	Structure and CASRN[1]	Function/use	Persistence (T1/2-freshwater)	Bio-accumulation BCF[2] (l/kg)	Toxicity		
					Acute L(E)C_{50} *Daphnia magna* (mg/l)	ED	CMR
BP3	 Benzophenone CAS: 119-61-9	Preservative	100	12	0.28	Yes	Yes
	(Danish Ministry of the Environment, 2005, Kunz et al., 2006, Nashev et al., 2010, Rhodes et al., 2007, TOXNET, 2009, Tosato et al., 1991)						
BHA	 The two isomers : Butylated Hydroxyanisole a) 2-tert-butyl-4-hydroxyanisole b) 3-tert-butyl-4-hydroxyanisole CAS: 25013-16-5	Preservative	28	269	7.0	Yes	Yes
	(Danish Ministry of the Environment, 2005, TOXNET, 2009, Jimenez, 1997, Jos et al., 2005, Meylan and Howard, 1995)						

CEC	Structure and CASRN[1]	Function/use	Persistence (T1/2-freshwater)	Bio-accumulation BCF[2] (l/kg)	Toxicity		
					Acute L(E)C_{50} *Daphnia magna* (mg/l)	ED	CMR
BHT	 Butylated hydroxytoluene CAS: 128-37-0	Preservative	7	2500	3.06	ND[4]	Yes
	(Fries and Puttmann, 2002, Danish Ministry of the Environment, 2005, TOXNET, 2009)						
DEP	 Diethyl Phthalate CAS: 84-66-2	Fragrance	28	117	52	Yes	Yes
	(Okkerman and van der Putte, 2002, Danish Ministry of the Environment, 2005, TOXNET, 2009)						
OMC	 Octyl methoxycinnamate	Sunscreen agent	21	5900	0.13	Yes	Yes

CEC	Structure and CASRN[1]	Function/use	Persistence (T1/2-freshwater)	Bio-accumulation BCF[2] (l/kg)	Toxicity		
					Acute L(E)C_{50} *Daphnia magna* (mg/l)	ED	CMR
	CAS: 5466-77-3						
	(Inui et al., 2003, Danish Ministry of the Environment, 2005, TOXNET, 2009)						
BP	 CAS: 94-13-3; 94-26-8; 99-76-3; 120-47-8;	Preservative	43	110	4.0	Yes	Yes
	(Andersen, 2008, Dobbins et al., 2009, Shaw and Decatanzaro, 2009, Tavares et al., 2009, Vo and Jeung, 2009, Vo et al., 2010, Danish Ministry of the Environment, 2005, TOXNET, 2009)						
D5	 CAS: 9016-00-6	Emollient	70	2000	0.14	Yes	Yes
	TOXNET, 2009, Alcock et al., 1999, Griessbach and Lehmann, 1999, Hayden and Barlow, 1972, He et al., 2003, Lehmann et al., 1999, Wang et al., 2009b)						
Nano TiO_2	CAS: 1317-70-0	Sunscreen agent	ND	56563	5.5	ND	Yes
	(Lovern and Klaper, 2006, Roh et al., 2010, Zhu et al., 2010b)						

CEC	Structure and CASRN[1]	Function/use	Persistence (T1/2-freshwater)	Bio-accumulation BCF[2] (l/kg)	Toxicity		
					Acute L(E)C_{50} *Daphnia magna* (mg/l)	ED	CMR
Triclosan	 Triclosan CAS: 3380-34-5	Anti-microbial	730	5000	0.42	Yes	Yes
	(Foran et al., 2000, Gee et al., 2008, Ishibashi et al., 2004, Stasinakis et al., 2010) TOXNET, 2009,						
Nano ZnO	CAS: 1314-13-2	Sunscreen agent	ND	ND	0.62	ND	Yes
	(Wang et al., 2009a)						
EU Limit			**T1/2>40**	**BCF>2000**	**L(E)C_{50}< 0.1**	**Yes**	**Yes**

1. CASRN is a single unique identifier number assigned to a material by the Chemical Abstracts Service (CAS) of the American Chemical Society (ACS). 2. BCF is a value of the bioconcentration factor of CEC in animal tissue. 3. L(E)C_{50} represents the concentration of the of emerging CEC to which the organisms were exposed that causes mortality (LC_{50}) or some other defined effect (EC_{50}). 4. ND means no data available for of CEC.

Table 5-6: $PEC_{initial}$ for CECs found in cosmetics in the UK

CEC	Quantity consumed in cosmetics (tonnes/yr)	Consumption per capita (DOSEai) (mg/d/ inh)	Products sampled containing emerging chemical (%)	Market penetration (Fpen) (%)	$PEC_{initial}$ (µg/l)
BHA	1.8	0.081	18.9	0.02	0.001
BHT	39.5	1.776	43.4	0.15	0.135
BP	229.2	10.303	71.7	0.17	0.871
BP3	55	2.471	18.9	0.02	0.024
D5	1364.9	61.357	62.3	0.14	4.285
DEP	62.4	2.807	73.6	0.23	0.320
Nano TiO_2	2986.9	134.275	45.3	0.11	7.621
Nano ZnO	1820.8	81.852	37.7	0.05	1.951
OMC	133.6	6.007	30.2	0.04	0.124
Triclosan	51.4	2.312	49.1	0.19	0.217

The CECs with the potential to cause concerns in the environment were traced back to products. Whilst products such as talcum powder, toilet soaps, oral care products, bath and shower care products, and products used for hair styling and treatment only contained less than 1% of these CECs per product, other products such as cleansers/toners

and sun care products contained over 40%, and facial make up had over 90% of these CECs per product (Table 5-7). However the distribution of these potential contaminants in products and the quantities used within each product varied greatly (Figure 5-2). Findings indicated that lip products contained 8 different CECs but in lesser quantities whilst products such as face cleansers/toners contained only 4 CECs with 1 chemical (nano TiO_2) being dominant and used in larger quantities (Figure 5-2). For example, approximately 2011.76 tonnes of nano TiO_2 are used in face cleansers/toners per annum in the UK, as compared to 12.33 tonnes of BP and 1.50 tonnes of triclosan. The same was evident for sun care products which primarily contained nano ZnO (1204.50 tonnes used per annum) and deodorants and antiperspirants, which had higher levels of D5 (698.13 tonnes) (Figure 5-2). It can therefore be suggested that nanoparticles are dominant ingredients used in cosmetics with the potential for environmental contamination. There is need for further assessment of these chemicals to fully understand the environmental implications of their use and disposal and the need for management of products containing these CECs. Although other CECs were present in products, their consumption and distribution within products were low, indicating a reduced chance for environmental contamination.

Limited data availability made it necessary to estimate some values for the quantities of CECs in different PCPs. Exact concentrations of chemicals in products were not always readily available from ingredient listings or material safety data sheets. Attempts to contact international personal care manufacturing companies to collect this data were futile due to company non-disclosure agreements. Estimates were used based on the existing concentration range for the specific CECs from other products. Where

upper limits exist in the Cosmetic Directive for the use of certain chemical in PCPs, these values were utilized for the study.

Table 5-7: Consumption of CECs per product in the UK

Products	Emerging chemicals consumed (tonnes/d)	No. of products sold (mu/d)	Emerging chemicals per product (mg)	Average size per product (ml)	% emerging chemicals per product
Face cleansers/toners	5.55	68.5	81.0	200	40.5
Sun care and tanning	3.41	41.8	81.5	200	40.8
Facial make-up	2.21	78.5	28.2	30	94.0
Deodorants & antiperspirants	2.08	417.5	5.0	200	2.5
Body creams and lotions	1.81	110.7	16.3	200	8.2
Face care	1.07	76.3	14.1	50	28.1
Shampoos & conditioners	0.72	247.2	2.9	250	1.2
Shaving products	0.30	37.6	7.9	200	3.9
Bath & shower products	0.24	329.5	0.7	500	0.1
Eye products	0.22	60.8	3.6	10	36.1
Depilatories	0.19	11.8	16.5	100	16.5
Hair styling & treatment	0.19	158.9	1.2	150	0.8

Nail products	0.17	23.7	7.3	20	36.3
Toilet soaps	0.15	522.3	0.3	250	0.1
Lip products	0.08	84.3	1.0	6	16.1
Perfumes	0.05	43.9	1.1	50	2.1
Oral care products	0.04	271.7	0.1	100	0.1
Talcum powder	0.0009	15	0.1	500	0.01

mu/d – million units of product sold per day

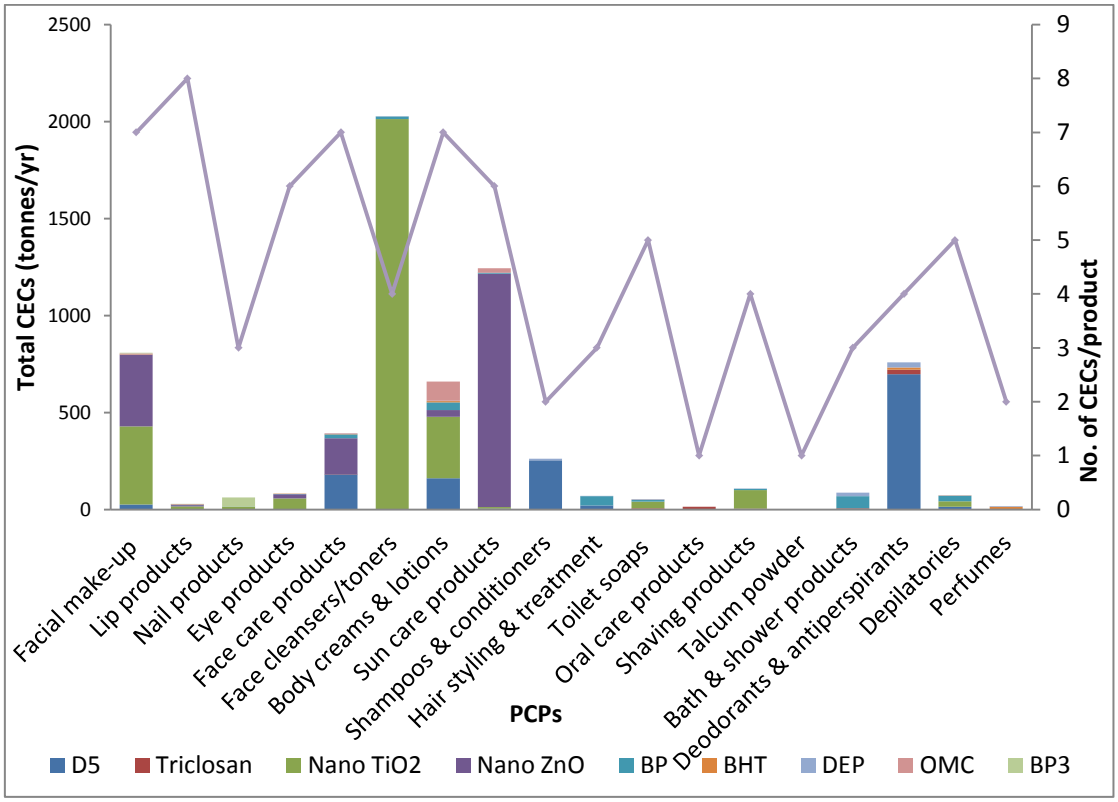


Figure 5-2: Distribution of CECs in cosmetics in the UK

5.4 Conclusion

Cosmetics in the UK contain CECs. Some of these emerging chemicals, in particular nanomaterials, have the potential to cause concerns on exposure to the environment. The $PEC_{initial}$ calculated for the CECs identified in this study illustrated the need for further research to assess whether these chemicals pose a significant risk to the environment upon exposure, since these chemicals are used continuously. Products such as facial make-up, face cleansers/toners and sunscreen/tanning products contained high levels of emerging chemicals, with nanomaterials being dominant. Hence, the use of cosmetics containing CECs has the potential to contribute to some of these chemicals reaching the environment in concentrations that might cause concern.

6 REACH GUIDELINES FOR ASSESSING HOUSEHOLD DISPOSAL OF CHEMICALS IN COSMETICS IN THE UK

This chapter examines how legislation mandates the screening of chemicals for environmental concerns, using available tools that are scientifically defensible. Predicted environmental concentrations and risk characterization ratios according to REACH technical guidelines were calculated for nine chemicals in order to assess the significance of household disposal of cosmetics as a pathway for the release of contaminants to the environment. Municipal wastewater is the major environmental pathway for these contaminants and municipal solid waste disposal is also a pathway by which chemicals used in cosmetics could reach landfills, but the predicted concentrations reaching the environment from landfill leachate are unclear.

6.1 Use and disposal of cosmetics

The UK cosmetic market, unlike other consumer sectors such as the motor trade, fashion and luxury products has remained a lucrative and highly innovative sector over the past years. Retail sales approached approximately £8 billion in 2009, an increase of 4.7% over the previous year, with companies replacing or reformulating approximately 25% of their products every year (Cosmetic Toiletry and Perfumery Association, 2009). Cosmetics commonly referred to as 'personal care products' (PCPs) are normally used for personal hygiene, with an indirect role in boosting people's self-esteem and confidence (Loden et al., 2007, COLIPA, 2008). Cosmetics used in the UK contain over 100 different chemicals (Euromonitor International, 2009a) and recent research has found that exposure to some of the chemicals (not the products containing them) can cause environmental effects. However, for certain chemicals such as chemicals of emerging concern (CECs), data on physicochemical and toxicological properties are not widely available, making it difficult to examine the potential effects of these chemicals

The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) initiative addresses both human safety and long term environmental impacts of the ingredients used in cosmetics by controlling the use of chemicals so exposure to every chemical can be demonstrated to be safe for the environment (Richter et al., 2008).Under this regulation, cosmetics containing CECs require a chemical safety assessment when they are used or imported in quantities greater than 10 tonnes per annum into the EU (European Commission, 2006).

Chemicals in cosmetics can enter the environment via 2 major exposure pathways, wastewater or solid waste (Figure 6-1). After personal use, products are washed from sinks, showers and baths as grey water and then enter conventional wastewater treatment

works (WWTWs). Release via this pathway is governed by the characteristics of the chemicals and their removal efficiencies and depends on variables such as local temperature and rainfall (Bound and Voulvoulis, 2005, Ruel et al., 2008). Additionally, expired or unwanted products may also be emptied into toilets, sinks and baths reaching wastewater systems. They may also be disposed of directly to municipal solid waste (MSW) and be entered into landfill sites. The influence from the disposal of cosmetics as solid waste with the potential to release CECs has been overlooked historically and there are no studies which estimate the volumes entering MSW and/or landfill leachate (Slack et al., 2004) More recently, findings by Yu et al., (2006), Kasprzyk-Hordern et al., (2009), Lishman et al., (2006) and Terzic et al., (2008) have illustrated that insufficiently treated municipal wastewater discharge is the major source of surface water contamination by the CECs commonly found in cosmetics.

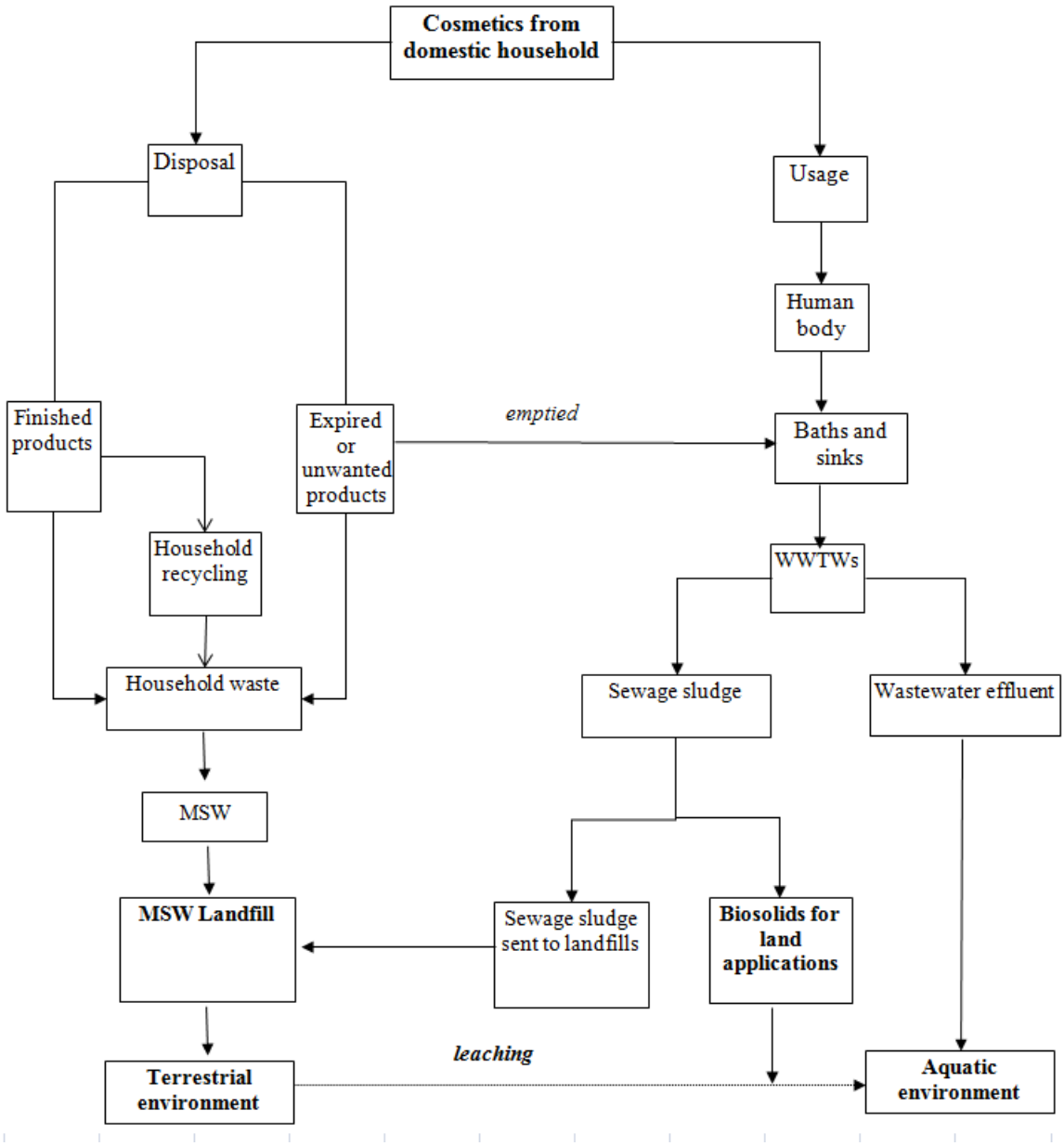


Figure 6-1: Exposure pathways for cosmetics from domestic households to the environment

Wastewater or solid waste disposal can expose the wider environment to contaminants via wastewater effluent, sludge and/or leachate to aquatic systems, terrestrial environments such as agricultural lands and groundwater systems (Trenholm et al., 2008). Despite this, many CECs have rarely been studied in environmental matrices and there is only limited evidence of their presence in the environment (Kasprzyk-Hordern et al., 2009).

Furthermore, no studies have examined household disposal directly, as a pathway for the release of potential contaminants to the environment, despite these CECs being present in PCPs which are used continuously and increasingly (COLIPA, 2008, Bound and Voulvoulis, 2005). Moreover, there is limited knowledge of the environmental risks and management issues posed by the disposal of cosmetics. This occurs as cosmetics are often categorized with human pharmaceuticals, due to similarities of their use by humans and their similar physicochemical (but not biological) properties (Boyd et al., 2004). Lack of material safety data and limited toxicological data for the chemicals also contributes to insufficient assessment of them (Loden et al., 2007, Ellis, 2006).

This chapter aims to assess the significance of the different environmental pathways for cosmetics to determine whether there is sufficient exposure to cause harm to the environment from their use and disposal. REACH technical guidelines were used to calculate the predicted environmental concentrations (PECs) and risk characterisation ratios (RCRs) for selected chemicals to evaluate their potential environmental effects within different environmental compartments (surface water, sediment and soil) and to assess their potential to cause harm to aquatic and terrestrial organisms. The results highlight the significance of household disposal of PCPs as a pathway of environmental contamination and illustrate the extent to which legislation can be used as a tool to manage the use of chemicals on the EU market.

6.2 Methodology for assessing the disposal of CECs in cosmetics

Nine CECs were selected for this study based on their use in PCPs, physicochemical properties and PBT characteristics as indicators of environmental risk (Table 6-1). These are benzophenone-3(BP3), butylated hydroxy-toluene (BHT) and butylparaben (BP) which act as preservatives to protect products from microbial growth and spoilage from

accidental contamination during consumer use. Diethyl phthalate (DEP), which is used as a fragrance, decamethyl-cyclopenta-siloxane (D5), used as an emollient to soften the skin, triclosan, an antimicrobial and the sunscreen agents: octylmethoxycinnamate (OMC), nano titanium dioxide (nano TiO_2) and nano zinc oxide (nano ZnO). Data on the occurrence and concentrations of these CECs were obtained from the ingredients listings of Euromonitor International's passport database on 'cosmetics and toiletries' (Euromonitor International, 2009a).

The predicted environmental concentration (PEC) was calculated and compared with the predicted no effect concentration (PNEC) to derive the risk characterisation ratio (RCR) of each chemical in the different environmental compartments (surface water, sediment and soil). This was used to consider if environmental concerns can be adequately controlled for each environmental compartment. The guidelines, published by the European Commission (EC) stipulate that an environmental risk assessment for each contaminant can be concluded if the PEC: PNEC ratio is below 1, indicating that the use of the substance can be considered to be of no immediate concern. Conversely, a ratio ≥ 1 suggests that recommendations for risk reduction are necessary (European Chemicals Agency, 2008b).

The PECs for each environmental compartment were estimated using equations 6.1-6.3, derived from the EUSES 2.1 mathematical model approved under REACH. The fractions of chemical release attributed to effluent and sludge (required for PEC calculation) were estimated from available scientific literature where possible (Table 6-2). Where data required for the PEC calculations were unavailable, estimations were made using simple treat 3.0 model and QSAR modelling (European Chemicals Agency, 2010).

The concentrations of CECs reaching MSW landfills were also estimated (Equation 6.4). This study, however, was unable to estimate the concentration of the CECs reaching the environment from landfills due to the absence of data on removal efficiencies of the selected chemicals by landfill leachate treatment facilities.

Table 6-1: Properties of selected CECs in PCPs and their environmental risk indicators

CECs	Physicochemical properties				Environmental risk indicator	References
	Chemical use (tonnes/d)	Log Kow[a]	Koc[b]	HENRY[c] (atm-m^3/mole)		
Benzo-phenone-3 (BP3)	0.151	3.18	517	1.94×10^{-6}	Endocrine disruption in fish affecting secondary sex characteristics, gonadal development and reproduction in fish. Detected in the environment	(Kunz et al., 2006) (Weisbrod et al., 2007)
Butylatedhydroxy-toluene (BHT)	0.108	5.1	44062[d]	4.12×10^{-6}	Not readily biodegradable and has moderate to high bioaccumulation potential in aquatic organisms	(Organization for Economic Cooperation and Development, 2002)
Butylparaben (BP)	0.628	3.57	2100	8.45×10^{-9}	Concerns of toxicity in aquatic environment Detected in the surface water and sediment	(Fatta-Kassinos et al., 2010)
Diethyl phthalate (DEP)	0.171	2.65	1726	6.1×10^{-7}	Confirmed endocrine disruptor. Detected in the environment	(Okkerman and van der Putte, 2002) (Nashev et al., 2010)
Octylmethoxy-cinnamate(O	0.366	6.1	440624[d]	1.78×10^{-6}	Estrogenic activity in fish Detected in the environment and has the potential to bioaccumulate in fish	(Inui et al., 2003) (Geyer et al., 2000)

CECs	Physicochemical properties				Environmental risk indicator	References
	Chemical use (tonnes/d)	Log Kow[a]	Koc[b]	HENRY[c] (atm-m^3/mole)		
MC)						
Decamethyl-cyclopenta-siloxane (D5)	3.739	5.71	24000	0.306	Used in large quantities per annum Very persistent and very bioaccumulative substance. Not readily biodegradable in aquatic systems. Detected in the environment	(Brooke et al., 2009) (Lehmann et al., 1999)
Nano titanium dioxide (nano-TiO_2)	8.183	4.6[e]	15850[f]	0[g]	Used in large quantities per annum. Potential bioaccumulation and toxicity to invertebrates. Detected in the environment	(Zhu et al., 2010a) (Zhu et al., 2010b) (Krysanov et al., 2010)
Triclosan	0.141	4.76	47454	4.99×10^{-9}	Potential endocrine disruptor. Undergoes bioconversion to methyl-triclosan (a more lipophilic compound), which can bioaccumulate in aquatic organisms. Increased microbial resistance following exposure leading to ecotoxicity to aquatic organisms. Degraded in sunlight to form dioxins such as 2,7/2,8-dibenzodichloro-*p*-dioxin which is very toxic	(Ishibashi et al., 2004) (Krysanov et al., 2010) (Ying et al., 2007) (Lozano et al., 2010) (Reiss et al., 2009)

CECs	Physicochemical properties				Environmental risk indicator	References
	Chemical use (tonnes/d)	Log Kow[a]	Koc[b]	HENRY[c] (atm-m^3/mole)		
Nano zinc oxide (nano-ZnO)	4.988	5.05[e]	50120[f]	0[g]	Used in large quantities per annum. Potential bioaccumulation in invertebrates. Concerns over toxicity in algae and fish embryo. Detected in the environment	(Krysanov et al., 2010) (Zhu et al., 2008) (Franklin et al., 2007)

[a]LogKow is the octanol water partition coefficient of chemical; [b]Koc is the soil organic carbon partition coefficient of chemical; [c]HENRY is Henry's law constant at 25^0C for the chemical; [d]Koc values are estimated based on Koc = 0.35Kow (Seth et al., 1999); [e]Estimated using an estimation program of U.S. Environmental Protection Agency's EPI Suite™, KOWWIN; [f] Estimated values from sensitivity analysis (Gottschalk et al., 2009) using Koc = Kd/foc (Organization for Economic Cooperation and Development, 2001); [f] Calculated using HLC = (VP)(M)(S), where VP is vapour pressure, M is molecular mass and S is solubility (European Chemicals Agency, 2010). ND means no data

Table 6-2: Fraction of chemical release directed to wastewater and sludge

Emerging chemical of concern	Fraction of release (%)		Treatment process	Reference
	Waste water	Sewage sludge		
BP3	14	4*	Mechanical, biological, chemical treatment & sand filtration. Avg. of 7 WWTWs,	(Balmer et al., 2005)
	30		Activated sludge	(Li et al., 2007)
	22		Activated sludge Avg. of 2 STP	(Trenholm et al., 2008)
	33		Activated sludge Avg. of 2 STP	(Pedrouzo et al., 2009)
	17		Activated sludge Avg. of 2 STP	(Kasprzyk-Hordern et al., 2009)
	23	**4**	**Average**	
BHT	24	47*	Activated sludge Avg. of 2 STP	(Trenholm et al., 2008)
BP	0.2	10*	Activated sludge Avg. of 2 STP	(Trenholm et al., 2008)
	1		Activated sludge Avg. of 2 STP	(Kasprzyk-Hordern et al., 2009)
	3		Activated sludge	(Villaverde-de-Saa et al., 2010)
	1	**10**	**Average**	
DEP	0	3	Activated sludge Avg. of 2 WWTWs.	(Clara et al., 2010)
	54	2*	Activated sludge	(Choi et al., 2006)

Emerging chemical of concern	Fraction of release (%)		Treatment process	Reference
	Waste water	Sewage sludge		
	10		Activated sludge	(Dargnat et al., 2009)
		2	Activated sludge	(Parker et al., 1994)
	21	**2**	**Average**	
OMC	8	19	Activated sludge	(Plagellat et al., 2006)
	15*	85*		
	12	**52**	**Average**	
D5	4	92	Activated sludge	(Parker et al., 1999)
	3		Activated sludge	(Kazuyuki et al., 2007)
	6		Activated sludge Avg. of 3 STP	(Price et al., 2010)
		85*		
	4	**91**	**Average**	
Nano-TiO_2	19	81	Estimated value from flow analysis	(Mueller and Nowack, 2008)
	56	38	Estimated value from sensitivity analysis	(Gottschalk et al., 2009)
		60*		
	38	**60**	**Average**	
Triclosan	5		Activated sludge Avg. of 2 STP	(Trenholm et al., 2008)
	8		Activated sludge Avg. of 2 STP	(Pedrouzo et al., 2009)
	27		Activated sludge Avg. of 2 STP	(Kasprzyk-Hordern et al., 2009)
	5		Activated sludge and	(Lishman et al., 2006)

Emerging chemical of concern	Fraction of release (%)		Treatment process	Reference
	Waste water	Sewage sludge		
			lagoon Avg. of 13 STP	
	31		Biological filter	(Yu et al., 2006)
	3		Activated sludge Avg. of 4 WWTWs	(Kumar et al., 2010)
	27		Activated sludge	(Villaverde-de-Saa et al., 2010)
		50	Activated sludge	(Heidler and Halden, 2007)
	6	20	Activated sludge Avg. of 2 STP	(McAvoy et al., 2002)
	15	13	Trickling filter Avg. of 2 STP	
		60*		
	14	**36**	**Average**	
Nano-ZnO	24	76	Average estimated from range sensitivity analysis	(Gottschalk et al., 2009)
		61*		
	24	**69**	**Average**	

***Estimated values derived from Simple Treat 3.0 model (European Chemicals Agency, 2010)*

$$\boldsymbol{PEC_{sw}(mg/l) = Clocal_{sw} \times \frac{Temission}{365}}$$ **Equation 6-1**

$$Clocal_{sw}(mg/l) = \frac{Clocal_{eff}}{\left(1 + Kp_{susp} \times SUSP_{water} \times 10^{-6}\right) \times DILUTION}$$

$$Clocal_{eff}(mg/l) = Clocal_{inf} \times Fstp_{water}$$

$$Clocal_{inf}(mg/l) = \frac{Elocal_{water} \times 10^{-6}}{EFFLUENT_{stp}}$$

$$Elocal_{water}(\text{kg/d}) = Q_{daily} \times RF \times 1000$$

$$EFFLUENT_{stp}\ (l/d) = CAPACITY_{stp} \times WASTEWinhab$$

$$Kp_{susp}(\text{l/kg}) = Foc_{susp} \times Koc$$

Where PEC_{sw} is the predicted environmental concentration in surface water, $Clocal_{sw}$ is the local concentration of CEC in surface water, $Clocal_{eff}$ is the concentration of CEC in the WWTWs effluent and $Clocal_{inf}$is the concentration of CEC in untreated wastewater, $Elocal_{water}$ is the release rate of CEC to wastewater, $EFFLUENT_{stp}$ is the effluent discharge rate of WWTWs and Kp_{susp} is the solid-water partitioning coefficient of suspended solids. Temission, the number of emission days, was calculated by annual use (kg/yr) /daily use (kg/d)= 365d/y and WASTEWinhab by the amount of wastewater per inhabitant (based on average wastewater flow per population equivalent from over 1200 municipal WWTWs in the UK) = 184 l/d.$Fstp_{water}$ (%fraction of release directed to wastewater effluent by WWTWs), Q_{daily}(daily use of CEC in the UK), RF (fraction of the used amount of CEC released into surface water) and Koc (soil organic carbon partition coefficient) were also calculated for this study. Default values used in Formula 1 include: $SUSP_{water}$ (concentration of suspended matter in the river) = 15 mg/l, DILUTION (dilution factor) = 10, $CAPACITY_{stp}$ (capacity of total WWTWs) = 10000 and Foc_{susp} (weight fraction organic carbon in suspended solids) = 0.1.

$$\boldsymbol{PEC_{sed}(\text{mg/kg}) = \frac{K_{susp-water}}{RHO_{susp}} \times PEC_{sw} \times 1000}\ \textbf{Equation 6-2}$$

Where PEC_{sed} is the predicted environmental concentration in sediments and $K_{susp\text{-}water}$ is the suspended matter-water partitioning coefficient. All other values used for this

[12] $\boldsymbol{K_{susp-water}}(m^3|m^{-3}) = [Fwater_{susp} + (Fsolid_{susp} \times \frac{Kp_{susp}}{1000})] \times RHOsolid$

calculation were default values adopted from EUSES 2.1 model: RHO_{susp} (bulk density of wet suspended matter) = 1150 kg/m^3, $Fwater_{susp}$ (fraction water in suspended solids) = 0.9, $Fsolid_{susp}$ (fraction water in suspended solids) = 0.1 and RHO_{solid} (density of the solid phase) = 2500 kg/m^3.

$$\boldsymbol{PEC_{soil}(mg/kg) = Clocal_{soil} = \frac{1}{T} \times \int_0^T C_{soil}(t)dt} \Rightarrow \textbf{Equation 6-3}$$

$$Clocal_{soil}(mg/kg) = \frac{D_{air}}{k} + \frac{1}{kT}\left[C_{soil}(0) - \frac{D_{air}}{k}\right] \times [1 - e^{-kT}]$$

$$C_{soil}(0)(mg/kg) = \frac{Csludge \times APPL_{sludge}}{DEPTH_{soil} \times RHO_{soil}}$$

$$C_{sludge}\,(mg/kg) = \frac{Fstp_{sludge} \times Elocal_{water} \times 10^6}{SLUDGERATE}$$

$$k\,(d) = k_{leach} + kbio_{soil} + k_{volat}$$

$$k_{leach}\,(d) = \frac{Finf_{soil} \times RAINrate}{K_{soil-water} \times DEPTH_{soil}}$$

$$K_{soil-water}(m^3|m^{-3}) = [Fair_{soil} \times K_{air-water} + Fwater_{soil} + (Fsolid_{soil} \times \frac{Kp_{soil}}{1000})] \times RHOsolid$$

$$K_{air-water} = \frac{HENRY}{R \times TEMP}$$

$$Kp_{soil}(\text{mg/kg}) = Foc_{soil} \times Koc$$

$$kbio_{soil}\,(d) = \frac{\ln(2)}{DT50bio_{soil}}$$

Where PEC_{soil} is the predicted environmental concentration in soil, C_{soil} (0) is the concentration contribution to the soil concentration for sludge application, C_{sludge} is the concentration of CEC in dry sewage sludge, k is the total constant rate of removal from soil, k_{leach} is the CEC removal from soil by leaching, $K_{soil\text{-}water}$ is the soil-water partitioning coefficient, $K_{air\text{-}water}$ is the air water partitioning coefficient, Kp_{soil} is the solids-water partitioning coefficient of suspended solids and $Kbio_{soil}$ is the CEC removal from soil by

degradation. Default values used in Formula 3 adopted from EUSES 2.1 model include: T(average time) = 30d,$APPL_{sludge}$ (dry sludge application rate) = 0.5kg/m^2/yr, $DEPTH_{soil}$ (mixing depth of soil) = 0.2 m, RHO_{soil} (bulk density of wet soil) = 1700 kg/m^3, SLUDGERATE (rate of sewage sludge production) = 710 kg/d,$Finf_{soil}$ (fraction of rain water that infiltrates into soil) = 0.25, RAINrate (rate of wet precipitation) = 0.00192 m/d, $Fair_{soil}$ (fraction of air in soil) = 0.2, $Fwater_{soil}$ fraction of water in soil) = 0.2, $Fsolid_{soil}$ (fraction of solids in soil) = 0.6, Foc_{soil} (weight fraction organic carbon in suspended solids) = 0.02, R (gas constant) = 8.314 and TEMP(temperature at the air water interface) = 285 K. D_{air} (aerial deposition flux per kg of soil) and K_{volat} (CEC removal from soil by volatilization) were calculated to be 0 as the CECs were non-volatile except for D5.$Fstp_{sludge}$ (% fraction of CEC directed to sludge by WWTWs) was derived from available literature and $DT50bio_{soil}$ values (half lives in soil) were extrapolated based on results from standardised biodegradation test results for half-lives in surface water (European Chemicals Agency, 2010).

$$\boldsymbol{ECC_{LF}(mg/kg) = Csludge_{LF} + CMSW_{LF}}$$[13] **Equation 6-4**

Where ECC_{LF} is the total concentrations of CEC reaching landfills and $CMSW_{LF}$ is the concentrations of CEC in MSW to landfills. $Csludge_{LF}$ (concentrations of CEC in sewage sludge to landfills), $Qdaily_{MSW}$ (daily production of MSW in the UK) and RFL (fraction of the used amount of CEC released into sewage sludge going to landfills) were calculated for this study.

In order to estimate the concentrations of CECs reaching different environmental compartments, PEC values were calculated using 2 scenarios, which represented the

[13] $\boldsymbol{CMSW_{LF}}$(mg/kg) = $\frac{Qdaily \times RFL \times 10^6}{Qdaily_{MSW}}$

diversion in percentage volume of chemicals between disposal to WWTWs and MSW (Table 6-3). This was based on the assumptions that consumers do not purchase and/or receive PCPs and dispose of them without any use, that there is 100% release of CECs from PCPs and disposal of cosmetics occurs at intervals throughout the year, rather than bulk disposal. These assumptions were essential as there are no existing data on the use and disposal patterns of cosmetics and there are none on the transformation and release processes of CECs in PCPs, in the UK. Dermal absorption of the chemicals during use was not considered in estimating the quantities of CECs reaching WWTWs and the effects of these chemicals on microbial activity during wastewater treatment processes were outside of the scope of the study.

Table 6-3: Scenarios for modelling the quantity of CECs discarded from households via different environmental pathways

Scenario (RF)		Assumptions	Description
1	**10% of CECs from products go to WWTWs and 90% to MSW**	Products barely used on the body due to personal preferences (dislike product after initial use, unwanted gift item) or passed expiry date and is discarded directly to household waste. Potential degradation/dilution of chemicals also considered.	Minimum CECs reaching WWTWs and maximum entering MSW.
2	**99% of CECs from products go to WWTWs and 1% to MSW**	All products used to completion. If product remains, the containers are emptied and washed out in bath and/or sinks before disposal to household waste.	Maximum CECs reaching WWTWs and minimum entering MSW.

The PNEC values for surface water ($PNEC_{SW}$) were estimated using the lowest toxicity value for routine test species in surface water from effect studies validated under REACH (European Chemicals Agency, 2008a). The lowest acceptable PNEC for each CEC was multiplied by an appropriate assessment factor (AF) as in the'Guidance on information requirements and chemical safety assessment, Part E: Risk Characterisation' (European Chemicals Agency, 2008b) (Table 6-4). To evaluate the adequacy and completeness of the data a Klimisch code was assigned to the ecotoxicity tests used to calculate PNECsw (Klimisch et al., 1997) (Table 6-4). The equilibrium partitioning method (EPM)was then used to estimate the PNEC values for sediment and soil because of the absence of toxicity data for these chemicals for sediment and soil organisms (Equations 6.5 and 6.6). This method used the $PNEC_{SW}$ for aquatic organisms and the suspended matter/water partitioning coefficient and soil/water partitioning coefficient as inputs to estimate the PNEC values (European Chemicals Agency, 2008b). It was assumed that sediment and soil dwelling organisms and water column organisms are equally sensitive to the concentration of the CECs.

For chemicals with a log Kow> 5, the EPM was modified by multiplying the RCRs by a factor of 10 to account for uptake via ingestion of sediment and soil (European Chemicals Agency, 2008a). However, this was only applicable to OMC, as the log Kow values for the other CECs were below or just marginally above 5. The use of this EPM method is generally unsuitable for nanomaterials, hence PNEC values for nano TiO_2 and ZnO in sediment and soil were derived according to the EPM for metals based on a PNECsw and a reasonable worst-case sediment/soil water distribution coefficient (10 percentile Kp value) (Equations 6.7 and 6.8) (European Chemicals Agency, 2008b).

Table 6-4: Effect concentrations for different test species exposed to CECs in surface water

Emerging chemical	Test	Klimisch rating	Test organism	Toxicity (µg/l)			AF	PNEC	References
				E(L)C 50	EC10	NOEC			
BP3	48h-EC50(OECD guideline 202 - acute immobilization)	1	*Daphnia magna*	1900			100	3.1	(Fent et al., 2009) (Coronado et al., 2008)
	21-day Rep. test (In vivo data on a single species-proposed OECD guideline)	2	Fish			310*			
BHT	96-hr LC50 (equivalent to OECD guideline 203)	1	Fish	570			100	0.7	(Organization for Economic Cooperation and Development, 2002)
	48-hr LC50 (equivalent to OECD guideline 202)	1	*Daphnia magna*	170					
	21-day Rep. test (OECD guideline 211- reproduction)	1	*Daphnia magna*			70			
DEP	96-h NOEC (OECD guideline 201 – growth inhibition)	1	Green alga			3700	50	7.4	(Sekizawa et al., 2003)

Emerging chemical	Test	Klimisch rating	Test organism	Toxicity (µg/l)			AF	PNEC	References
				E(L)C 50	EC10	NOEC			
	21-day NOEC(OECD guideline 211-reproduction)	1	*Daphnia magna*			13000			
	96-h NOEC (OECD guideline 203-acute toxicity)	1	Fish			1700			
OMC	48h-EC50 (QSAR prediction)	4	Green alga	437			1000	0.44	(Sabaliunas et al., 2000)
BP	96-h LC50 (OECD guideline 203-acute toxicity)	1	Fish	2900			50	12	(Yamamoto et al., 2007)
	48-hr LC50 (OECD guideline 202-acute immobilization)	1	*Daphnia magna*	1900					
	21-day-NOEC (OECD guideline 211-reproduction)	1	*Daphnia magna*			640			
	96-h NOEC (OECD guideline 201 – growth inhibition)	1	Green alga			600			
D5	14-day-NOEC (OECD guideline 204-	1	Fish			16	10	1.2	(Brooke et al., 2009)

Emerging chemical	Test	Klimisch rating	Test organism	Toxicity (µg/l)			AF	PNEC	References
				E(L)C 50	EC10	NOEC			
	prolonged toxicity)								
	21-day-NOEC (OECD guideline 211- reproduction)	1	*Daphnia magna*			15			
	14-day-NOEC (OECD guideline 221- growth inhibition)	1	Green alga			12			
Nano TiO_2	48-h acute toxicity (U.S. EPA standard operating procedure 2002 a,b)	1	*Daphnia magna*	6500			100	10	(Hall et al., 2009)
	IC25 (U.S. EPA standard operating procedure 2002 b)	1	Green alga			1000			
	48-h-acute toxicity (U.S. EPA standard operating procedure 2024)	1	*Daphnia magna*	5500		1000			(Lovern and Klaper, 2006)
	21-day-NOEC (OECD guideline 211- reproduction)	1	*Daphnia magna*			3000			(Wiench et al., 2009)
	21-day-EC50 (OECD	1	*Daphnia magna*	460		1000			(Zhu et al., 2010a)

Emerging chemical	Test	Klimisch rating	Test organism	Toxicity (µg/l)			AF	PNEC	References
				E(L)C 50	EC10	NOEC			
	guideline 211-reproduction)								
Triclosan	61day-NOEC (OECD guideline 210 – early life stage toxicity)	1	Fish			34.1	10	0.053	(Capdevielle et al., 2008)
	21day-NOEC (OECD guideline 211-reproduction)	1	*Daphnia magna*			40			(Zhu et al., 2008)
	3day-NOEC (OECD guideline 201 – growth inhibition)	1	Green alga			0.53			
Nano ZnO	48h-EC 10(OECD guideline 202 - acute immobilization)	1	*Daphnia magna*		2700		1000	1.7	(Wiench et al., 2009)
	48h-EC50 (OECD guideline 202 - acute immobilization)	1	*Daphnia magna*	1700					(Blinova et al., 2010)
	48h-EC50 (OECD guideline 202 - acute immobilization)	1	*Daphnia magna*	2600					(Heinlaan et al., 2008)

*NOEC = LOEC (620 µg/l)/2 when LOEC > 10 and < 20% effect (European Chemicals Agency, 2008a)

$$PNEC_{sed}{}^{14} = \frac{K_{susp-water}}{RHO_{susp}} \times PNEC_{water} \times 1000 \quad \textbf{Equation 6-5}$$

$$PNEC_{soil}{}^{15} = \frac{K_{soil-water}}{RHO_{soil}} \times PNEC_{water} \times 1000 \quad \textbf{Equation 6-6}$$

$$PNEC_{sed} = PNEC_{sw} \times Kp_{susp} \quad \textbf{Equation 6-7}$$

$$PNEC_{soil} = PNEC_{sw} \times Kp_{soil} \quad \textbf{Equation 6-8}$$

6.3 Analysis of environmental risks from the disposal of CECs

PEC calculations were carried out for 9 CECs, using exposure estimation algorithms coded into the European Union System for the Evaluation of Substances (EUSES 2.1, 2008) model. To make the study specific to the UK, some of the default values suggested for the model were substituted by UK specific data, reducing some uncertainties of the study. The amount of wastewater used per inhabitant (based on Yorkshire Water's average wastewater flow per population equivalent from over 650 municipal WWTWs in the UK) was estimated at 184l/d/head compared to the EU guidelines of 200l/d/head. The amount of CECs in sewage sludge going to different compartments was also estimated, based on the proportion of sludge that goes to each compartment (agricultural land and landfill) in the UK. It is estimated that approximately 74% of sewage sludge is sent to farmland or used for land restoration/reclamation (Department for Environment Food and Rural Affairs, 2006). The guidelines further suggest estimation of the fraction of release of CECs directed to wastewater effluent and sewage sludge using Simple Treat 3.0 'look up' tables (European Chemicals Agency, 2010). Instead, data were obtained from existing studies where possible, and cross referenced to the simple treat data table (see Table 6-2).

[14] **$PNEC_{sed}$** = PNEC for sediments
[15] **$PNEC_{soil}$** = PNEC for standard soils with 60% solids, 20% water and 20% air, and with 2% organic carbon in the soil solids

The findings from this study demonstrated that PEC values for the selected CECs ranged from 0.003µg/l to 16.343µg/l for surface water, 0.16µg/l to 5643.92µg/l for sediment and 0.05µg/l to 1473.4µg/l for soil, when cosmetics are disposed of to conventional WWTWs (Table 6-5). Nano-TiO_2, nano-ZnO and D5 had the highest environmental concentrations respectively, whilst BP, had the lowest predicted concentrations for all the environmental compartments, when the maximum quantity of CECs were released to WWTWs. The PEC values were then divided by the PNEC values for each chemical to determine their RCR (Table 6-5). Risk characterization ratios were above 1 for nano-TiO_2 and nano-ZnO in surface water, sediments and soil, hence the potential for these chemicals to be of concern in both aquatic and terrestrial environments. Findings illustrated that triclosan had a RCR>1 for surface water and sediments but not for soil. All the other chemicals (BP3, BHT, DEP, OMC, BP and D5) had RCR values of less than 1, even when the maximum quantities were disposed of to WWTWs. This suggests that these CECs probably pose little or no risk to either aquatic and/or terrestrial organisms.

Table 6-5: The environmental exposure and risk characterization of CECs from cosmetics disposal via WWTWs

Emerging chemical of concern	SURFACE WATER					SEDIMENTS					SOIL				
	PEC (ug/l))		PNEC (ug/l)	RCR_{sw} (PEC:PNEC)		PEC_{sed} (ug/kg)		$PNEC_{sed}$ (ug/kg)	RCR_{sed} (PEC:PNEC)		PEC_{soil} (ug/kg)		$PNEC_{soil}$ (ug/kg)	RCR_{soil} (PEC:PNEC)	
	Min	Max		Min	Max	Min	Max		Min	Max	Min	Max		Min	Max
BP3	0.019	0.186	3.10	0.006	0.060	0.23	2.24	37.27	0.006	0.060	0.1	1.1	19.48	0.006	0.057
BHT	0.013	0.131	0.70	0.019	0.187	12.69	125.66	671.06	0.019	0.187	0.9	9.1	370.18	0.002	0.025
DEP	0.019	0.193	7.40	0.0026	0.026	0.75	7.38	283.45	0.003	0.026	0.1	0.5	153.86	0.000	0.003
OMC	0.004	0.036	0.44	0.008	0.081	34.42	340.76	4215.01	0.080	0.810	0.3	2.8	2326.5	0.000	0.010
BP	0.003	0.034	12.00	0.0003	0.003	0.16	1.56	557.22	0.000	0.003	0.05	0.5	303.36	0.000	0.002
D5	0.078	0.777	1.20	0.065	0.647	41.00	405.91	627.03	0.065	0.647	11.4	112.7	345.70	0.033	0.326
Triclosan	0.011	0.106	0.05	0.202	2.002	11.06	109.54	54.72	0.202	2.002	0.6	5.8	30.18	0.020	0.193
Nano TiO_2	1.651	16.343	10.00	0.165	1.634	570.09	5643.92	1585	0.360	3.561	151.3	1497.6	317	0.477	4.724
Nano ZnO	0.605	5.991	1.70	0.356	3.524	659.85	6532.54	852.04	0.774	7.667	64.0	633.4	170.41	0.375	3.717

RCRs could not be calculated for landfill sites because it was impossible to estimate a PEC: PNEC ratio for CECs reaching landfills. However, the concentrations of the chemicals with the potential to reach landfill sites directly from MSW disposal as well as from sewage sludge were estimated (Table 6-6). Nano-TiO_2 and nano-ZnO had the highest concentrations, 451.42mg/kg and 215.47mg/kg respectively, based on the maximum amount of CECs disposed to household waste, whilst BP3 and DEP had the lowest concentrations. These findings also illustrate that even when the minimum concentrations of nanomaterials are disposed of in household waste, their concentrations exceed the maximum concentrations of the other chemicals with the potential to reach landfills.

Table 6-6: Predicted concentrations of CECs reaching landfills

Emerging chemical of concern	Concentration of CEC in sludge to LF (mg/kg)		Concentration of CEC in MSW to LF (mg/kg)		Total concentration of CEC at LF (mg/kg)	
	min	max	min	max	min	max
BP3	0.024	0.241	0.027	2.463	0.052	2.705
BHT	0.202	1.996	0.020	1.769	0.221	3.765
DEP	0.013	0.125	0.031	2.795	0.044	2.920
OMC	0.061	0.599	0.066	5.984	0.127	6.583
BP	0.011	0.109	0.114	10.265	0.125	10.374

D5	2.415	23.907	0.679	61.130	3.094	85.037
Nano TiO_2	32.086	317.647	1.486	133.774	33.572	451.422
Triclosan	0.125	1.237	0.026	2.302	0.151	3.539
Nano ZnO	13.527	133.917	0.906	81.548	14.433	215.465

6.4 Assessing environmental risks from the disposal of CECs in cosmetics

The modelling environmental concentrations for chemicals is subject to many factors such as the reliability and availability of information used in the model as well as the assumptions used in the model, including the spatial and temporal distribution of chemicals. In the case of CECs, the unavailability of data on physicochemical properties and, costly and time consuming toxicity testing has supported the use of PECs as a screening tool for environmental impacts. The PEC values estimated for this study used algorithms from the EUSES model under REACH guidelines taking into consideration specific data on per capita use of chemicals and average daily wastewater flow in the UK, physicochemical data (Koc and Kd), dilution and in-river dissipation, and the fraction of release of the selected CECs from wastewater and sewage sludge to minimises uncertainties in the study.

Several studies have reported concentrations similar to the PECs estimated for this study. The PECs for D5 was modelled for 2 rivers in the UK by Price et. al.(2009). The study estimated a maximum D5 level of 0.71µg/l, similar to the maximum PEC value (0.58 µg/l) obtained by Brooke et. al. (2009) using the EUSES model. These values are similar to the PEC for this study (0.78µg/l). Another study in the UK using the Geography-Referenced Regional Exposure Assessment Tool for European Rivers (GREAT-ER, 2001) generated an average PEC for OMC at 0.057µg/l (Sabaliunas et al., 2000). This was of the same order of magnitude (0.036µg/l) as in our study. A study carried out by Capdevielle et. al. (2007) using GREAT-ER model simulations (based on the levels of triclosan in use) suggested that the maximum (90th percentile) triclosan concentration was approximately 0.18µg/l for the Aire–Calder catchment in the UK, again similar to the results estimated in this study (0.12µg/l). In Denmark, a "realistic worst-case" study for sewage sludge application to agricultural soil modelled the PEC values for triclosan to be between 0.04µg/kg to 5.6µg/kg, again, similar to this study. Mueller and Nowack (2008) modelled nano-TiO_2 in surface water (16µg/l), and produced similar PEC values to this study (16.34µg/l).

Few studies have assessed the measured environmental concentrations (MECs) of the CECs considered in this study, especially nanomaterials. Research carried out in Norway by Langford and Thomas (2008) on surface waters receiving wastewater effluent showed that the MECs for BP3 ranged from less than the detection limit to a maximum of 0.44µg/l, the results of this study falling within the range (0.0194µg/l - 0.2µg/l). Another study conducted in Germany by Fries and Puttmann (2002) found the measured concentration of BHT in surface water to be between 0.007µg/l and 0.791µg/l. This study estimated the PEC for BHT to be between 0.013µg/l and 0.131µg/l. The higher levels of

BP3 and BHT in modelled data compared to the measured data may be due to overall levels of these CECs in surface water and not specifically from PCPs, since these chemicals are commonly found in food and pharmaceuticals (Fries and Puttmann, 2002, Fent et al., 2010, Langford and Thomas, 2008).

RCRs for CECs such as nano ZnO, nano TiO_2 and triclosan were greater than 1 for the study, identifying household disposal of cosmetics via wastewater treatment as a pathway for environmental contamination, which may affect both aquatic and terrestrial organisms. This may be due to the limited ability of wastewater treatment plant to degrade triclosan to inert substances during wastewater treatment and the non-degradability of the nanoparticles (nano TiO_2 and ZnO are not organic and will not degrade) (Franklin et al., 2007). Nanoparticles are also agglomerating which can affect their hazardous properties in the environment (Bottero et al., 2006).

All other CECs assessed had RCRs of less than 1 which indicates that although PCPs may contain CECs, not all of the chemicals may pose environmental concerns. This may be because some CECs (for example BHT) are not used in sufficient quantities, wastewater treatment is effective in the degradation of the contaminants (BP and BP3) and/or the concentrations of the contaminant required to have a toxic effect is greatly exceeded by the concentration of the contaminant in the environment (DEP) and, data reliability and paucity. For example, PNECs are deficient for OMC (where there is only one ecotoxicity value derived from a QSAR, shown for green algae).

The EPM used for estimating PNECs for soil and sediment is only an estimated value based on the PNEC values derived from the aquatic environment and lack of effects data for the soil and sediment matrices made it difficult to spot-check the validity of the EPM used. The EPM can result in either an overestimation or underestimation of toxicity to

organisms (European Chemicals Agency, 2008a) and lack of research in this area leaves doubt as to whether environmental concern exists for the use and disposal of these chemicals. This method was only used as a screen for assessing the levels of CECs to sediment and soil dwelling organisms that require further testing, in the absence of ecotoxicological information. The integrated testing strategy in Section R.7.11.6.3 of REACH, states if the RCR for a CEC is greater than 1, using the EPM, tests on sediment and soil organisms should be considered essential for a refined effects assessment, highlighting the need for further studies to predict with greater certainty a substance's potential long-term environmental concerns.

The predicted concentrations of CECs reaching MSW landfills were of a higher magnitude (mg/kg) than the PECs (µg/l) for the CECs in surface water, sediment and soil. This can be attributed to the lack of solid waste management technologies for these contaminants in MSW disposal. Cosmetics are not specifically mentioned in the European Waste List (EWL, 2005) as separately collected fractions, hence this waste stream is excluded from hazardous waste controls. Consequently products containing CECs, some of which could be potentially hazardous are classified as non-hazardous when collected with the rest of household waste and sent to non-hazardous disposal facilities. Lack of legal requirement for householders to separate waste can contribute to household waste containing CECs to be co-disposed to MSW, possibly causing environmental concerns (Slack et al., 2005).There are currently no reuse or recycling schemes for these products in the UK and CECs in these products have the potential to reach landfills via direct disposal of PCPs to municipal waste.

The CECs can also reach landfills from sewage sludge disposal. In the UK the quantity of sludge going to landfills is declining (Department for Environment Food And Rural

Affairs, 2006.) implying that there may be temporal reductions and/or variation in CECs reaching landfill sites via this route. Instead, the sewage sludge is being diverted for use as biosolids in farmlands (Department for Environment, Food And Rural Affairs, 2006.) which means that the CECs will now be used in land spreading with increased potential for exposure to soil organisms and plants via uptake. It was impossible to compare and hence validate the concentrations of CECs at landfill sites estimated for this study with findings from other studies as this work is the first attempt to quantify these concentrations at landfill sites. In order to determine the environmental concerns associated with the release of these chemicals, further assessments need to be carried out on landfill leachate and groundwater. However, it can be assumed that within a landfill environment, most of the CECs are likely to be slowly released from products as they degrade. Based on adsorption properties and water solubility they are not likely to be mobile, hence the CECs are likely to partition to the organic phase in landfills.

6.5 Conclusion

PECs and RCRs of selected chemicals using REACH technical guidance were estimated to illustrate how this guidance can be an effective screening tool for environmental impacts. PECs for triclosan, nano-zinc oxide and nano-titanium dioxide were estimated as occurring at levels capable of causing environmental harm to both terrestrial and aquatic organisms as indicated by RCRs greater than 1. Household disposal of cosmetics therefore represents a potential pathway for the release of CECs to the environment, hence the need for further evaluation for the effective management of these contaminants. All other chemicals investigated had RCRs of less than 1, suggesting that these CECs pose no immediate concerns to the environment. The study also estimated the quantities of these chemicals reaching landfill sites but further work is required to assess their

environmental concerns and effects, although it is expected that these CECs will be released only slowly, if at all, from landfills.

7 A PRECAUTIONARY APPROACH FOR MANAGING ENVIRONMENTAL RISKS: CHEMICALS OF EMERGING CONCERN IN COSMETICS

Based on the environmental source-pathway-effects linkages identified for CECs in cosmetics, a multi-criteria analysis approach was used to compare and rank the alternative risk management options for the use and disposal of CECs in cosmetic products. Two nanomaterials were identified as the main emerging chemicals with the potential to cause harm to the environment. Management options were assessed over three main criteria: environmental effects, economic importance and stakeholder preference to determine the need for management of these chemicals and the best option. Uncertainty and sensitivity analysis were conducted to determine the effects that the weights and scores used in the MCA had on the overall ordering of the management options.

7.1 The need for environmental risk reduction

In recent years, there has been a shift from reactive measures to protect the environment such as heavy reliance on the regulation of emissions from processes and facilities, to more proactive approaches aimed at preventing or minimising (rather than remediating) environmental damage and loss (Lee, 2010). This change in emphasis has been reflected in the use of risk assessment tools for making decisions about environmental management, particularly in the context of sustainable development (Evironment Agency and Instituite for Environment and Health, 2000).

Understanding the environmental risks associated with the CECs involves addressing the concerns associated with source – pathway – receptor linkages and selecting strategic alternatives and mitigation measures to alleviate the concerns. Survey data collected for this thesis showed that cosmetic products contain a plethora of chemicals many of which are still in the emerging phase. The household disposal of these products represents a pathway for CECs used in cosmetic formulations to reach the environment. Risk characterisation ratios for selected CECs indicated that two particular nanoparticles, nano zinc oxide and nano titanium dioxide (NMOs) can pose potential risks to the environment from the use and disposal of cosmetics (Chapter 6). Although more research is required to confirm these risks, there is still need to apply precaution and understand how these CECs can be managed if need be.

Nanotechnology has been featured in cosmetic formulations for many years, having two principal functions, as "encapsulation or carrier systems" to transport agents to deeper skin layers, and as optimal ultra violet (UV) protective filters in sunscreen agents (Greßler et al., 2010). NMOs are the most widely used sunscreen ingredients in cosmetic formulations, acting as physical blockers, reflecting or scattering UV rays rather than

absorbing them as compared to traditional UVA/UVB chemical absorbers. The use of NMOs in cosmetics allows low opacity increasing aesthetic appeal, makes them less greasy and increases skin absorptivity leaving a smoother feel (Greßler et al., 2010). While the main market for these sunscreen ingredients is sun protection products, the trend for everyday protection of the skin from aging has encouraged the use of NMOs in a range of skin care products (facial moisturisers, anti-ageing products, and general purpose body care), hair care products and facial make up (Faunce, 2008).

The uncertainties associated with the usage of NMOs in cosmetics highlights major challenges for the evaluation of the need for management of cosmetic products containing NMOs (Lee, 2010). The benefits gained from these products versus their environmental cost cannot be accurately determined due to lack of sufficient and reputable data as well as inadequacy of research methodologies or tools to assess the balance between the environmental and societal benefits and concerns associated with nanomaterials (Linkov et al., 2007).The International Risk Governance Council (IRGC) has therefore proposed a framework for global risk governance of nanotechnology (Renn and Roco, 2006) and made several recommendations on models for governance of this new technology. The findings propose a risk assessment and risk management framework utilizing multi-criteria analysis (MCA) and adaptive management for nanomaterials regulation. Additionally, guidance on the EU Registration, Evaluation and Authorization of Chemicals (REACH) legislation also recommends the use of socio economic analysis (SEA) using the multi-criteria framework to intergrate environmental, health, economic and social impacts as part of a decision making process for the restriction of manufacturing, placing on the market and/or use of a stubstance of concern.

These integrated approaches to reducing potential risks have the common goal of achieving sustainable development, that is, ensuring a better quality of life for everyone now and for generations to come, ensuring that the needs of the present should not compromise the ability of future generations to meet their own needs (Jardine et al., 2003, Guelere et al., 2007). The accomplishment of sustainable development requires collective partnership approaches to decision-making for environmental protection including integrating economic demands and social needs with the capacity of the environment to cope with discharges, pollution and other perturbations, and to support human and other life.

This chapter aims to demonstrate how MCA can be used as a tool to help manage potential environmental risks of NMOs, by comparing alternative risk management options (RMOs). This is done by assessing the net benefits to the environment and the net costs to importers, distributers, consumers and society as a whole. By using elements of MCA with comparative environmental and economic assessment results, a systematic and transparent framework is created to integrate different types and sources of decision-relevant information to describe and analyse all relevant potential effects (both positive and negative) of the important NMOs use in cosmetics (Kim et al., 2010).

7.2 Comparing RMOs using a MCA methodology

Given the uncertainty in all aspects related to nanomaterials, the structured, transparent, and justifiable tools offered by MCA for quantifying both scientific, economic and decision makers' values, as well as for developing a system of performance metrics consistent with regulatory requirements, can be especially valuable for this emerging field (Linkov et al., 2009). MCA is often used as a tool to identify the best from a range of alternatives in an environment of conflicting and competing criteria (Santos et al., 2002).

It is both an approach and a set of techniques, with the goal of providing an overall order of options, from the most preferred to the least preferred option. It is a way of looking at a complex problem that is characterised by any mixture of objectives, breaking the problems into more manageable pieces to allow data and judgements to be brought to bear on the pieces, and then reassembling the pieces to present a coherent picture to the decision-maker (Department of Communities and Local Government, 2009).

Although MCA tools may not be able to resolve contradictions in current risk estimates, application of MCA can help bring further enlightenment by making trade-offs explicit. The development and implementation of such a framework will make clear what information should be collected to support decisions. MCA tools, coupled with value of information analysis and adaptive management, can also provide a good foundation for both bringing together multiple information sources to assess risks associated with nanomaterials and also for developing justifiable and transparent regulatory decisions (Linkov et al., 2007). This research used the DEFINITE 3.0 software for conducting the MCA, using the Analytic Hierarchy Process (AHP) methodology (Saaty, 1994) also known as pair wise comparisons. This approaches decision making by arranging the important components of a problem into a hierarchical structure similar to a family tree (Mendoza et al., 1999). An overview of the MCA approach is illustrated in Figure 7-1

Four alternatives were chosen to represent different risk management options (RMOs) as possible management options for the use of NMOs in cosmetics. They included:

Option 1 – Do Nothing Option or baseline scenario: Continue the manufacturing, marketing and use of these NMOs in cosmetic products in the UK. Product formulation is unchanged and there is no change in legislation regulating these nano based cosmetics (REACH is currently being implemented). Manufacturing and production will meet the

required demand and competition within and outside the EU will be the same. There will be an increased amount of NMOs reaching the environment due to increased use and disposal of products as population increases.

Option 2 – Substitution: Substitute naturally occurring ingredients with the NMOs used in cosmetics. These will replace NMOs in cosmetics with no loss in functionality and/or durability of the products. There is growth in demand for natural ingredients as consumers are becoming more aware of what they are putting on their skin. These alternatives are expected to greatly reduce environmental impacts due to their ability to be broken down in the environment and their limited toxicity. The use of natural alternatives is expected to greatly increase the cost of research and development for the use of active natural ingredients to replace the synthetic ones, allowing for high premium if efficacy is perceived to be good and increased market price for products. There is no need for these products to be regulated as they do not meet the requirements under REACH and the Cosmetic Directive and manufacturing and marketing will fluctuate dependent of the source of these natural ingredients.

Option 3-Temporary Restriction: Temporarily restrict the use of these NMOs in cosmetic products for a maximum of 5 years. The manufacture of NMOs for use in cosmetics products will be halted and the current products on the market will be phased out. This will allow scientific evidence to become available through innovation and research to adequately assess the environmental concerns associated with the use of these chemicals in products together with the availability of compulsory product labelling to increase consumer awareness of these chemicals in cosmetics, applying the precautionary principle. REACH will be fully implemented and all required chemical safety studies carried out for the use of these NMOs in cosmetics. Temporary restriction of the use of

these NMOs in cosmetic products means that the quantity of NMOs reaching the environment will decrease over time. However, cosmetics containing NMOs will be temporarily unavailable and consumers will have to find alternatives. This will influence the market price of these alternative products as well as increase market competition within and outside the UK.

Option 4 – Total Restriction: Prohibit the manufacture, marketing and use of these NMOs in cosmetic products at a community-wide level with phase out of the substance within 24 months. There is no current restriction on the manufacturers of these NMOs in the UK. No behavioural change is expected by manufacturers of these NMOs since no restrictions are being proposed on manufacturing these chemicals although a proportion of the market may disappear (dependent on percentage used in cosmetics in the UK, currently high at 13% and expected to increase) (Department for Business Innovation and Skills, 2010).

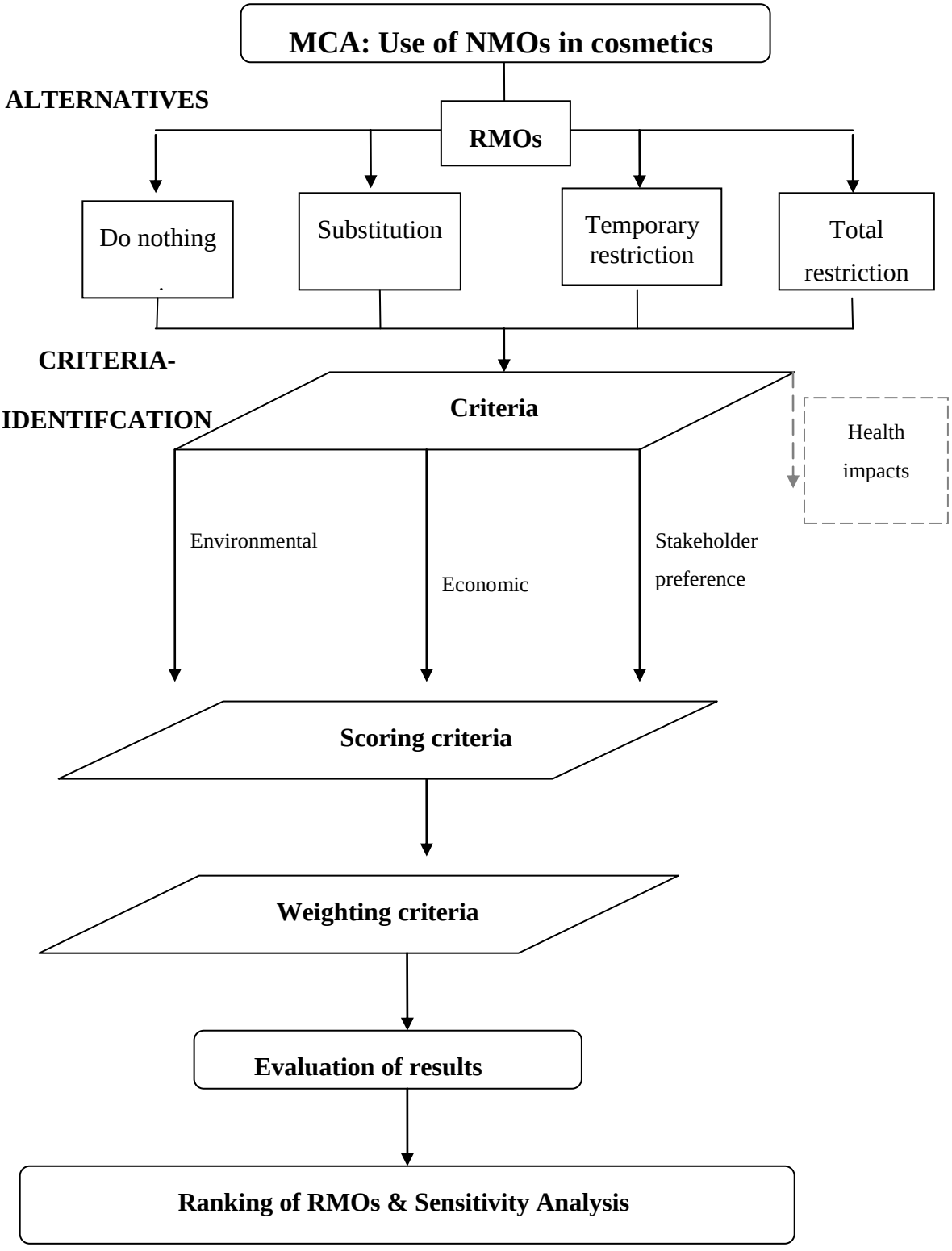


Figure 7-1: MCA approach to evaluate the management options to reduce risk of NMOs in cosmetics

The performance of each management option was systematically measured against different criteria, using established techniques to estimate quantitative and monetary values or qualitative data where effects could not be quantified on a scale. The 3 major criteria were evaluated using the following methodology.

- Environmental effects: predicted environmental concentrations were used to estimate water, sediment and soil quality impairment and risk characterisation ratios were used to determine ecological harm (Chapter 6 and Appendix D);
- Economic importance: a comparative methodology for estimating the economic value of nano innovations in cosmetics prepared for and used by DEFRA (2010), (Walsh et al., 2010) and Porter's 5 Force Analysis for assessing market competition (Appendix D);
- Stakeholder preference: public preference was considered using existing survey results on public perception on nanoparticles in cosmetics and political preference was scored based on ease of implementation of each RMO (Appendix D).

The full definitions of the criteria and the basis for measuring their performances are outlined in Table 7-1. Impacts on employment (social impacts) were not considered as a separate criterion for this work as this was discussed under the other criteria where possible. The use of these NMOs in cosmetic formulation is not expected to change the manufacturing/production processes hence no major change in employment is expected. Human health impacts were not considered as a criterion for this study as this thesis focused on environmental effects of use and disposal of cosmetics and management measures to mitigate this impact. In addition, reliable data on human health impacts from the use of NMOs in cosmetics are sparse. The few studies that were carried out were not

conclusive due to the novelty of this field and the insufficient timeframe for health assessments (Richter and Bastian, 2008, Hu and Gao, 2010, Schmid and Riediker, 2008)

Weightings were assigned to each criterion using the AHP method or pair wise comparison, to determine the differing levels of importance of each criterion to each alternative (Appendix D). This is reflected in the pair wise comparisons made between the different criteria for the weighting process. The RMOs were then ranked and represented graphically. An uncertainty analysis was conducted to estimate the probability that each alternative can occupy a certain ranking in response to variation in either weightings or criteria scores. A larger circle in each row meant a higher probability that an alternative can receive a certain ranking from the MCA. To illustrate this procedure a percentage of 25% was applied for each criterion under environmental effects and a percentage of 50% for each criterion under economic importance and stakeholder preference. A sensitivity analysis was conducted to illustrate how the weighting and scores affected the overall ordering of the alternatives by examining the extent to which vagueness about the inputs or disagreements between people made differences to the final decision of which RMO was the best alternative.

Table 7-1: Criteria and associated sub-criteria for evaluating risk management options of NMOs in cosmetics in the UK

Criterion	Sub-criterion	Description	Scale of measurement
Environmental effects	Water quality	Changes in concerns over surface water quality in freshwater aquatic environments	Interval scale: Higher PEC→ increased NMO concentrations to environment
	Soil quality	Changes in concerns over soil quality in terrestrial environments	
	Sediment	Changes in concerns over sediment quality in	

	quality impairment	freshwater aquatic environments	
	Ecological impairment	Changes in concerns over aquatic and terrestrial flora and fauna	Interval scale: Higher RCR → greater deviation from environmental limit
Economic importance	MVA	Market value added to the economy from the final benefits accrued from producer and consumer surplus	Monetary value
	Market competition	The potential for profitability of the cosmetic industry due to market competition	--/++ scale
Stakeholder preference	Public preferences	% of population in the UK willing to support each RMO based on product use	Ratio scale % population : product use
	Political preferences	The flexibility and ease of implementing each RMO based on conformity to legislation and policy	Ordinal scale - 1-5, 1being the easiest to conform and 5 the most difficult

PEC- Predicted Environmental Concentrations and RCR – Risk Characterisation Ratio based on REACH guidelines. PNEC-Predicted No Effect Concentrations

7.3 Multi-criteria analysis results

Sub-criterion scores for each management options used in the MCA are summarised in Table 7-2. Detailed calculations and explanations for the scores given to each sub-criterion for each alternative are detailed in Appendix D.

Table 7-2: Performance matrix for the RMOs

Criterion	Sub-criterion	Unit of measure	Scenario 1 Do nothing	Scenario 2 Substitution	Scenario 3 Temporary restriction	Scenario 4 Total restriction
Environmental effects	**Water quality impairment**	**PEC (µg/l)**	**11.17**	**6.75**	**12.1**	**11.4**
	Sediment quality	**PEC**	**6088.23**	**3678.31**	**6595.58**	**6215.07**

	impairment	**(µg/l)**				
	Soil quality impairment	**PEC (µg/l)**	**1065.5**	**643.74**	**1154.29**	**1087.7**
	Ecological impairment	**RCR**	**4.14**	**2.5**	**4.48**	**4.22**
Economic importance	**MVA**	**£mn**	**0.74**	**0.21**	**76.36**	**3.42**
	Market competition	**'--' to '++'**	**++**	**--**	**+**	**-**
Stakeholder preference	**Public preference**	**%**	**61**	**33**	**24**	**5**
	Political preference		**1**	**3**	**2**	**4**

The results from the MCA identified *temporary restriction* as the best RMO for reducing the risks associated with the use and disposal of these NMOs in cosmetic products as illustrated in Figure 7-2 (bar graph showing total weights). This alternative had the best score (0.77) as compared to *total restriction* (0.29), *do nothing* (0.22) and *substitution* (0.06). Figure 7-2 further demonstrates the perspective charts for this analysis, emphasising particular interest in the decision making by altering weighting ratios in the MCA. For all perspective (environmental effects, economic importance and stakeholder preference), *temporary restriction* RMO was ranked as the best alternative. Do nothing option is almost always better than *substitution* except for the perspective: environmental effects and *total restriction* is always a better alternative than the *do nothing* option. Detailed analysis for the MCA can be found in Appendix E.

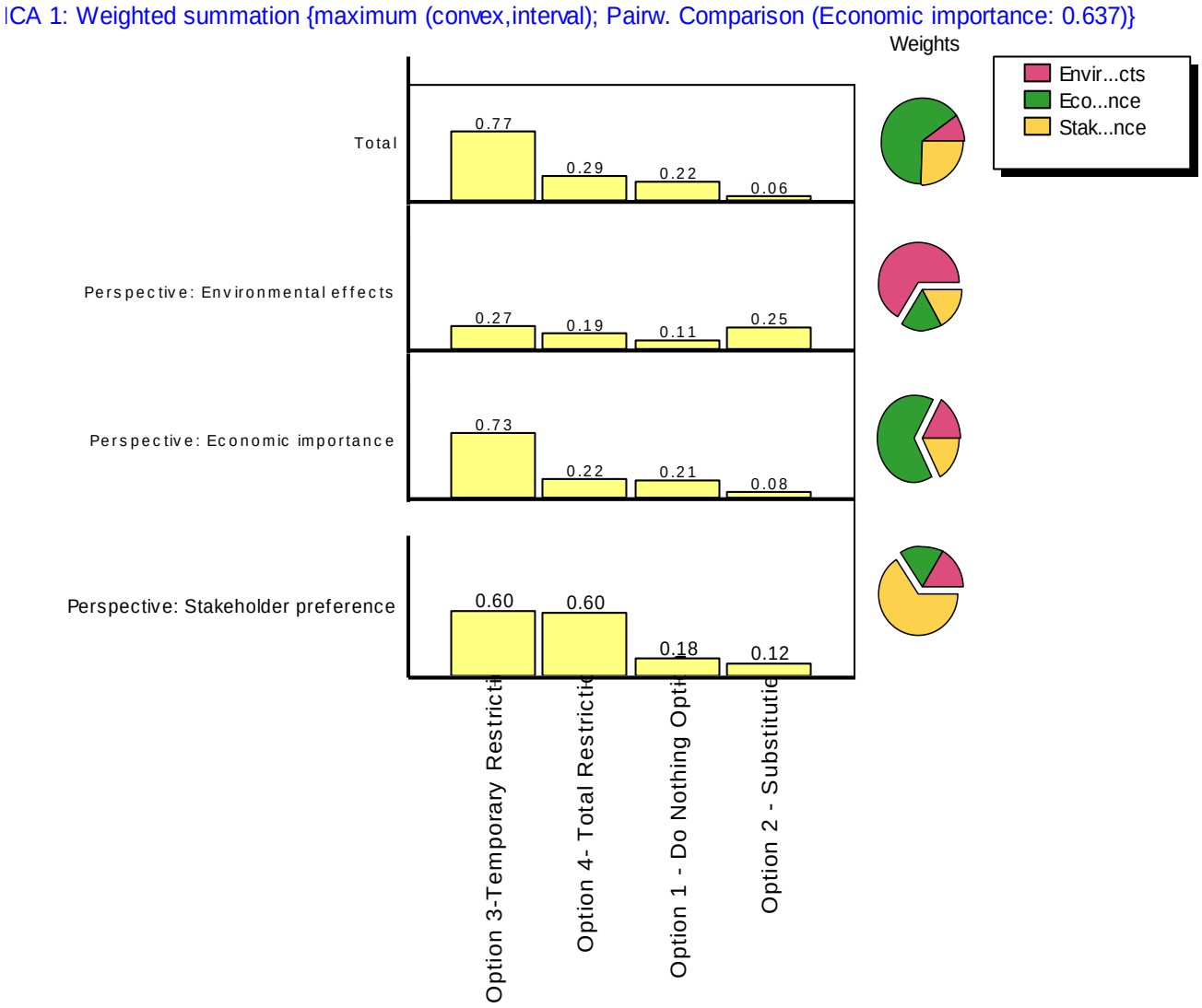


Figure 7-2: MCA results illustrating different weighting preferences

The reliability of a ranking depends on the certainty of the sub-criterion scores hence an uncertainty analysis was done to illustrate how uncertainties regarding the sub-criterion scores affect the ranking. Figure 7-3 shows the probability that an alternative is ranked first, second, third or fourth, given the uncertainties in the scores. *Temporary restriction* has the highest probability of being ranked first regardless of the level of uncertainty applied, whilst *total restriction* and *do nothing* options can be interchanged for the second

and third alternative. *Substitution* has the greatest probability of being ranked fourth. The large-sized circles on the main diagonal indicate that the ranking of the alternatives under 25% score uncertainty is relatively stable.

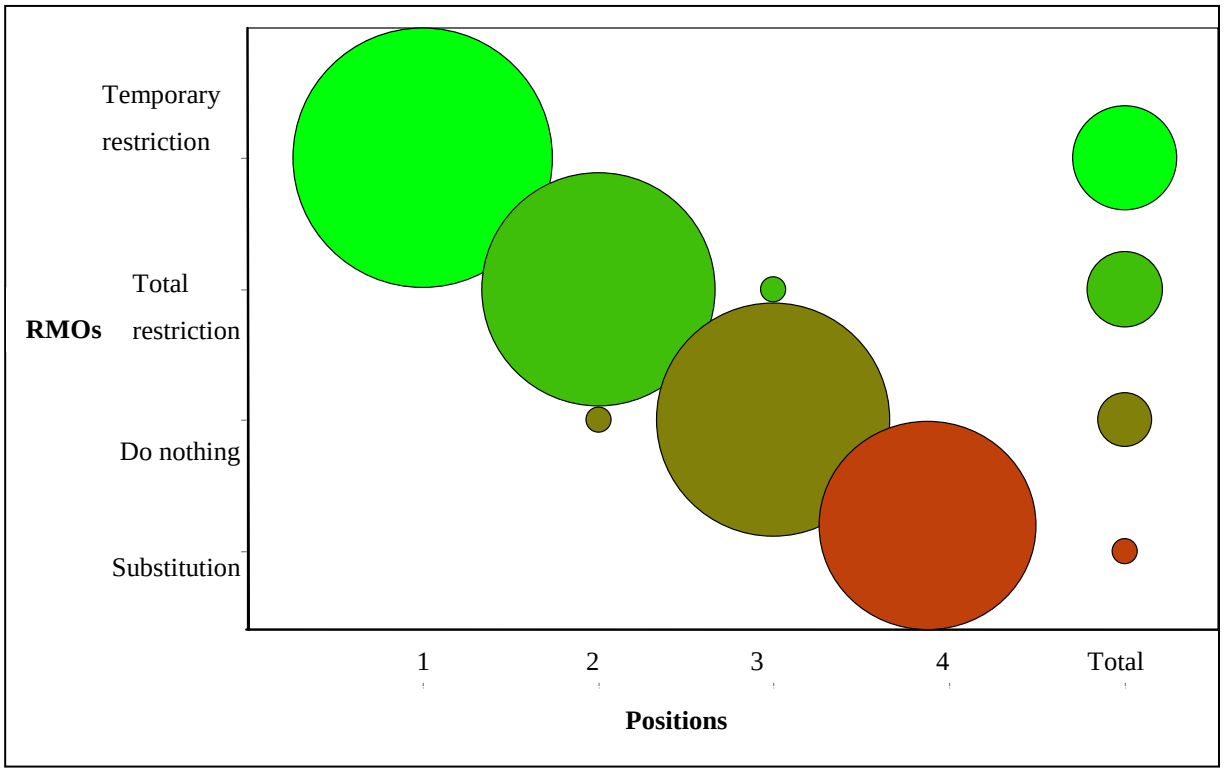


Figure 7-3: Probability of ranking of alternatives in different positions

Sensitivity analysis is an important part of the MCA process and is used to examine the behaviour of a model by measuring the variation in outputs resulting from changes to its inputs. The results from the sensitivity analysis to changes in weightings are illustrated in Figures 7-4 to 7-6. Figure 7-4 shows that only if the weighting for environmental effects is above 0.7 will *substitution* be a better RMO than *total restriction.* The other alternatives remain worse management options. The sensitivity analysis to changes in weightings for economic importance (Figure 7-5) illustrates that only when the weighting is very low (<0.2), would *total restriction* be the best option; otherwise *temporary restriction* is the primary option for management of the identified NMOs in cosmetics.

The result to changes in weightings for stakeholder preference (Figure 7-6) demonstrates that only at a high weight (almost 0.8) will *total restriction* be the best option.

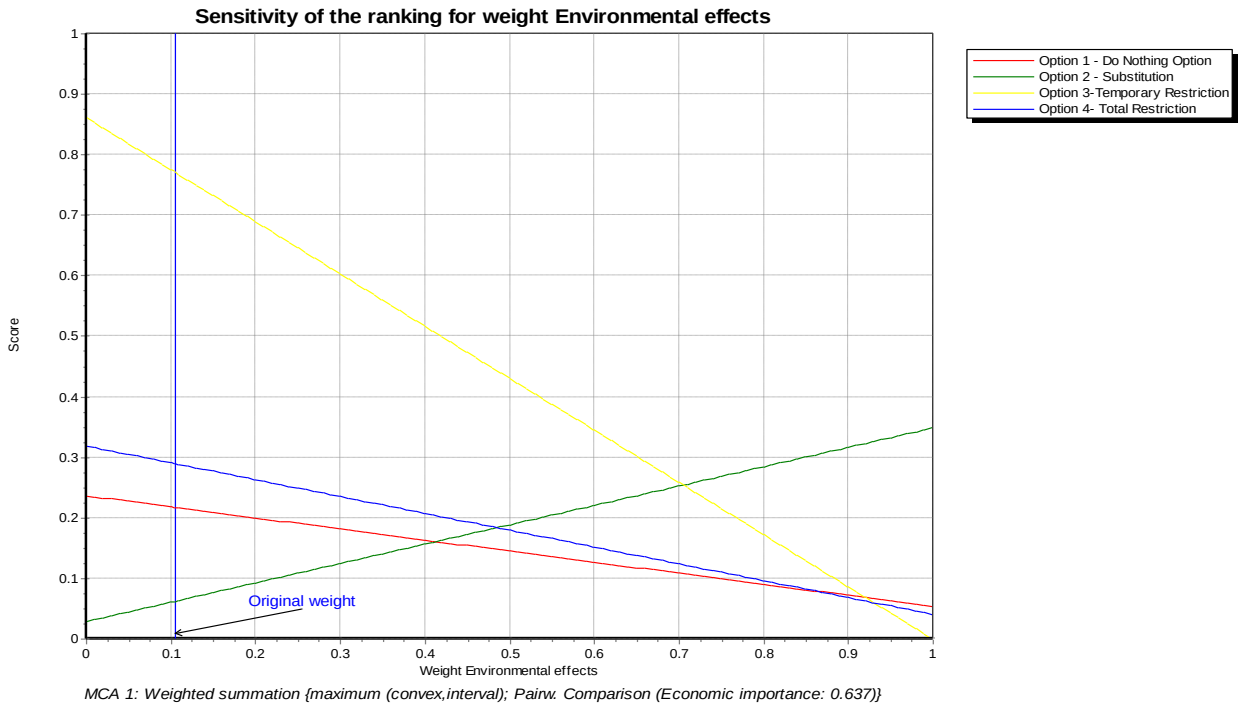
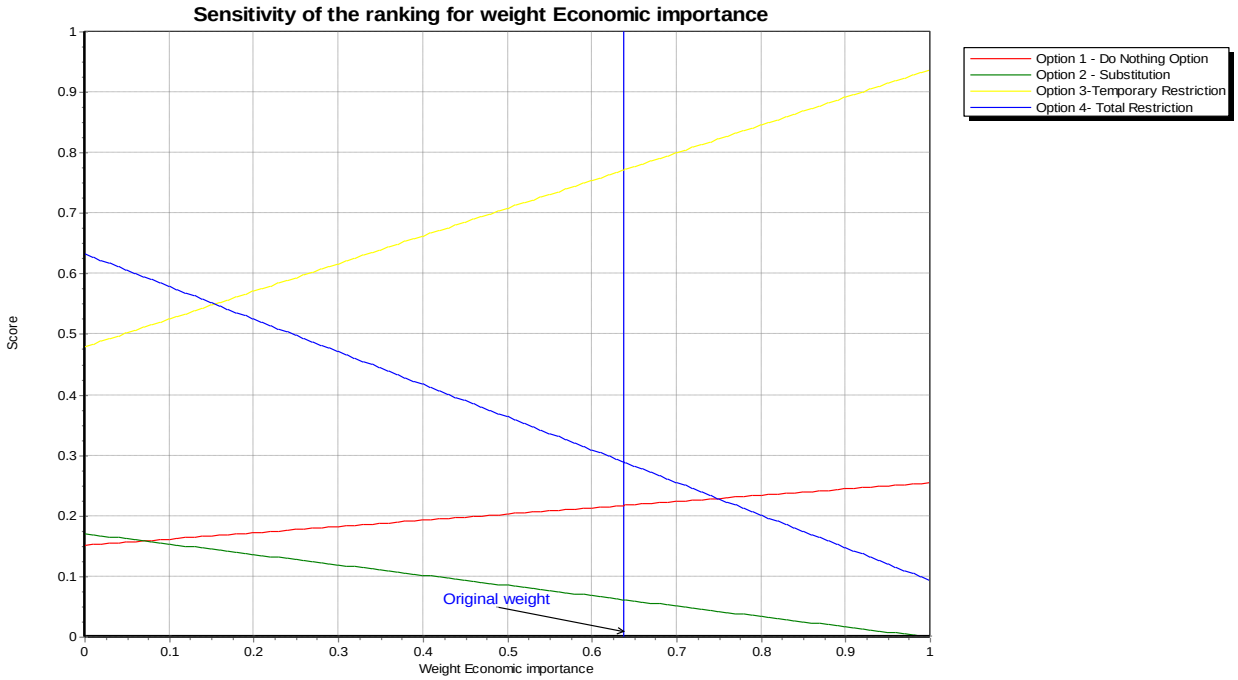
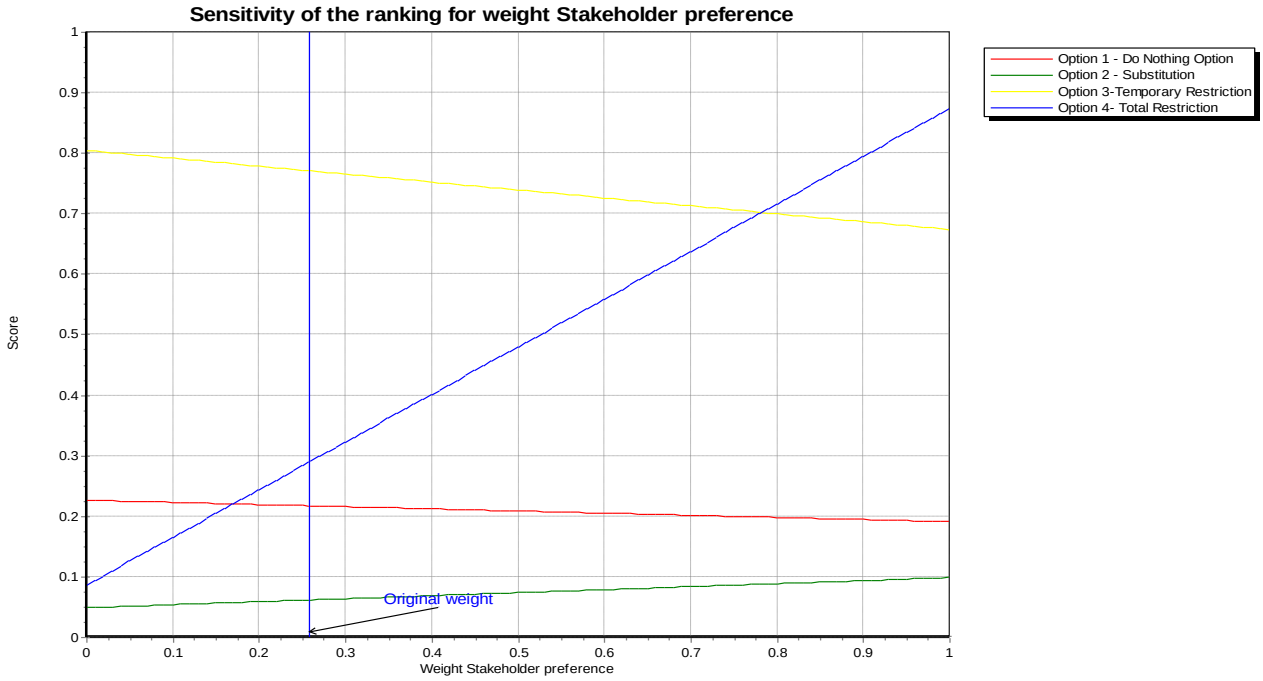


Figure 7-4: Sensitivity of the ranking for weight environmental effects



MCA 1: Weighted summation {maximum (convex,interval); Pairw. Comparison (Economic importance: 0.637)}

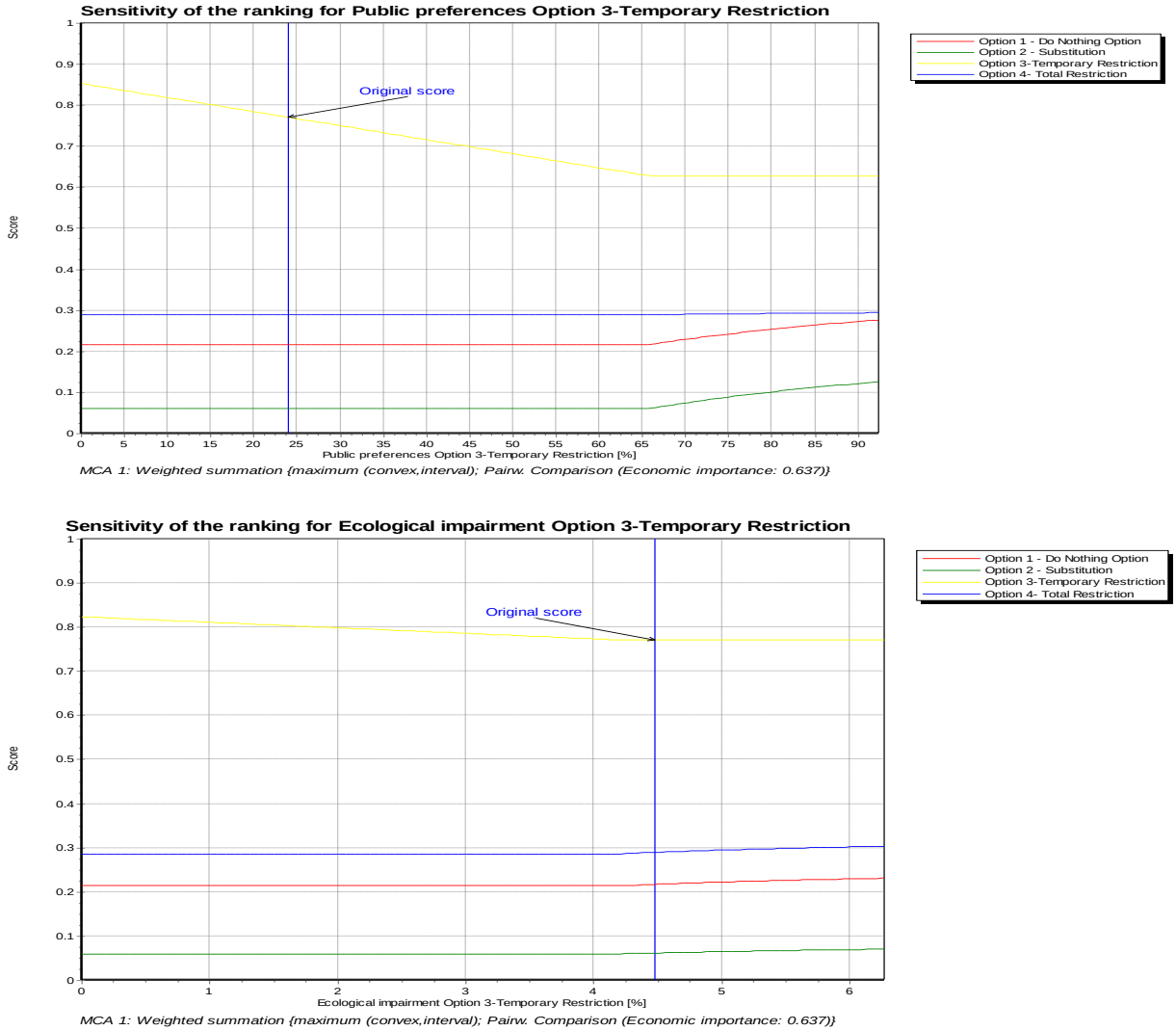
Figure 7-5: Sensitivity of the ranking for weight economic importance



MCA 1: Weighted summation {maximum (convex,interval); Pairw. Comparison (Economic importance: 0.637)}

Figure 7-6: Sensitivity of the ranking for weight stakeholder preference

Given that the sensitivity analysis to changes in weightings illustrated that *temporary restriction* was ranked as the best option for managing NMOs in cosmetics, the sensitivity of the ranking of management options to changes in sub-criterion scores was analysed (Figure 7-7). The graphs illustrate that regardless of the adjustment of weightings for the different criteria, *temporary restriction* (represented by the yellow line) was still ranked as the best option for reducing the risks associated with the use and disposal of NMOs in cosmetic products. *Total restriction* (blue line) was ranked as the second best alternative, with *do nothing* (red line) and *substitution* (green line) being ranked third and fourth respectively.



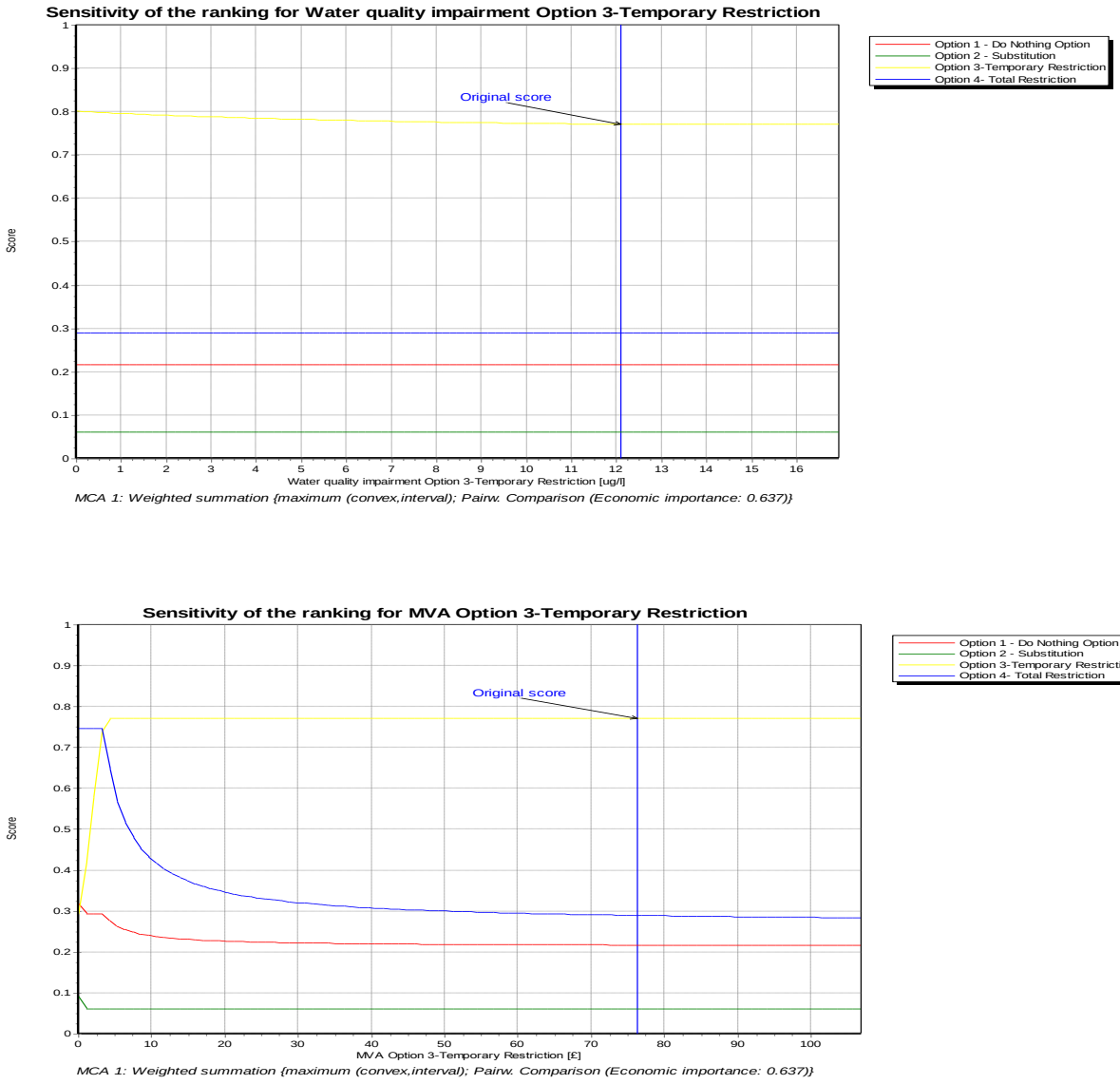


Figure 7-7: Sensitivity of the ranking for scores for temporary restriction

Sensitivity analyses to changes in scores of each sub-criterion for criteria environmental effects, economic importance and stakeholder preference were carried out and detailed in Appendix E. The results illustrated that *temporary restriction* was the best RMO under most circumstances. However, there were few deviations from this, as demonstrated in Figure 7-8 to Figure 7-13. For environmental effects perspective (Figure 7-8), *substitution* appeared to be the best option if the sub-criterion 'public preferences' was given a lower

score. Figure 7-9 to Figure 7-13 illustrate that the 'stakeholder preference' perspective had the most variability when the sub-criterion scores were weighted and in all cases indicated that the best alternative would be the *total restriction* of the use of NMOs in cosmetics. However, the graphs illustrate that *temporary restriction* RMO ranked second in all instances and the scores indicate that these 2 options can be interchangeable for the management of NMOs in cosmetics. The *do nothing* and *substitution* options were ranked as the worst RMOs for managing the use of NMOs in cosmetic products.

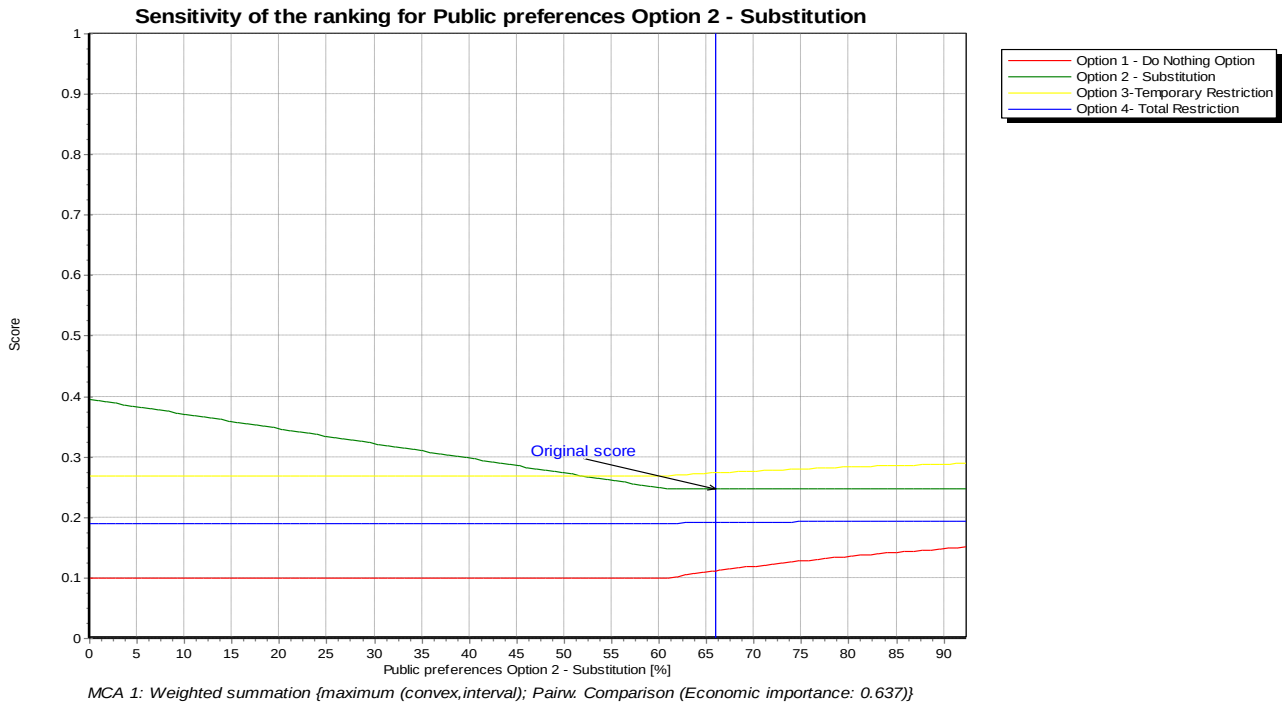


Figure 7-8: Sensitivity of the ranking for public preferences Option 2 – Substitution (perspective: environmental effects)

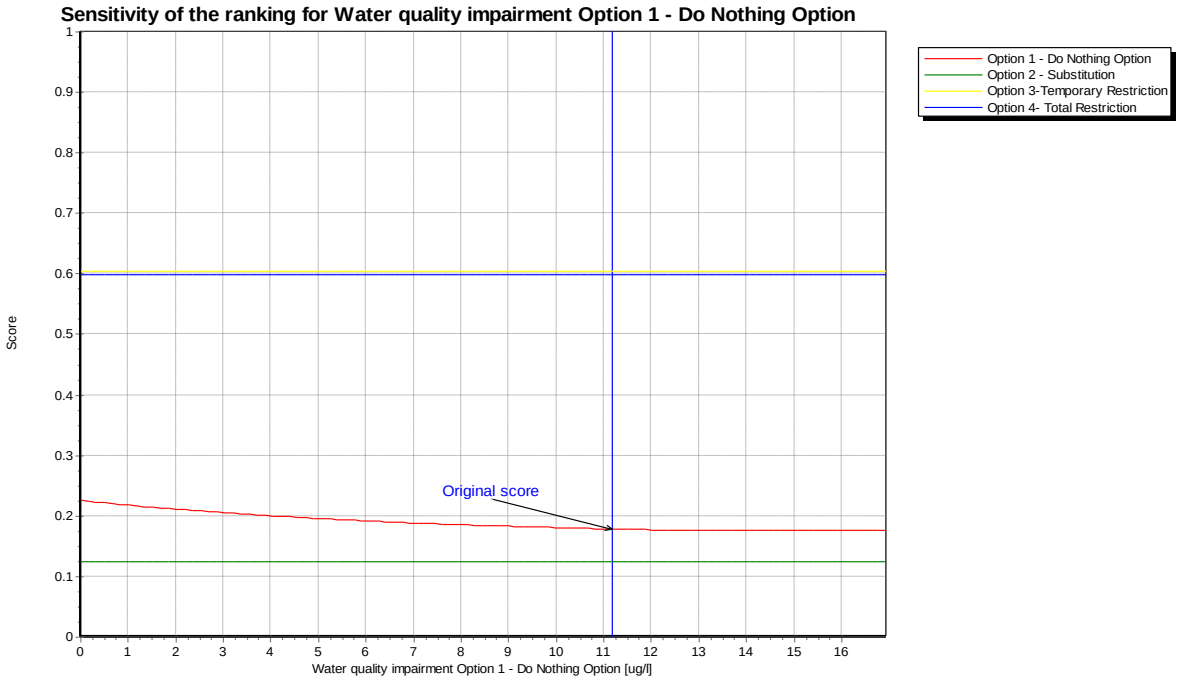


Figure 7-9: Sensitivity of the ranking for water quality impairment Option 1 – Do Nothing Option (perspective: stakeholder preference)

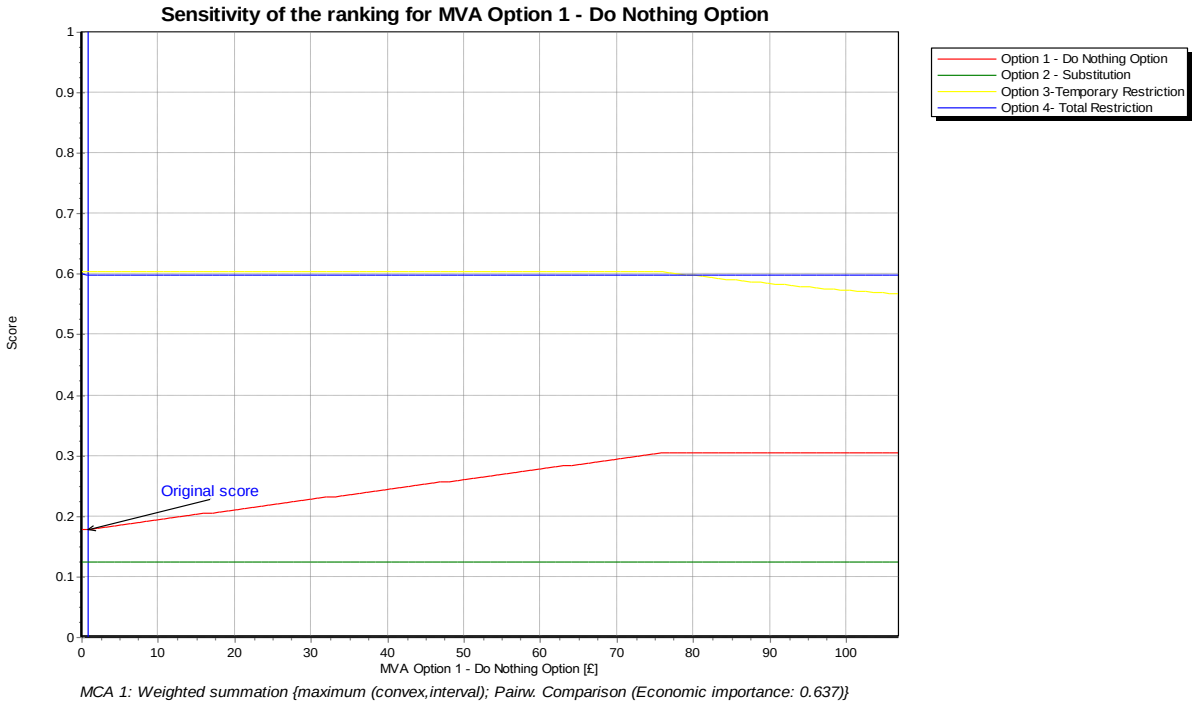


Figure 7-10: Sensitivity of the ranking for MCA Option 1 – Do Nothing Option: (perspective: stakeholder preference)

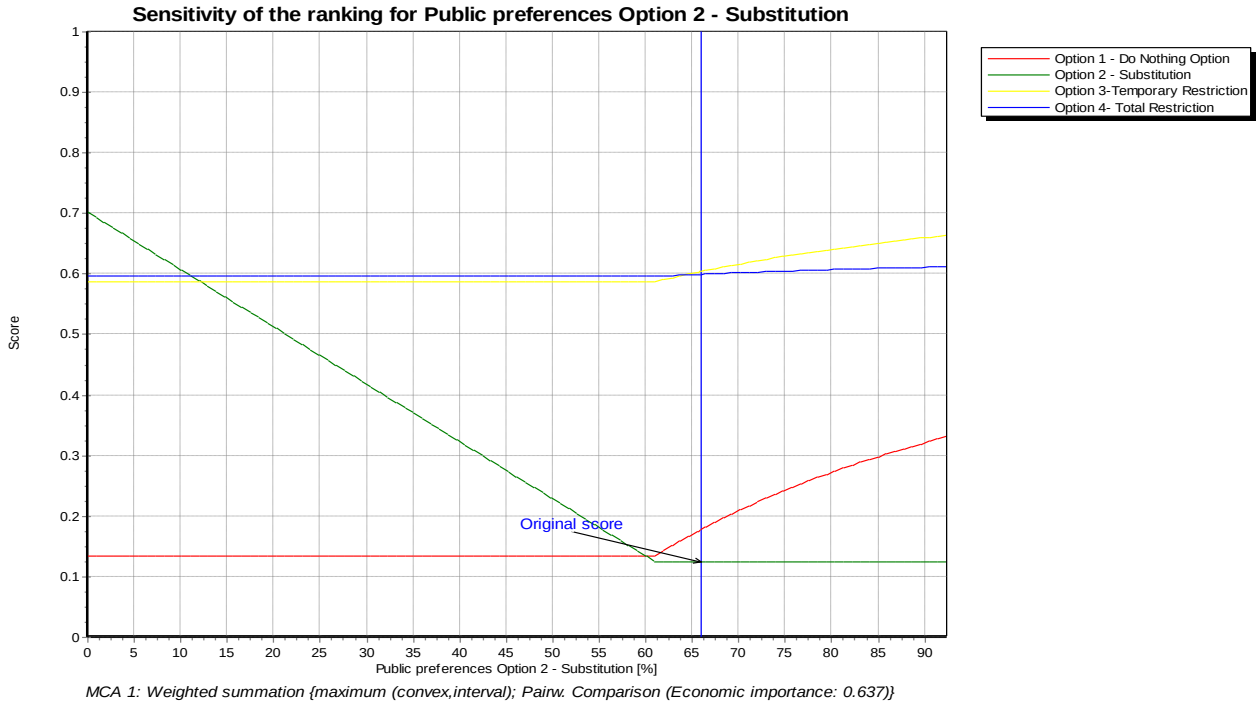


Figure 7-11: Sensitivity of the ranking for public preference Option 2 – Substitution (perspective: stakeholder preference)

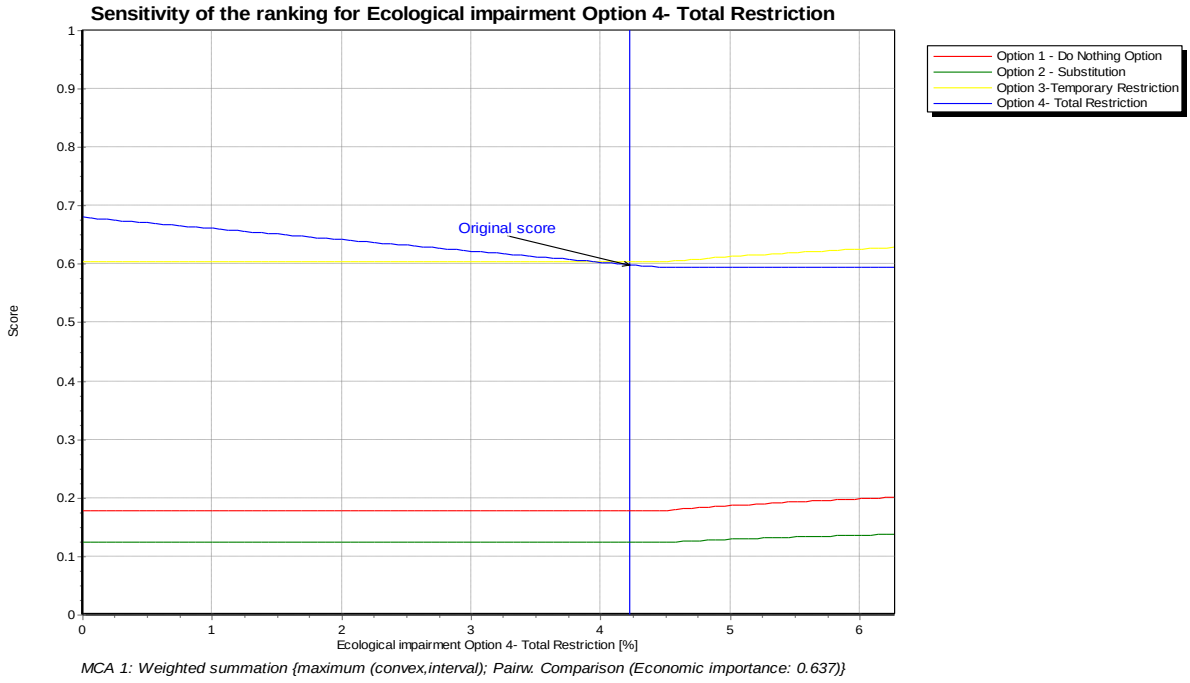


Figure 7-12: Sensitivity of the ranking for ecological impairment Option 4 – Total Restriction (perspective: stakeholder preference)

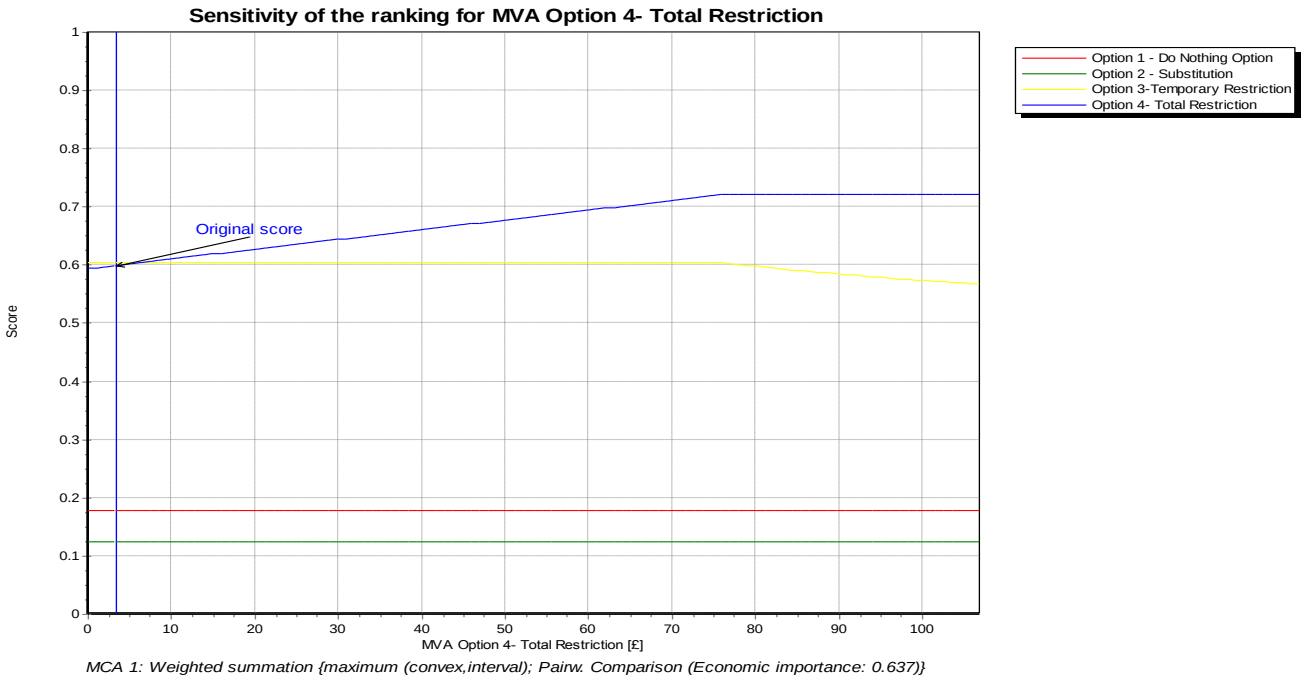


Figure 7-13: Sensitivity of the ranking for MCA Option 4 – Total Restriction: (perspective: stakeholder preference)

7.4 Should the disposal of cosmetic products be managed?

NMOs, as with any other CECs require specific frameworks for selecting appropriate management systems. The lack of precise information such as limited data on physicochemical properties, measured environmental concentrations and ecotoxicity to quantify risks has made the assessment and reduction of risks for these chemicals a major challenge. Even though the understanding and application of the risk management paradigm has been successful for many years, applying this to NMOs is problematic due to the large levels of uncertainty as compared to other chemicals. Additionally, tools used for uncertainty analysis such as probabilistic modelling and predictive structure-activity analysis may not be easily applied to these NMOs (Linkov et al., 2007).

The economic evaluation of products constitutes part of the MCA process and determines from a monetary standpoint, the net benefits versus costs to manufacturers, importers and users of cosmetics. Under REACH Regulation, economic evaluation is considered under the SEA assessment for restriction of the use of chemicals, assessing the economic impacts in supply chains and the broader economic impacts for society as a whole. Although the economic impacts of the proposed restriction are an important factor in addressing unacceptable risks, the SEA is not carried out for the sake of the analysis but rather to support and complement the decision making process for restriction of a substance under REACH.

The use of SEA for assessing the economic valuation of NMOs is hindered by inaccessible or unavailable data. Therefore, the methodology adopted by DEFRA (2010) (Appendix D) for assessing the economic evaluation of NMOs was used in this study to address the evidence gap established under REACH to determine the economic benefits, in monetary terms, of nano-enabled products. The results can then be drawn on in conjunction with consideration of emerging evidence on potential environmental and health risks to enhance SEA under REACH. Although this approach was developed with valuing nano-enabled products in mind, the methodology can also be used to value innovation in other CECs in products.

More work is definitely required to sanction the need to manage the environmental risks of these CECs, but the process of data acquisition will take many years, hence MCA can be a useful tool to compare RMOs that can be used now as a precautionary measure to reduce the potential concerns associated with CECs. This chapter illustrates how MCA is used to reduce the risks associated with NMOs used in cosmetic products in the UK. The MCA approach provides a good foundation for bringing together multiple information

sources to reduce the risks associated with the NMOs and also for developing justifiable and transparent regulatory decisions for managing these products in the future.

The MCA for this study clearly indicated that there is a need for managing the use and disposal of cosmetic products in the UK, ranking *temporary restriction* as the best RMO for the use and disposal of NMOs in cosmetics. The different perspectives analysed (environmental, economic and stakeholder) also illustrated that *temporary restriction* was the best RMO (see Figure 7-2). This demonstrates that the potential risks to the environment from the use and disposal of NMOs from cosmetic products exceed the economic benefits gained from these products, hence it may be best to temporarily restrict the use of NMOs in cosmetics.

Temporary restriction will ultimately restrict the quantity of NMOs disposed to the environment as products containing NMOs on the retail market will eventually be phased out. Since testing of finished products for NMOs may be an impractical task and the monitoring for these contaminants in environmental media is unfeasible, *temporary restriction* can be implemented as an option to manage CECs in products by reducing the product available for use, which directly influences the quantity disposed. Furthermore, *temporary restriction* will allow research and development in this emerging field, allowing better informed decision-making for the management of NMOs in cosmetic products. It may also encourage regulators to slow the expansion of the nanocosmetics sector until safety testing ensures that cosmetics containing nanomaterials are safe for the environment into which products are inevitably released (Miller et al., 2006).

To evaluate MCA effectively as a credible basis for decision-making, an uncertainty analysis was done to understand how different sources of uncertainty contribute to the overall variability of the final RMO. Even when the sub-criterion scores were given an

uncertainty value of 50%, the end ranking demonstrated that *temporary restriction* would still be the best alternative. Some of the uncertainties were impossible to eliminate (residual uncertainties) due to a lack of scientific knowledge and can only be minimised when data become available. Environmental monitoring data as well as data on producer and consumer surplus will take many years before there is sufficient and reputable information.

7.5 Conclusion

MCA can be an effective tool in the decision-making process for understanding and reducing the risks associated with the use and disposal of CECs in cosmetic products. The identified NMOs were used as a case study to illustrate the efficacy of the adopted methodology as part of the MCA approach which provides a framework for integrating heterogeneous information (environmental and economic) as well as stakeholders' value judgements in management where there are limited data. The MCA illustrated that *temporary restriction* is the best RMO for the management of NMOs in cosmetic products. Uncertainty and sensitivity analysis further illustrated that regardless of changes in sub-criterion the scores or weightings used in the study, *temporary restriction* was ranked as the best RMO.

8 OVERALL DISCUSSION

In this chapter, the knowledge gained during this research is summarised and the need for managing chemicals of emerging concern in cosmetics is assessed in light of REACH legislation. The relative importance of managing the disposal of cosmetics to reduce chemicals of emerging concern reaching the environment is discussed to ensure product sustainability in the future.

Cosmetics or personal care products (PCPs), as previously mentioned, comprise a very large and diverse spectrum of chemicals of emerging concern (CECs), most of which have received little attention. Some consumer chemicals such as those used in cosmetics are considered to be ‘‘emerging’’ and they have the potential to enter the environment from their initial use and/or disposal. Furthermore, the continuous use and disposal of cosmetic products based on sales figures for these products (over 2 billion products sold in 2008) signify that CECs in cosmetics can be considered as potential sources of environmental contaminants. This continual infusion of CECs to the environment indicates that even if these chemicals have low persistence they can display the same exposure potential as truly persistent pollutants, since their transformation/removal rates can be compensated by their replacement rates, leading to potential unwanted long term environmental effects (Daughton and Ternes, 1999).

Improved analytical techniques and increased scientific curiosity has augmented the recognition of potential significance or environmental ramifications of CECs and more chemicals are currently being targeted for environmental assessment. The current lack of information regarding the physicochemical and toxicological data for these bioactive ingredients and the potential impact associated with the occurrence and fate of CECs in the environment limits the assessment of long-term exposure to low concentrations of CECs. The scarcity of inventories for CECs, compounded by a lack of legal obligation or incentives for proper disposal of unwanted cosmetics, means that out-of-date or unwanted products are commonly disposed of via municipal wastewater system to the environment or dumped in household waste and taken to landfill sites with no pretreatment (see Figure 6-1).

Although existing chemical legislation has brought about substantial environmental benefits, a more sustained effort is now needed to develop a consistent framework in order to break the link between economic growth and the manufacture of products containing potentially harmful CECs. The Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) legislation via guidelines for environmental risk assessment (ERA) and socioeconomic analysis (SEA) introduces the foundation for an effective management schemes for CECs in products creating the opportunity for future reduction of CECs in products. However, the time taken to deliver decisions using the current risk assessment system is lengthy and there are still many unknowns about the possible impact of chemicals on the environment. More than 25 years after the introduction of the new chemicals scheme and almost 10 years since that of the Existing Substances Regulation, the proportion of chemicals on the market that have been properly tested and assessed remains small (Royal Commision on Environmental Pollution, 2003). Despite this lack of progress, many regulators and industry bodies continue to argue strongly that control must be on the basis of known risk, regardless of other indications of concern. This is regardless of the fact that problems may continue to occur due to unforeseen risks and that the system is unable to react quickly to emerging concerns.

This chapter discusses the use and disposal of cosmetics as a case study to bring into focus the potential risks associated with the environmental exposure of CECs used in products and assesses the best management options for these products. Although the Cosmetic Directive is the main driver for the safe use of chemicals in cosmetics, the environmental risks of CECs in these products are almost always overlooked. Emphasis is therefore placed on the possibility of REACH facilitating the assessment and management of these CECs in household products. However, the evaluation under

REACH progress report indicates that only limited dossiers submitted under REACH have been evaluated as the process is relatively new to both the regulatory body (ECHA) and individual companies and the learning curve is lengthy (European Chemical Agency, 2011).

The methodologies proposed in the ERA and SEA guidelines for chemical assessment under REACH were discussed to illustrate the extent to which this guidance can be used as a tool to manage the use of chemicals on the EU market. Inadequacies in the REACH system were highlighted and recommendations were developed to mitigate the drawbacks of REACH, to ensure the early identification of CECs before they become pervasive in the environment. This mechanism for the real-time detection of the presence of CECs is important for protecting the environment from the effects of inadvertent pollution and managing the use of these chemicals in products.

8.1 REACH legislation for assessing CECs in cosmetics

This section of the thesis argues for a different approach to chemical assessment and management that can be utilized to improve the existing chemical safety assessment (CSA) and socioeconomic analysis (SEA) guidelines under REACH.

8.1.1 Assessing environmental risks

Chemical safety assessment is the main end point for data assessment under REACH in which hazard and exposure data are considered together to assess the risk posed by a substance. REACH legislation states that the manufacturer or importer of amounts of chemicals greater than 10 tonnes per annum are required to complete a CSA of risks to the environment and determine how those risks can be controlled for the identified uses (Figure 8-1). However, for chemicals used in small quantities such as nanomaterials or

for specific purposes as in cosmetic formulations, some of these chemicals may fall outside such legislation. Cosmetic products generally range in sizes from 50ml to 500ml, hence manufacturers/importers of these products use small quantities of chemicals in product formulation, most likely below the recommended limit for a CSA under REACH (10 tonnes/year). It therefore means that chemicals, in particular CECs in these products which can potentially be substances of very high concern (SVHC), will not be assessed under REACH unless they are used by other industries in larger quantities. Although this may apply to some CECs such as triclosan, DEP or parabens, CECs such as nanomaterials and BHT may never be used in such large quantities and thus are inadequately assessed. Additionally, the data needed to determine persistence, bioaccumulation and toxicity (PBT) characteristics for CECs are limited and this creates further complications for the hazard assessment, an integral part of the CSA.

To assess the environmental risks associated with the use and disposal of cosmetics a different approach was established. This can be applied to CEC use in products where REACH may not be as effective, as is done with cosmetics in this study. The thesis introduces a different approach, as explained in Chapters 5 and 6, to specifically assess CECs. Whereas REACH proposes the merger of all chemicals whether new or existing, this approach suggests that CECs, relatively new and emerging chemicals, should be assessed separately. Lack of sufficient quantities of these chemicals currently on the market and limited analytical technology to identify them in the environment only adds insult to injury by increasing the 'burden of the past' for chemicals already on the market. This thesis therefore developed a rapid assessment methodology for new, emerging chemicals to examine these CECs on the market and to select some for further, more detailed investigation leading to risk management measures. This disregards the

prolonged process for assessing chemicals under the REACH legislation, whilst taking a cautious approach for assessing CECs which can potentially cause harm to the environment.

A two tiered approach was used to assess the environmental risk posed by CECs, using cosmetics as the case in point (Figure 8-2). Tier 1 assessed the initial exposure to the environment based on the screening and sorting of CECs and consumption of cosmetic products. This estimation was carried out for CECs in cosmetics with the potential to cause environmental harm, irrespective of their route of administration, metabolism and excretion. Unlike REACH, this approach focused on sorting chemicals based on PBT characteristics instead of tonnage of chemicals produced.

This reduces the number of potential candidates for investigation and selects a more manageable number that can be studied in greater detail whilst creating a cost effective means of focusing resources on selected chemicals. REACH considers a chemical for further investigation dependent on whether the substances are PBT, very persistent, very bio-accumulative (vPvB) and carcinogenic, mutagenic or toxic to reproduction (CMR) and endocrine disrupting chemicals. However, chemicals that exceed the limits for only 1 criterion or 2 criteria may go undetected under REACH. This approach assesses each CEC once the PBT limit is exceeded for only 1 criterion. If toxicity data are not available, both persistence and bioaccumulation can indicate the potential for long term environmental damage and where information is not readily available, it can be attained from simple basic tests using physicochemical data.

The use of consumption data to estimate initial environmental exposure once the chemicals identified in cosmetics are sorted, gives a better estimation of environmental concentration compared to assessing the quantity of chemical used in production as this

may overestimates the quantity of chemicals reaching the environment. Although tonnage limitations may be necessary to limit the size of the list of chemicals under REACH, this approach rejects the concept due to the wide range of concentrations of different chemicals that can exert diverse physiological effects and the widely divergent behaviours of the chemicals in the environment. The non-selected chemicals that have not been identified for further assessment in Tier 1 do not undergo full testing but are kept under review as reappraisal may trigger improved understanding of the fate and effects of the CECs in the environment.

Tier 2 then goes on to estimate the predicted environmental concentration (PEC) and predicted no effect concentration (PNEC) for the selected CECs to predict the risk characterisation ratio (RCR) for different environmental compartments. The guidelines for environmental exposure estimation, characterisation of dose [concentration] response for environment and risk characterisation under REACH were used to determine whether the selected CECs can pose environmental risks. However, it is unlikely that the guidelines in their original form, using the EUSES model, will contain information that can be used to make reliable risk predictions on particular groups of organisms in particular locations. Most ERAs are currently designed to produce generic risk assessments and so do not normally provide useful site-specific information. Even when site-specific data are requested during a risk assessment these are usually anonymous to maintain company confidentiality and the response rate can be very poor.

Only site-specific monitoring data would change this, and such data are expensive to gather reliably, especially if there are many potential discharges. This would not be cost-effective in those cases where the costs of restriction are apparently low and slow down the chemical assessment process under REACH. However, this study suggests that site

specific data, where accessible, should be used to enhance the ERA process by reducing uncertainty. For example, the chemicals used in cosmetics were surveyed from ingredient listings and MSDS for these products and their concentrations in products together with the number of products sold per annum were used to estimate quantity, the fraction of chemical release attributed to effluent and sludge were calculated based on degradation of these chemicals from existing WWTWs, and specific wastewater flow for the UK (184l/d) was used instead of the default assumptions predicted using the EUSES 2.1 modelling software. The data can improve the final estimates of the PECs used for ERA and more accurately describe the environmental concerns associated with CECs reaching the environment. To further enhance the ERA under REACH, it is also suggested that critical toxicity results (those used to estimate a PNEC) with its specific rating to assess the test methodology used should be fully reported in CSRs in tabular form so that they can be reanalysed if necessary.

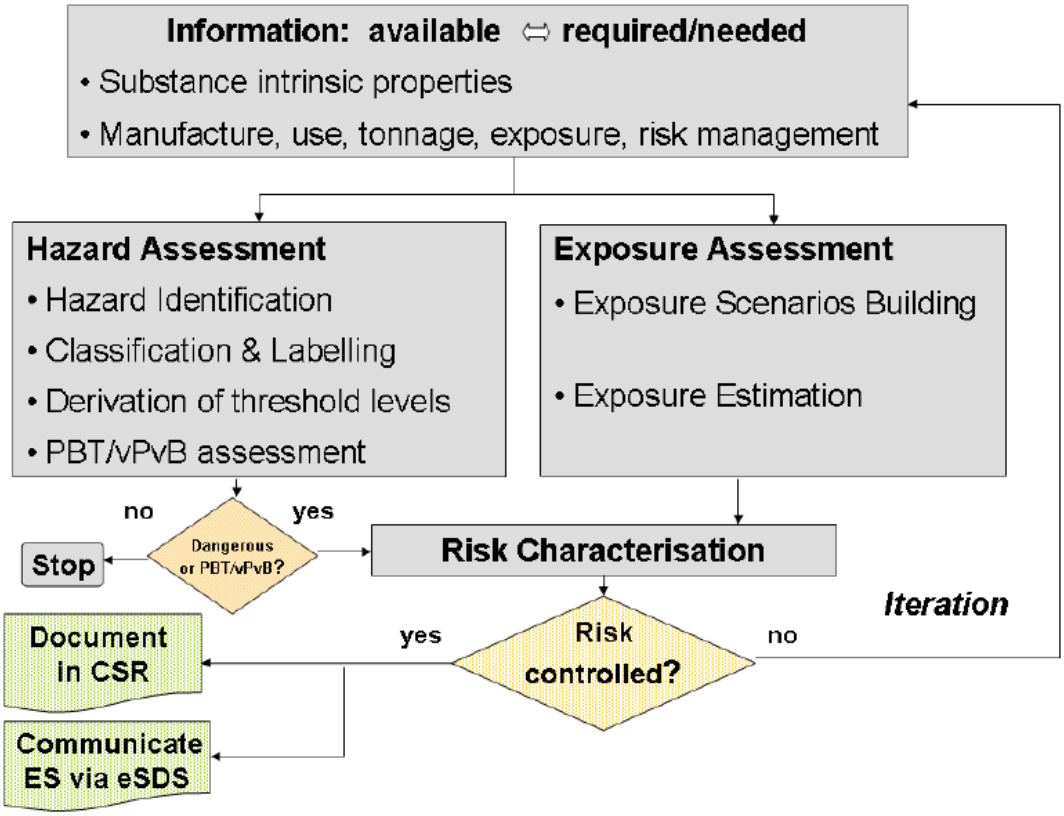


Figure 8-1: CSA overview for assessing environmental risk (ECHA, 2009) (CSA summary)

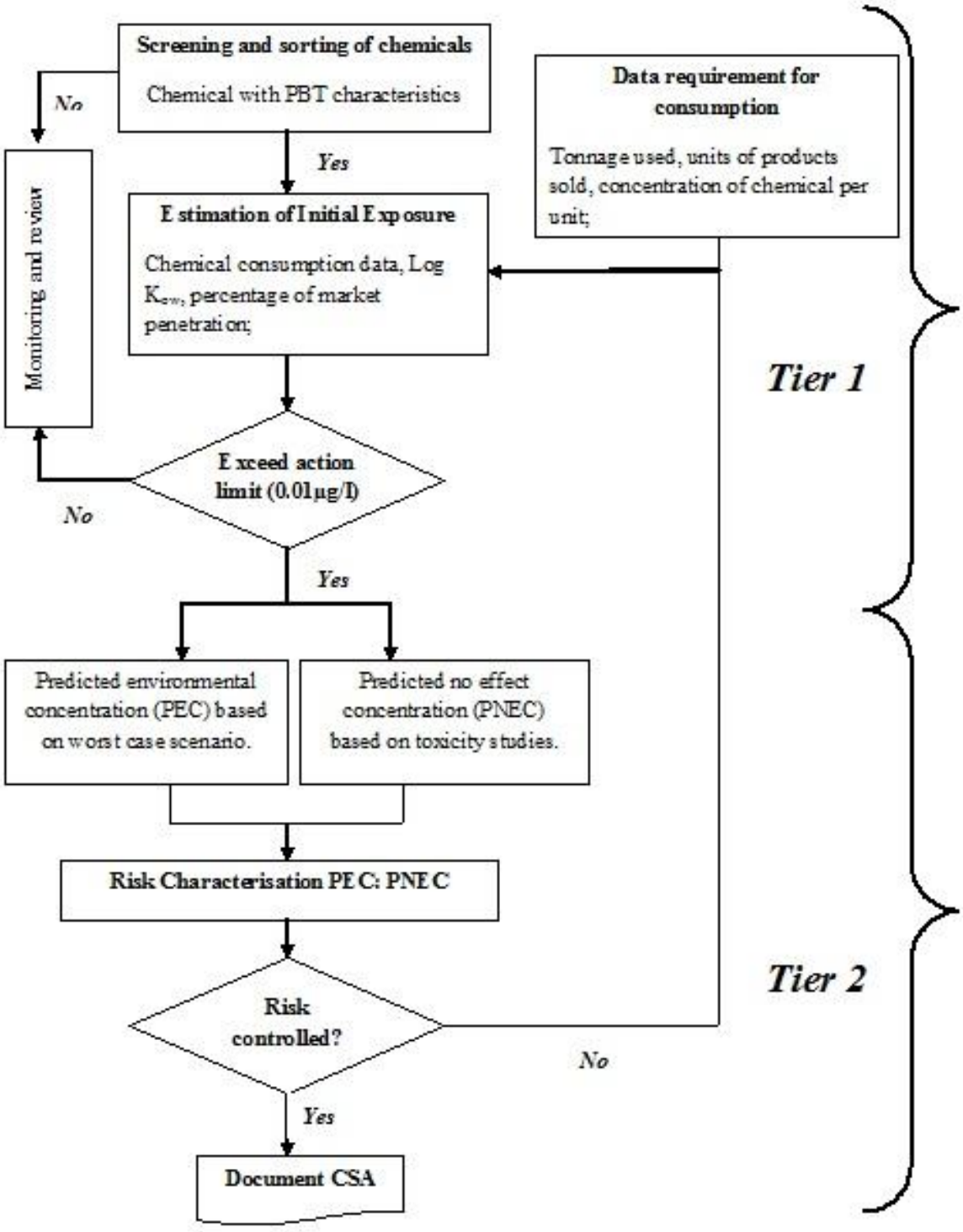


Figure 8-2: Improved methodology for assessing environmental risk

8.1.2 Reducing environmental risks of CECs in cosmetics

The restriction procedure under REACH is designed to address unacceptable risks to the environment that arise from the manufacture, use, or placing on the market of a substance. This thesis deals specifically with the use and disposal of CECs in cosmetics. Chapter 6 illustrated that two nanomaterials (NMOs) found to be present in cosmetic formulation can pose potential environmental risks. This triggered the need for further assessment of these CECs to determine whether disposal of cosmetic products containing these two NMOs should be managed. The European Chemicals Agency (ECHA) committee under REACH for risk assessment (RAC) and socio-economic analysis (SEA) must therefore be used to form an opinion on the best management option for these products. The SEA must be used to form an opinion about the proportionality of a proposed risk reduction measure, while the RAC must be used to form an opinion on the measure's adequacy at reducing the risk.

Unfortunately, the outputs from standard ERAs are not the same as the impact assessment inputs required for socioeconomic analysis (SEA) under REACH, as ERAs are usually in the form of RCRs and the socioeconomic impacts under SEA require the translation of this RCR or its underpinning data into a 'value'. This makes it difficult to develop co-ordinated and coherent opinions about restrictions for product use and disposal using the SEA. It is very important to note that under REACH the text on authorisation indicates that for an authorisation to be granted, the socio-economic benefits must outweigh the risks and does not specify that the actual impacts have to be understood. The problem of even identifying environmental impact, let alone quantification of impact, is a significant one for SEAs which rely on at least the possibility of understanding the impacts, so that the costs and benefits can be understood and assessed.

Additionally, the integration of data from multidisciplinary fields into the decision making process for authorisation or restriction of a CEC under SEA is a difficult and time demanding process. This may be due to lack of information due to companies' confidentiality policies as mentioned in Chapter 5 and limited market data for economic analysis, as some chemicals may still being 'emerging' (Chapter 4). For example, the use of the benefits transfer approach recommended by ECHA is currently hampered by a lack of suitable studies in the environmental valuation reference inventory (EVRI) database. This leads to over-reliance on a very few studies that may not be truly representative. It is therefore unlikely that the economic information available in the EVRI database is sufficiently robust to provide reliable inputs to a cost-benefit analysis.

A multi-criteria analysis (MCA) framework can be used for conducting a SEA as qualitative or semi-quantitative data can be used in the absence of fully quantitative data for assessing the use of CECs in products (Chapter 7). MCA can be used to assess the costs and benefits of different risk management options (RMOs), as it seems that data for reliable costing of benefits will not be available sufficiently soon for the purposes of REACH. The MCA approach adopted for this study assessed different RMOs for the disposal of cosmetics containing CECs in order to assess the need for management of these products given the use patterns of cosmetics. Uncertainty and sensitivity analyses were done to ensure validity of the study. The findings ranked *temporary restriction* of the use of the selected NMOs as the best RMO. This management option outranked the other options of *total restriction, substitution* and *does nothing*. The *do nothing* option was ranked as the least preferred RMO emphasising the need for the active management of cosmetic products.

The major hurdle for conducting the MCA for this research was based on the lack of data for assessing the economic importance and stakeholder preferences for the use and disposal of the two NMOs in cosmetics. The thesis illustrated how the finding from the ERA can be used to assess environmental effects when conducting the MCA and implemented a methodology successfully used by DEFRA, 2010 'A comparative methodology for estimating the economic value of innovation in nanotechnology' to estimate the economic benefits of the use of the two NMOs in cosmetics (Appendix D). This methodology is applicable to any CEC used in products and can therefore form an integral part of the MCA where economic data are not available to assess the economic importance of CECs in products. Although, existing surveys were used to determine stakeholder preferences for this study, it is recommended that stakeholders, in particular consumers, should be an active part of the management process to ensure the widest possible range of opinions is considered.

8.2 Chemical management for CECs in cosmetics

This research validates the need for chemical management for CECs in products. The case in point indicates that whilst most CECs identified in this study have no adverse environmental effects and pose no risks to the environment, others such as nanoparticles (NMOs) can in fact be a cause for concern. Some of the uncertainties in understanding the environmental fate and effects of CECs, and the interaction and effects of chemical combinations in products, will not be resolved for many years, hence an intrinsically precautionary approach must be adopted. This principle deals with situations in which, despite the best efforts of science, the data and the safety margins are insufficient to give the necessary level of assurance of adequate risk management (Royal Commision on Environmental Pollution, 2003). In this context, a precautionary decision is preferable to

relying on existing regulatory procedures, which delay action until further research becomes available while CECs continue to enter the environment. Where there is evidence of concern about the use of NMOs in cosmetics as shown in this research, decisions about chemical management of products must be taken and acted upon promptly, even though the evidence is not fully conclusive.

NMOs are active ingredients used in many cosmetic products and they function not only as UV filters making sun products more effective by absorbing UV radiation, but also make products easier to apply, increasing their coating effects and reducing their visibility on the skin. The two CECs were found to be present in very high concentrations in sunscreen products (up to 25%) but are also present in numerous other cosmetic products used daily (Chapter 5).

Temporary restriction of the use of these two NMOs in cosmetics was identified as the best management option for the disposal of products containing these chemicals. Given that sunscreen products containing these two NMOs comprise approximately 67% of products currently on the market and the concentrations of these NMOs and the products are high, temporarily restricting the use of these products could greatly reduce the environmental risk posed by these two NMOs. The lack of information for CECs highlighted throughout this study means that further scientific evidence needs to become available through innovation and research to adequately assess the environmental concerns associated with the disposal of these two NMOs used in products.

The temporary restriction of NMOs has been suggested by scientific working groups around the world and this research reemphasises the urgency for this. In 2006 the environment and consumer organisation "Friends of the Earth" (Australia and USA) pointed to the potential risks of nanomaterials in cosmetics, criticised the fact that there

was no requirement to label nano-products and called for a moratorium. In 2007 "Friends of the Earth" published a brochure on sunscreens containing nanoparticles which highlighted vividly their risks. In Austria, the International Society of Doctors for the Environment (ISDE), asked for the precautionary principle to be applied, more financial support for research into risks and, in common with Friends of the Earth, the compulsory labelling of products containing nanoparticles. "Which?" (UK), Europe's biggest consumer organisation, also requested an independent group of experts to be set up which can advise the government on the advantages and risks of sunscreens containing nanoparticles (Greßler et al., 2010).

The mechanism for assessing and managing NMOs is complex, which means that the models applied to it must be intricate and supplied with accurate data in order for them to be effective. The discrepancies in decision making for the use of NMOs by the scientific community further increase the intricacies of managing products. Scientific observations suggests that nanomaterials have improved or markedly different properties from their bulk counterparts, whilst simultaneously stating that regulating NMOs should be equivalent to their bulk counterparts since their effects on the environment have not been adequately studied (Malsch et al., 2004). In an attempt to resolve this issue, biodegradability of nanomaterials and their toxicological effects in animal models are being tested. While risk assessment and management may not be precise, it can be used to focus effective chemical management of these CECs in cosmetics (Figure 8-3).

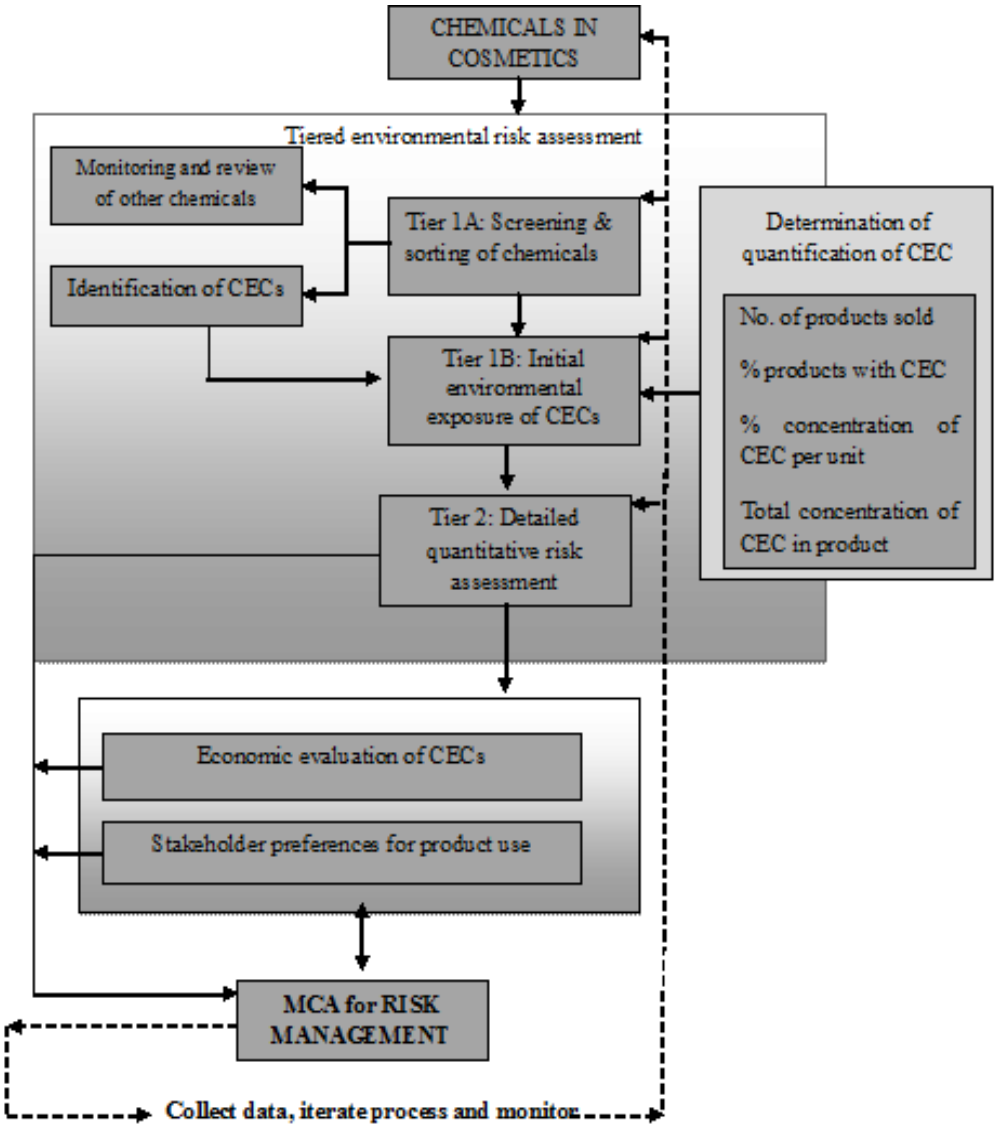


Figure 8-3: Framework for assessing and managing CECs from cosmetics

The cosmetic industry is greatly influenced by the consumer market hence the management of chemicals from a consumer perspective can greatly influence the reduction of CECs from cosmetic products reaching the environment. Although REACH legislation and its suggested amendments can bring substantial environmental benefits, a more sustained effort is needed to develop a consistent framework in order to bring about the more environmentally sustainable products. The implementation of REACH complements the Sustainable Development Strategy (SDS) 2006 and Integrated Product

Policy (IPP) in the UK. This plays a fundamental part in ensuring sustainability of the disposal of CECs from cosmetic products. SDS introduces the concept of sustainable consumption and production in the future which aims to deliver new products & services with lower environmental impacts across their life cycle, while boosting competitiveness. The IPP looks at all phases of a product's life-cycle and attempts to stimulate each part of these individual phases to improve the environmental performance of products. This involves legal initiatives as the main tool for change, but a combination of fiscal incentives, producer responsibility concepts and voluntary schemes can be implemented to improve the framework in which chemicals are managed. The following section recommends some non-statutory measures that would complement the statutory approach used to manage these NMOs and facilitate the temporary restriction of the use and disposal of cosmetic products.

8.2.1 Reducing the quantity of cosmetics disposed to waste disposal facilities including WWTWs and landfill sites

Household disposal of cosmetics via domestic wastewater systems was identified as the major pathway for CECs in cosmetics to reach the aquatic environment. Municipal waste disposal as well as sludge disposal from WWTWs was also identified as a disposal pathway for CECs to landfills. It is estimated that approximately 5000 tonnes of NMOs are disposed to the environment per annum (see Table 5-6). In order to effectively target the management of chemicals, the quantity of cosmetics used can be reduced. Although this would definitely have the greatest effects for reduction in environmental contamination it will be difficult to convince consumers to reduce the use of sunscreen products given the paramount importance of these products for sun protection. Other cosmetic products containing NMOs include body lotion, anti-wrinkle creams,

moisturisers and decorative make up, products used on a daily basis for hygiene and to boost self-esteem. A reduction in the quantity of products disposed may therefore be the best option for reducing the quantity of CECs reaching the environment. This could be achieved by the use of smaller package sizes as is the case with sunscreens and extended shelf life of products to avoid excessive wastage and disposal.

Another area of interest is producer responsibility, where cosmetic products could be returned to retailers and eventually returned to manufacturers when an agreed quantity of unwanted or unused products is collected. Currently, there is no legal requirement for unused or expired cosmetic products to be returned to the retailer. Many consumers assume that the chemicals in these products are harmless and can safely be disposed of to household waste, hence it is important to communicate any risk from the use of these products to consumers. Compulsory product labelling needs to be implemented as this will improve the flow of information along the supply chains and provide information to end users to ensure consumer awareness of the chemicals in cosmetics.

8.2.2 Achieving public acceptance, sharing knowledge and ensuring equity

There are a number of issues that affect public acceptance of the use of products and these vary in importance depending on different societies and populations. Within any society there will be a whole spectrum of feelings pertaining to advances in nanotechnology and their impact on such aspects as personal integrity; safety and security; the well-being of future generations; health; economic growth and environmental impacts. Although developments in nanotechnology for cosmetics have the potential to improve skin care by a reduction in skin related illness from UV radiation, there are questions of invasion of privacy and sharing of information. Companies currently have the right to determine what information can be disclosed and communicated to consumers. As such there must be

regulations protecting the consumers which should be established at the onset of the placing of nano-enabled products on the market stating the possible health and environmental implications to ensure informed consent of use.

Acceptance of new technologies necessitates an understanding of not only the science behind them, but also the value of this technology to society. Therefore the public must be given sufficient information to make an informed decision. This information should be correct, should not be misleading and must address public concerns, in order to avoid deeply polarised debates. This is likely to happen when companies involved in the research, development and ultimate commercialisation of nanotechnologies may have different agendas with the expansion of new technology that can lead to controversy over data access, patents and publications. It is important to convey scientific findings to others that do not have the specific knowledge or language of science. What is often necessary is not to focus on a future development that may have a major and comprehensible impact on society, but to explain and describe the processes in between. Achieving this understanding gives ownership to the audience and promotes a better dialogue between all parties. Recognition of what is known and what still needs to be determined is therefore essential, and so it is just as important that gaps in knowledge are conveyed to the general public as well as the facts about benefits.

Although REACH suggests that the role of the consumer is to create pressure on the industry to develop safer alternatives, it is vital to consider that this requires an informed public, one that is able to demonstrate concern about the effects of CECs in the environment and therefore a significant public education campaign would be needed. Campaigns will have to be established to target manufacturers and retailers of household products, to find out what they are doing to eliminate risky chemicals from the products

they make and/or sell. Making such information available to the public could encourage companies to face up to the issue of chemicals in their products and help consumers make informed purchasing decisions. Some companies in the UK have already instituted chemicals programmes but these now need to be more widely established to facilitate REACH. Finally it is essential that information about and access to nanotechnology developments is made freely available to all, especially regarding those that give most benefit to humanity (Malsch et al., 2004).

8.2.3 Facilitating scientific and social research

It is important that scientific and social research be conducted on NMOs to determine the extent of the impacts of the use and disposal of cosmetics products containing these chemicals. The involvement of social scientists that have been specifically trained to research and analyse the societal implications of technological developments can ensure that probable effects can be ascertained by individuals that have an independent and objective stance to those performing the R&D and those making policies. Allied with the approach from the R&D scientists, this will allow a balanced and thorough description of the state of the art and future directions for the use of NMOs in products. The process for research and development should involve many individuals with skills that will prove invaluable to the effective analysis and communication of developing policies, what public opinion is and how that is changing, and individuals who will be able to act as mediators in public debates. For example, there are political and economic scientists that have been trained to analyse policy making and can provide clarity on the nature and dynamics of economies and environments on how these will impact each other and future technological developments. Therefore, trained and experienced individual need to work

together as a scientific committee to determine the considerations and the long term implications for nanotechnology developments.

8.2.4 Substitutes for NMOs

Although, within the last couple of years there has been a significant growth in shampoos, shower gels, detergents and hand washes that are nearly 100% natural ingredients, substituting the use of NMOs in products with less harmful products is an almost unattainable task. While research has shown that the two NMOs most commonly used in cosmetics can be replaced by naturally occurring NMOs such as English Ivy (*Hedera helix)* or Pongamia, extracted from the Karanja tree and is said to have UV-absorbing properties, information is extremely limited and not fully conclusive (Euromonitor International, 2009b). Researchers also believe that other natural ingredients such as black tea extract, sulforaphane extracted from broccoli and modified oil from the milkweed seed have the potential to absorb UV rays and protect against skin damage (Euromonitor International, 2009b). The scientific research needed to fill these data gaps will take many years and is expected to be at a significant cost.

Substitution therefore should be facilitated through a re-design of products and delivery (green chemistry) and through the wider adoption of service-based approaches. Product re-design is starting to happen and can involve altering the concentrations of NMOs used in cosmetic formulation to achieve the desired effects, whilst service based approach could entails a shift from maximization of the volume of a product sold to a partnership in which material savings are shared between suppliers and consumers.

8.2.5 Economic Instruments

The EU commission for Integrated Product Policy (IPP) identified that product policy should exert its influence through the market using economic instruments. In the case of NMOs in cosmetics, incentives could be used for research and development into the alternatives suggested in section 8.3.4. An alternative chemical charge can based on usage of NMOs in cosmetic formulations using the polluter pays principle. This would also encourage manufacturing companies to seek alternative, stimulating innovation in the development of other products.

8.3 Limitations for managing nanomaterials

The major limitation to assessing NMOs lies with the uncertainties and information gaps in data to accurately assess and manage the use of these CECs in products. Nanotechnology is a rapidly growing industry of economic importance, but it has led to concerns regarding its potential impact on the environment. It was predictable that significant amounts of NMOs would reach the environment, and the aquatic environment is particularly at risk of exposure to NMOs, as it acts as a sink for most environmental contaminants. However, the following limitations restrict the efficiency of assessing and managing the environmental risks associated with these CECs.

- The persistence of NMOs can gives rise to trans-boundary issues, with this further complicating both the quantification of effects and any attempts to value such effects.
- An absence of environmental monitoring data together with transport, fate and behaviour data limits the establishment of the geographic extent of environmental concentrations above the no effects level.

- Ecology and ecotoxicology studies are currently unable to deliver theoretical or empirical answers to assess the environmental impacts of NMOs such as to determine population reduction in the most sensitive species and consequent changes at the ecosystem level over time. There are also difficulties in linking data on toxicity for most sensitive species to other species or to ecosystem effects.
- Companies' policies for disposal and environmental discharge of NMOs are under strict confidentiality and will not change under REACH. It is therefore not possible to map the precise geographical extent of emissions (and possible impacts) without breaking confidentiality, unless those substances are reported in public domain databases such as the European Pollutant Release and Transfer Register.
- The best probable solution to reducing or mitigating the problems encountered in assessing the environmental risks of NMOs involves environmental monitoring. However, this is a lengthy, time consuming and expensive process.

9 CONCLUSION

Chemicals present at lower environmental concentrations that have only recently been thought of as potential pollutants and are of largely unknown scope, are known as chemicals of emerging concern (CECs). These CECs are used as ingredients in a wide range of household products, all of which are marketed throughout the world and frequently discharged during or after use despite concerns about the control and use of chemicals in such products and the extent of their impacts on the environment. Traditionally, chemicals have mainly been assessed and quantified on the basis of emissions levels but policymakers are now moving towards an approach that relies more on co-operation and incentivisation such as the REACH legislation. This legislation updates the concept of chemical regulations by bringing products containing chemicals into focus, placing emphasis on the source management rather than 'end of pipe' emission levels.

Cosmetics represent an extraordinarily diverse group of products containing multiple chemical ingredients, some of which may be CECs. This group represents one of the most frequently used products in households and as such CECs from these products can be continually introduced into the environment. Several of these chemicals used intensively in cosmetics are persistent, bioactive and exhibit accumulation potential as well as cause endocrine disruptions. However, for many CECs, data on physicochemical and toxicological characteristics are insufficient, making it difficult to accurately predict the levels and/or combination of chemicals that may cause environmental harm. Few of these CECs are inventoried or regulated worldwide, and no legal requirements exist to assess the impact of long-term exposure to low concentrations of these chemicals.

Product ingredient listings were used to identify and quantify over 100 potential CECs in cosmetics using a methodology developed under the guidelines of REACH legislation. The initial predicted environmental concentrations (PECs) calculated for CECs identified in this study illustrated the need for further research to assess whether these chemicals pose a significant risk to the environment. Products such as facial make-up, face cleansers/toners and sunscreen/tanning products contained high levels of emerging chemicals. Hence, the usage of cosmetics containing CECs has the potential to contribute to some of these chemicals reaching the environment in concentrations that might cause concern.

Detailed PECs of selected chemicals when compared to their predicted no effect concentrations (PNECs) using REACH technical guidance illustrated how legislation can be an effective screening tool for environmental impacts. In the UK, CECs used in cosmetics can potentially affect terrestrial and even more so, aquatic organisms once these chemicals enter the environment. PECs for triclosan, nano-zinc oxide and nano-titanium dioxide (NMOs) were estimated to be at levels capable of causing environmental harm to both terrestrial and aquatic organisms, as indicated by risk characterisation ratios (RCRs) greater than 1. Household disposal of cosmetics therefore represents a potential pathway for the release of CECs to the environment, triggering the need for further evaluation to enable the effective management of these contaminants. All the other CECs investigated had RCRs of less than 1, indicating that these CECs pose no immediate concerns to the environment. The environmental exposures estimated for CECs in this study were comparable with limited results of field measurements and other model simulations using adequate margins of safety and the scenarios developed estimated the possible range of exposure to facilitate best and worst case scenarios for the study when

estimating environmental concerns. The quantity of the CECs reaching landfill sites were also estimated (see Table 6-6) but further work is required to assess these environmental concerns and effects, although it is expected that these CECs will be released only slowly, if at all, from landfills.

Multi-criteria analysis **(**MCA) was used to compare and rank the alternative risk management options for the use and disposal of CECs in cosmetic products. NMOs were identified as CECs used in cosmetic formulation with the greatest potential to cause environmental harm and MCA was used as a framework for integrating heterogeneous information (environmental and economic) as well as stakeholders' value judgements to illustrate the best risk management option for products containing these chemicals where data is limited. *Temporary restriction* was ranked as the best risk management option for the management of NMOs in cosmetic products. Uncertainty and sensitivity analysis further illustrated that regardless of the uncertainty and sensitivity of the scores or weights used in the study, *temporary restriction* was ranked as the best RMO.

It was therefore considered essential to manage the use of some CECs in cosmetic products to mitigate the potential for environmental contamination. Although REACH is currently being implemented and the success of this piece of regulation is still unknown, the guidelines under REACH could be amended to improve the risk assessment and management process for CECs. This research demonstrated the efficacy of a modification of the guidelines to produce sound assessments, whilst emphasising the need for effective management of CECs in cosmetic products.

9.1 Recommendations for further research

The following recommendations are put forward for future work.

- Research into the fate of CECs in cosmetic products in landfill sites along with leachate treatment efficiency and movement of potential contaminants into groundwater and surrounding surface would be invaluable in quantifying the contribution to environmental contamination.
- The release and degradation of NMOs from cosmetic formulations during wastewater treatment to accurately estimate the quantities of the CECs reaching the receiving environment.
- The chronic toxic effects of CECs in cosmetics using test species under field conditions. This will enhance ecotoxicity assessments as species sensitivity distributions for groups of species, or dose-response curves for single species data can be analysed to provide more detailed and directly comparable assessments of toxicity.
- The risk assessment and management of combined effects of chemical mixtures used in cosmetic formulations and the potential of REACH legislation to manage these chemicals. This is important as it is representative of real world exposure situations and needs to be incorporated in the assessment of environmental risks for cosmetics. This can be done by using mathematical models to determine the concentration and potency of individual mixture components which means that potential hazards can be predicted from basic information about the components of the mixture and its composition.
- Application of probabilistic methods in combination with species sensitivity distributions (use of dose-response curves from individual tests for those

substances with low amounts of test data) to calculate the notional fraction of species affected in the environment, or media affected for a particular emission level could potentially be beneficial in socioeconomic analysis (SEA).

- Further development of the methodology for SEA, focusing on the level of detailed information required for socioeconomic analysis such as the capacity in which the different tools suggested by the SEA can be used and how this data will need to vary on a case by case basis. Additionally, the development of structured results and analysis can ensure that the outcomes of the SEA are comparable and transparent.

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APPENDIX A

Screening and Sorting of Chemicals

Screening of chemicals in cosmetics

All chemicals present in ingredient listings and MSDS of cosmetic products were screened to identify CECs in cosmetics. Chemicals present in 1% of the products sampled and/or had a 0% or 100% data gap were identified using the '✓' below. These chemicals were therefore omitted from the data set and the rest of chemicals were considered emerging and proceeded to be sorted.

Table A-1: Screening of chemicals in cosmetics

Chemicals in cosmetics	Chemical used in < 1% (500 products) of products sampled	Chemicals with data gaps	
		0%	90%-100%
Acetone	✓		
Alkanolamines	✓		✓
Alkoxylated fatty esters			✓
Alkyl isethionates			
Alkyl poly glucosides	✓		✓
Aluminium compounds (Aluminum chlorohydrate; aluminium oxide)			
Ammonia	✓		
Amphodiacetates			
Bentonite	✓		
Benzoic acid/benzoate			
Benzophenone-3			
Bis-ethylhexyloxyphenol-methoxyphenyltriazine	✓		✓
Bronopol	✓		
Butylated hydroxylanisole			
Butylated hydroxyltoluene			
Butylene glycol			

Chemicals in cosmetics	Chemical used in < 1% (500 products) of products sampled	Chemicals with data gaps	
		0%	90%-100%
Butylmethoxydibenzoylmethane	✓		✓
Butyrolactone	✓		
Carbomers			✓
Carboxylates	✓		✓
Citric acid			
Cocamidopropylbetaine			
Copolymers			
Decamethyl-cyclopenta-siloxane			
Dialkylquats	✓		✓
Diethyl phthalate			
Diethylhexylbutamidotriazone	✓		
Dimethyl ether			
DMDM Hydantoin			
Ethylenediaminetetraacetic acid			
Ethylhexyltriazone	✓		✓
Fatty alcohols	✓		✓
Fluorocarbons	✓		✓
Formaldehyde	✓		
Glycerin			
Glycerol monostearate			
Hectorite	✓		
Hydrocarbon wax			
Hydrocarbons	✓		
Hydrogen peroxide			
Isothiazolinones	✓		✓
Kaolin			
Lactic acid			
Lanolin & derivatives			
Linear alkylbenzene sulphonate	✓		

Chemicals in cosmetics	Chemical used in < 1% (500 products) of products sampled	Chemicals with data gaps	
		0%	90%-100%
Magnesium aluminium silicate			
Magnesium sulphate			
Mica			
Mineral oil			
Monalkylquats	✓		✓
Mono- and diglycerides of fatty acids	✓		✓
Nitrocellulose			
Octocryelenes	✓		✓
Octylmethoxycinnamate			
Panthenol			
Parabens			
Paraffin			
PCA dimethicone	✓		✓
PEG- 40 hydrogenated castor oil			
Petrolatum			
Phenoxyethanol			
Phenyl benzimidazolesulphonic acid	✓		✓
Phosphate ester			✓
Phosphates			✓
Phospholipid	✓		✓
Piroctoneolamine	✓		
Polyacrylamide			
Polyalkylene glycols			✓
Polycarboxylates			
Polychlorophenol	✓		✓
Polyglycerol esters	✓		✓
Polythene bead	✓		
Potassium chloride	✓		

Chemicals in cosmetics	Chemical used in < 1% (500 products) of products sampled	Chemicals with data gaps	
		0%	90%-100%
Propylene carbonate			
Propylene glycol			
Pumica	✓		✓
Pyrithione	✓		
Pyrophosphates			
Quaternary salts	✓		✓
Salicylic acid			
Sarcosinates/sarcosines	✓		
Silicates	✓		✓
Sodium chloride		✓	
Sodium fluoride			
Sodium flurophosphate	✓		✓
Sodium hydroxides			
Sodium hypochlorite	✓		
Sodium lauryl sulfate			
Sorbic acid/sorbate			
Sorbitan esters of fatty acids	✓		✓
Sorbitol			
Strontium salts	✓		✓
Talc			
Taurates			✓
Terepthalylidenedicamphorsulphonic acid	✓		✓
Thioglycollates	✓		✓
Titanium dioxide (nanoparticle)			
Tocopheryl acetate			
Triclosan			
Triethanolamine			
Urea			

Chemicals in cosmetics	Chemical used in < 1% (500 products) of products sampled	Chemicals with data gaps	
		0%	90%-100%
Water		✓	
Zinc oxide (nanoparticle)			
Zinc phenolsulphonate	✓		

Sorting of chemicals in cosmetics

Over 50 CECs were sorted based on their persistence in the environment, ability to bioaccumulate and toxicity, using limits outlined in Annex XIII of the REACH Regulation (see Table 5.4). Any CEC that identified as a 'Y' was considered for the next assessment phase, where their $PEC_{initial}$ was estimated to determine the exposure of these CECs to the environment.

Table A-2: Sorting of chemicals in cosmetics

List of CECs in cosmetics		Environmental Concerns				
	CAS number	P	B	T		
				AT	ED	CMR
Alkyl isethionates	ND	N	N	N	N	N
Aluminium compounds (Aluminum chlorohydrate; aluminium oxide)	ND	N	N	N	N	N
Amphodiacetates	ND	N	N	N	N	N
Benzoic acid/benzoate	65-85-0	N	N	N	N	N
Benzophenone-3	119-61-9	Y	N	Y	Y	N

List of CECs in cosmetics		Environmental Concerns				
	CAS number	P	B	T		
				AT	ED	CMR
Butylated hydroxylanisole	25013-16-5	N	N	N	Y	Y
Butylated hydroxyltoluene	128-37-0	N	N	ND	Y	Y
Butylene glycol	107-88-0	N	N	N	N	N
Citric acid	77-92-9	N	N	N	N	N
Cocamidopropylbetaine	68603-42-9	N	N	N	N	N
Copolymers	27100-68-1	N	N	N	N	N
Decamethylcyclopentasiloxane	9016-00-6	Y	Y	ND	Y	Y
Diethyl phthalate	84-66-2	N	Y	Y	Y	Y
Dimethyl ether	ND	N	N	N	N	N
DMDM Hydantoin	6440-58-0	N	N	N	N	N
Ethylenediaminetetraacetic acid	60-00-4	N	N	N	N	Y
Glycerin	56-81-5	N	N	N	N	Y
Glycerol monostearate	ND	N	N	N	N	N
Hydrocarbon wax	ND	N	N	N	N	N

List of CECs in cosmetics		Environmental Concerns				
	CAS number	P	B	T		
				AT	ED	CMR
Hydrogen peroxide	7722-84-1	N	N	N	N	Y
Kaolin	1332-58-7	N	N	N	N	N
Lactic acid	ND	N	N	N	N	N
Lanolin & derivatives	ND	N	N	N	N	N
Magnesium aluminium silicate	ND	N	N	N	N	N
Magnesium sulphate	7487-88-9	N	N	N	N	Y
Mica		N	N	N	N	N
Mineral oil	8020-83-5	N	N	N	N	N
Nitrocellulose	ND	N	N	N	N	N
Octylmethoxycinnamate	5466-77-3	Y	Y	ND	Y	Y
Panthenol	ND	N	N	N	N	N
Parabens	99-76-3	Y	N	N	Y	N
Paraffin	ND	N	N	N	N	N
PEG- 40 hydrogenated castor oil	ND	N	N	N	N	N

List of CECs in cosmetics		Environmental Concerns				
	CAS number	P	B	T		
				AT	ED	CMR
Petrolatum	ND	N	N	N	N	N
Phenoxyethanol	122-99-6	N	N	N	N	N
Polyacrylamide	ND	N	N	N	N	Y
Polycarboxylates	ND	N	N	N	N	N
Propylene carbonate	ND	N	N	N	N	N
Propylene glycol	57-55-6	N	N	N	N	Y
Pyrophosphates	ND	N	N	N	N	N
Salicylic acid	69-72-7	N	N	N	N	Y
Sodium fluoride	7681-49-4	N	N	N	N	Y
Sodium hydroxide	1310-73-2	N	N	N	N	N
Sodium laurethsulfate	151-21-3	N	N	N	N	N
Sorbic acid/sorbate	110-44-1	N	N	N	N	N
Sorbitol	ND	N	N	N	N	N
Talc	ND	N	N	N	N	N

List of CECs in cosmetics		Environmental Concerns				
	CAS number	P	B	T		
				AT	ED	CMR
Titanium dioxide (nanoparticle)	13463-67-7	ND	ND	Y	ND	N
Tocopheryl acetate	58-95-7	N	N	N	N	N
Triclosan	3380-34-5	Y	Y	Y	Y	Y
Triethanolamine	102-71-6	N	N	N	N	N
Urea	57-13-6	N	N	N	N	N
Zinc oxide (nanoparticle)	1314-13-2	Y	Y	Y	Y	Y

Y – Yes; N – No and ND – No data

APPENDIX B

Quantification of CECs in cosmetics

Table B-1: Quantification of CECs used in cosmetics in the UK

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
D5	DC	Facial make-up products	4136	1186	28.68	Foundation/ concealer	48.2	13.82	20	3.40	5.50	0.68	1.1	9398.53	15203.51
						Blusher/bronzer/highlighter	9.1	2.61	10	3.40	5.50	0.34	0.55	887.36	1435.434
						Powder	21.2	6.08	13	3.40	5.50	0.44	0.715	2687.43	4347.314
		Lip products	4710	222	4.71	Lip moisturisers	37.4	1.76	5	1.60	2.00	0.08	0.1	141.02	176.2803
						Lipstick	26.8	1.26	3	1.60	2.00	0.05	0.06	60.59	75.7368
						Lip gloss	17.9	0.84	6	1.60	2.00	0.10	0.12	80.94	101.1708
						Lip liner /pencil	2.2	0.10	1.2	1.60	2.00	0.10	0.024	1.99	2.48688
		Eye products	3846	276	7.18	Mascara	35.6	2.55	8	0.10	1.50	0.01	0.12	20.44	306.571
						Eye shadow	19	1.36	1.5	0.10	1.50	0.01	0.022	2.05	30.6945
						Eye liner /pencil	6.2	0.45	1.2	0.10	1.50	0.01	0.018	0.53	8.01288
	Skin care	Face care products	9111	6105	67.01	Facial moisturisers	36.8	24.66	50	0.10	5.50	0.05	2.75	1232.93	67811
						Nourishers /anti-agers	34.1	22.89	50	0.10	5.50	0.05	2.75	1144.06	62923.03
						Face masks	5.4	3.62	50	0.10	5.50	0.05	2.75	181.17	9964.35

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
		Body creams and lotions	3806	533	14.00	Firming/anti-cellulite body care	6.8	0.952	200	0.10	5.50	0.2	11	190.46	10475.14
						General purpose body care	74.6	10.44	200	0.10	5.50	0.2	11	2088.80	114884
		Sun care products	3343	942	28.18	Sun protection	28.9	8.14	100	0.10	0.30	0.1	0.3	814.35	2443.057
						After sun	8.7	2.46	100	0.10	0.30	0.1	0.3	245.17	735.498
						Self-tanning	2.5	0.70	200	0.10	0.30	0.2	0.6	140.90	422.7
						Baby sun care	1.7	0.48	200	0.10	0.30	0.2	0.6	95.81	287.436
		Baby care products	411	9	2.19	Baby skin care	12.4	0.27	300	0.00	0.10	0	0.3	0.00	81.45985
	Hair care	Shampoos and Conditioners	3811	396	10.39	Shampoo	146.8	15.25	250	2.00	2.60	5	6.5	76269.8	99150.67
						Conditioners	74.6	7.75	400	2.00	2.60	8	10.4	62007.5	80609.78
						2-in-1 products	25.8	2.68	250	2.00	2.60	5	6.5	13403.1	17424.03
		Hair styling agents	1847	288	15.59		121.7	18.98	150	0.10	0.40	0.15	0.6	2846.48	11385.9
		Colouring shampoos, hair dyes, bleaches	2370	400	16.88		36.4	6.14	50	0.10	1.60	0.05	0.8	307.17	4914.768

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
		Perms and relaxants	117	117	100.00		0.8	0.8	80	0.10	0.50	0.08	0.4	64.00	320
	Tlt	Shaving products	943	56	5.94	Pre-shave	31.9	1.89	200	0.10	0.50	0.2	1	378.88	1894.38
						Men's post-shave	5.7	0.34	100	0.10	0.50	0.1	0.5	33.86	169.29
		Deodorants and anti perspirants	941	604	64.19	Deodorant sprays	232	148.91	200	0.80	1.20	1.6	2.4	238262	357393.4
						Deodorant roll-ons/cream	90.5	58.09	50	0.80	1.20	0.4	0.6	23236.8	34855.17
						Deodorant sticks	20.9	13.42	50	0.80	1.20	0.4	0.6	5366.28	8049.426
						Men's deodorants	74.1	47.56	250	0.80	1.20	2	3	95129.6	142694.4
		Depilatories	200	33	16.50		11.8	1.94	100	0.10	5.50	0.1	5.5	194.70	10708.5
Triclosan	DC	Eye products	3846	33	0.86	Mascara	35.6	0.31	8	0.10	0.40	0.008	0.032	2.44	9.774727
						Eye shadow	19	0.16	1.5	0.10	0.40	0.0015	0.006	0.25	0.9804
						Eye liner/pencil	6.2	0.05	1.2	0.10	0.40	0.0012	0.0048	0.06	0.255936
	Skin care	Face care products	9111	105	1.15	Facial moisturisers	36.8	0.42	50	0.10	0.40	0.05	0.2	21.21	84.82055
						Nourishers	34.1	0.39	50	0.10	0.40	0.05	0.2	19.61	78.43

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
						/anti-agers									
						Face masks	5.4	0.06	50	0.10	0.40	0.05	0.2	3.11	12.42
		Face cleansers, toners & make up removers	2351	101	4.30	Liquid/cream/ gel/bar cleansers	38.3	1.65	200	0.10	0.40	0.2	0.8	329.38	1317.52
						Facial cleansing wipes	26.3	1.13	10	0.10	0.40	0.01	0.04	11.31	45.236
						Toners	3.9	0.17	200	0.10	0.40	0.2	0.8	33.54	134.16
	Tlt	Toilet soaps	4992	111	2.22	Bar soap	397.7	8.83	125	0.10	0.30	0.125	0.375	1103.62	3310.853
						Liquid soap	124.6	2.77	250	0.10	0.30	0.25	0.75	691.53	2074.59
		Oral Hygiene	1338	71	5.31	Toothpaste	180.2	9.57	100	0.10	0.40	0.1	0.4	956.86	3827.448
						Mouthwashes/ dental rinses	54.5	2.89	500	0.10	0.40	0.5	2	1446.98	5787.9
						Denture cleansers	19.2	1.02	1000	0.10	0.40	1	4	1019.52	4078.08
						Mouth fresheners	5.2	0.28	9	0.10	0.40	0.009	0.036	2.49	9.94032
						Tooth whiteners	12.6	0.67	15	0.10	0.40	0.015	0.06	10.04	40.1436
		Shaving products	943	43	4.56	Pre-shave	31.9	1.45	200	0.10	0.40	0.2	0.8	290.92	1163.69
						Men's post-shave	5.7	0.26	100	0.10	0.40	0.1	0.4	25.99	103.968

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
		Bath & shower products	2571	55	2.14	Baby bath products	36.6	0.78	300	0.10	0.30	0.3	0.9	234.97	704.916
						Bath foam/gel/oil/pearls	59	1.26	500	0.10	0.30	0.5	1.5	631.30	1893.9
						Bath salts/powder	4	0.09	400	0.10	0.30	0.4	1.2	34.24	102.72
						Body wash/shower gel	229.9	4.92	250	0.10	0.30	0.25	0.75	1229.97	3689.895
		D&A	941	285	30.29	Deodorant sprays	232	70.27	200	0.00	0.10	0	0.2	0.00	14053.13
						Deodorant roll-ons/cream	90.5	27.41	50	0.00	0.10	0	0.05	0.00	1370.623
						Deodorant sticks	20.9	6.33	50	0.00	0.10	0	0.05	0.00	316.5305
						Men's deodorants	74.1	22.44	250	0.00	0.10	0	0.25	0.00	5611.223
Nano TiO_2	DC	Facial make-up products	4136	2678	64.75	Foundation /concealer	48.2	31.21	20	6.80	14.00	1.36	2.8	42444	87384.64
						Blusher/bronzer/highlighter	9.1	5.90	10	6.80	14.00	0.68	1.4	4006.73	8249.15
						Powder	21.2	13.73	13	6.80	14.00	0.884	1.82	12134.7	24983.14
		Lip products	4710	3115	66.14	Lip moisturisers	37.4	24.73	5	0.70	3.40	0.035	0.17	865.72	4204.919

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
						Lipstick	26.8	17.73	3	0.70	3.40	0.021	0.102	372.24	1808.003
						Lip gloss	17.9	11.84	6	0.70	3.40	0.042	0.204	497.24	2415.168
						Lip liner/pencil	2.2	1.46	1.2	0.70	3.40	0.0084	0.0408	12.22	59.36726
		Nail products	982	594	60.49	Nail polish	14.4	8.71	12	0.10	0.80	0.012	0.096	104.53	836.2138
						Nail treatment /strengthener	4.8	2.90	15	0.10	0.80	0.015	0.12	43.55	348.4224
						Polish remover	4.5	2.72	100	0.10	0.80	0.1	0.8	272.21	2177.64
		Eye products	3846	3034	78.89	Mascara	35.6	28.08	8	2.30	5.80	0.184	0.464	5167.42	13030.9
						Eye shadow	19	14.99	1.5	2.30	5.80	0.0345	0.087	517.12	1304.052
						Eye liner/pencil	6.2	4.89	1.2	2.30	5.80	0.0276	0.0696	135.00	340.4261
	Skin care	Face cleansers, toners & make up removers	2351	530	22.54	Liquid/cream/ gel/bar cleansers	38.3	8.63	200	2.00	25.00	4	50	34531.28	431641
						Facial cleansing wipes	26.3	5.93	10	2.00	25.00	0.2	2.5	1185.60	14820.05
						Toners	3.9	0.88	200	2.00	25.00	4	50	3516.24	43953

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
		Body creams and lotions	3806	1346	35.37	Firming/anti-cellulite body care	6.8	2.40	200	0.10	1.30	0.2	2.6	480.97	6252.57
						General purpose body care	74.6	26.39	200	0.10	1.30	0.2	2.6	5277.20	68603.65
		Baby care products	411	6	1.50	Baby skin care	12.4	0.19	300	0.10	3.00	0.3	9	55.80	1674
	Tlt	Toilet soaps	4992	988	19.79	Bar soap	397.7	78.70	125	0.00	0.10	0	0.125	0.00	9838.104
						Liquid soap	124.6	24.66	250	0.00	0.10	0	0.25	0.00	6164.585
		Shaving products	943	62	6.57	Pre-shave	31.9	2.10	200	1.00	5.00	2	10	4194.70	20973.49
						Men's post-shave	5.7	0.37	100	1.00	5.00	1	5	374.49	1872.45
		Depilatories	200	23	11.50		11.8	1.36	100	0.10	5.00	0.1	5	135.70	6785
Nano ZnO	DC	Facial make-up products	4136	1055	25.51	Foundation /concealer	48.2	12.29	20	2.00	25.00	0.4	5	4917.89	61473.65
						Blusher/bronzer/highlighter	9.1	2.32	10	2.00	25.00	0.2	2.5	464.28	5803.525

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
						Powder	21.2	5.41	13	2.00	25.00	0.26	3.25	1406.11	17576.39
		Lip products	4710	125	2.65	Lip moisturisers	37.4	0.99	5	2.00	25.00	0.1	1.25	99.26	1240.711
						Lipstick	26.8	0.71	3	2.00	25.00	0.06	0.75	42.61	532.65
						Lip gloss	17.9	0.47	6	2.00	25.00	0.12	1.5	56.92	711.525
						Lip liner/pencil	2.2	0.06	1.2	2.00	25.00	0.024	0.3	1.40	17.49
		Eye products	3846	205	5.33	Mascara	35.6	1.90	8	2.00	25.00	0.16	2	303.61	3795.112
						Eye shadow	19	1.01	1.5	2.00	25.00	0.03	0.375	30.38	379.7625
						Eye liner/pencil	6.2	0.33	1.2	2.00	25.00	0.024	0.3	7.93	99.138
	Skin care	Face care products	9111	316	3.47	Facial moisturisers	36.8	1.28	50	2.00	25.00	1	12.5	1276.35	15954.34
						Nourishers /anti-agers	34.1	1.18	50	2.00	25.00	1	12.5	1183.27	14790.88

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
						Face masks	5.4	0.19	50	2.00	25.00	1	12.5	187.38	2342.25
		Body creams and lotions	3806	86	2.26	Firming/anti-cellulite body care	6.8	0.15	200	0.10	0.20	0.2	0.4	30.73	61.46085
						General purpose body care	74.6	1.69	200	0.10	0.20	0.2	0.4	337.19	674.384
		Sun care & tanning products	3343	624	18.67	Sun protection	28.9	5.40	100	2.00	25.00	2	25	10791.26	134890.8
						After sun	8.7	1.62	100	2.00	25.00	2	25	3248.58	40607.25
						Self-tanning	2.5	0.47	200	2.00	25.00	4	50	1867.00	23337.5
						Baby sun care	1.7	0.32	200	2.00	25.00	4	50	1269.56	15869.5
		Baby care products	411	55	13.38	Baby skin care	12.4	1.66	300	0.10	1.10	0.3	3.3	497.81	5475.912
OMC	DC	Facial make-up products	4136	467	11.29	Foundation /concealer	48.2	5.44	20	0.30	3.80	0.06	0.76	326.54	4136.157
						Blusher/bronzer/highlighter	9.1	1.03	10	0.30	3.80	0.03	0.38	30.82	390.4082

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
						Powder	21.2	2.39	13	0.30	3.80	0.039	0.494	93.35	1182.379
		Lip products	4710	979	20.79	Lip moisturisers	37.4	7.77	5	0.30	3.80	0.015	0.19	116.61	1477.022
						Lipstick	26.8	5.57	3	0.30	3.80	0.009	0.114	50.15	635.1761
						Lip gloss	17.9	3.72	6	0.30	3.80	0.018	0.228	66.99	848.4815
						Lip liner/pencil	2.2	0.46	1.2	0.30	3.80	0.0036	0.0456	1.65	20.85653
	Skin care	Face care products	9111	1588	17.43	Facial moisturisers	36.8	6.41	50	0.10	0.30	0.05	0.15	320.70	962.1073
						Nourishers/ anti-agers	34.1	5.94	50	0.10	0.30	0.05	0.15	297.18	891.5445
						Face masks	5.4	0.94	50	0.10	0.30	0.05	0.15	47.06	141.183
		Body creams and lotions	3806	607	15.95	Firming/anti-cellulite body care	6.8	1.08	200	0.30	3.80	0.6	7.6	650.70	8242.186
						General purpose body care	74.6	11.90	200	0.30	3.80	0.6	7.6	7139.22	90430.12

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
		Sun care & tanning products	3343	822	24.59	Sun protection	28.9	7.11	100	0.10	3.80	0.1	3.8	710.65	27004.74
						After sun	8.7	2.14	100	0.10	3.80	0.1	3.8	213.93	8129.454
						Self-tanning	2.5	0.61	200	0.10	3.80	0.2	7.6	122.95	4672.1
						Baby sun care	1.7	0.42	200	0.10	3.80	0.2	7.6	83.61	3177.028
BP	DC	Facial make-up products	4136	1310	31.67	Foundation /concealer	48.2	15.27	20	0.10	0.20	0.02	0.04	305.33	610.6576
						Blusher/bronzer/highlighter	9.1	2.88	10	0.10	0.20	0.01	0.02	28.82	57.6394
						Powder	21.2	6.71	13	0.10	0.20	0.013	0.026	87.28	174.565
		Lip products	4710	284	6.03	Lip moisturisers	37.4	2.26	5	0.20	4.50	0.01	0.225	22.55	507.4013
						Lipstick	26.8	1.62	3	0.20	4.50	0.006	0.135	9.70	218.1654
						Lip gloss	17.9	1.08	6	0.20	4.50	0.012	0.27	12.95	291.4299

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
						Lip liner/pencil	2.2	0.13	1.2	0.20	4.50	0.0024	0.054	0.32	7.16364
		Nail products	982	96	9.78	Nail polish	14.4	1.41	12	0.10	0.30	0.012	0.036	16.90	50.69952
						Nail treatment /strengthener	4.8	0.47	15	0.10	0.30	0.015	0.045	7.04	21.1248
						Polish remover	4.5	0.44	100	0.10	0.30	0.1	0.3	44.01	132.03
		Eye products	3846	1958	50.91	Mascara	35.6	18.12	8	0.10	0.50	0.008	0.04	144.99	724.9589
						Eye shadow	19	9.67	1.5	0.10	0.50	0.0015	0.0075	14.51	72.54675
						Eye liner/pencil	6.2	3.16	1.2	0.10	0.50	0.0012	0.006	3.79	18.93852
	Skin care	Face care products	9111	3634	39.89	Facial moisturisers	36.8	14.68	50	0.30	1.00	0.15	0.5	2201.70	7338.997
						Nourishers /anti-agers	34.1	13.60	50	0.30	1.00	0.15	0.5	2040.37	6801.245
						Face masks	5.4	2.15	50	0.30	1.00	0.15	0.5	323.11	1077.03

CEC	Product Category	Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
									Min	Max	Min	Max	Min	Max
	Face cleansers, toners & make up removers	2351	1263	53.73	Liquid/cream/ gel/bar cleansers	38.3	20.58	200	0.10	0.20	0.2	0.4	4115.72	8231.436
					Facial cleansing wipes	26.3	14.13	10	0.10	0.20	0.01	0.02	141.31	282.6198
					Toners	3.9	2.10	200	0.10	0.20	0.2	0.4	419.09	838.188
	Hand care products	1628	384	23.89	Hand care	16.9	4.04	100	0.10	0.30	0.1	0.3	403.74	1211.223
	Body creams and lotions	3806	1798	47.24	Firming/anti-cellulite body care	6.8	3.21	200	0.10	0.30	0.2	0.6	642.48	1927.441
					General purpose body care	74.6	35.24	200	0.10	0.30	0.2	0.6	7048.21	21144.62
	Sun care & tanning products	3343	731	21.87	Sun protection	28.9	6.32	100	0.10	0.30	0.1	0.3	632.04	1896.129
					After sun	8.7	1.90	100	0.10	0.30	0.1	0.3	190.27	570.807
					Self-tanning	2.5	0.55	200	0.10	0.30	0.2	0.6	109.35	328.05

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
						Baby sun care	1.7	0.37	200	0.10	0.30	0.2	0.6	74.36	223.074
		Baby care products	411	223	54.26	Baby skin care	12.4	6.73	300	0.10	0.20	0.3	0.6	2018.39	4036.788
	Hair care	Colouring shampoos, hair dyes, bleaches	2370	1007	42.49		36.4	15.47	50	0.20	4.50	0.1	2.25	1546.62	34798.86
		Perms and relaxants	117	16	13.68		0.8	0.11	80	0.00	0.10	0	0.08	0.00	8.752137
	Tlt	Toilet soaps	4992	125	2.50	Bar soap	397.7	9.94	125	0.10	0.30	0.125	0.375	1242.81	3728.438
						Liquid soap	124.6	3.12	250	0.10	0.30	0.25	0.75	778.75	2336.25
		Shaving products	943	315	33.40	Pre-shave	31.9	10.66	200	0.10	0.20	0.2	0.4	2131.18	4262.354
						Men's post-shave	5.7	1.90	100	0.10	0.20	0.1	0.2	190.38	380.76
		Bath & shower	2571	26	1.01	Baby bath products	36.6	0.37	300	0.20	4.50	0.6	13.5	221.80	4990.41

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
		products				Bath foam/gel/oil/pearls	59	0.60	500	0.20	4.50	1	22.5	595.90	13407.75
						Bath salts/powder	4	0.04	400	0.20	4.50	0.8	18	32.32	727.2
						Body wash/shower gel	229.9	2.32	250	0.20	4.50	0.5	11.25	1161.00	26122.39
		Depilatories	200	78	39.00		11.8	4.60	100	0.20	4.50	0.2	4.5	920.40	20709
BHT	DC	Facial make-up products	4136	448	10.83	Foundation /concealer	48.2	5.22	20	0.10	0.50	0.02	0.1	104.40	522.006
						Blusher/bronzer/highlighter	9.1	0.99	10	0.10	0.50	0.01	0.05	9.86	49.2765
						Powder	21.2	2.30	13	0.10	0.50	0.013	0.065	29.85	149.2374
		Lip products	4710	1056	22.42	Lip moisturisers	37.4	8.39	5	0.10	0.50	0.005	0.025	41.93	209.6306
						Lipstick	26.8	6.01	3	0.10	0.50	0.003	0.015	18.03	90.1284
						Lip gloss	17.9	4.01	6	0.10	0.50	0.006	0.03	24.08	120.3954

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
						Lip liner/pencil	2.2	0.49	1.2	0.10	0.50	0.0012	0.006	0.59	2.95944
		Eye products	3846	281	7.31	Mascara	35.6	2.60	8	0.10	0.50	0.008	0.04	20.81	104.0416
						Eye shadow	19	1.39	1.5	0.10	0.50	0.0015	0.0075	2.08	10.41675
						Eye liner/pencil	6.2	0.45	1.2	0.10	0.50	0.0012	0.006	0.54	2.71932
	Skin care	Face care products	9111	649	7.12	Facial moisturisers	36.8	2.62	50	0.10	0.50	0.05	0.25	131.07	655.3397
						Nourishers/anti-agers	34.1	2.43	50	0.10	0.50	0.05	0.25	121.40	606.98
						Face masks	5.4	0.38	50	0.10	0.50	0.05	0.25	19.22	96.12
		Body creams and lotions	3806	351	9.22	Firming/anti-cellulite body care	6.8	0.63	200	0.10	0.50	0.2	1	125.42	627.1151
						General purpose body care	74.6	6.88	200	0.10	0.50	0.2	1	1375.62	6878.12
	Tlt	Toilet soaps	4992	152	3.04	Bar soap	397.7	12.09	125	0.00	0.10	0	0.125	0.00	1511.26

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
						Liquid soap	124.6	3.79	250	0.00	0.10	0	0.25	0.00	946.96
		D&A	941	150	15.94	Deodorant sprays	232	36.98	200	0.00	0.10	0	0.2	0.00	7396.387
						Deodorant roll-ons/cream	90.5	14.43	50	0.00	0.10	0	0.05	0.00	721.285
						Deodorant sticks	20.9	3.33	50	0.00	0.10	0	0.05	0.00	166.573
						Men's deodorants	74.1	11.81	250	0.00	0.10	0	0.25	0.00	2952.885
		Depilatories	200	14	7.00		11.8	0.83	100	0.10	0.50	0.1	0.5	82.60	413
	Fra-grance	Parfum&Fra	1716	212	12.35	Parfum&Fra	43.9	5.42	50	0.10	5.00	0.05	2.5	271.08	13554.13
BP3	DC	Facial make-up products	4136	113	2.73	Foundation/concealer	48.2	1.32	20	2.00	10.00	0.4	2	526.75	2633.752
						Blusher/bronzer/highlighter	9.1	0.25	10	2.00	10.00	0.2	1	49.69	248.43
						Powder	21.2	0.58	13	2.00	10.00	0.26	1.3	150.48	752.388

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
		Lip products	4710	332	7.05	Lip moisturisers	37.4	2.64	5	2.00	10.00	0.1	0.5	263.63	1318.132
						Lipstick	26.8	1.89	3	2.00	10.00	0.06	0.3	113.36	566.82
						Lip gloss	17.9	1.26	6	2.00	10.00	0.12	0.6	151.43	757.17
						Lip liner/pencil	2.2	0.16	1.2	2.00	10.00	0.024	0.12	3.72	18.612
		Nail products	982	615	62.63	Nail polish	14.4	9.02	12	2.00	10.00	0.24	1.2	2164.49	10822.46
						Nail treatments/ strengthener	4.8	3.01	15	2.00	10.00	0.3	1.5	901.87	4509.36
						Polish remover	4.5	2.82	100	2.00	10.00	2	10	5636.70	28183.5
	Skin care	Face care products	9111	490	5.38	Facial moisturisers	36.8	1.98	50	2.00	10.00	1	5	1979.15	9895.73
						Nourishers/ anti-agers	34.1	1.83	50	2.00	10.00	1	5	1834.58	9172.9
						Face masks	5.4	0.29	50	2.00	10.00	1	5	290.52	1452.6

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
		Body creams and lotions	3806	329	8.64	Firming/anti-cellulite body care	6.8	0.59	200	2.00	10.00	4	20	2351.23	11756.17
						General purpose body care	74.6	6.45	200	2.00	10.00	4	20	25781.76	128908.8
		Sun care & tanning products	3343	874	26.14	Sun protection	28.9	7.55	100	2.00	10.00	2	10	15108.92	75544.6
						Aftersun	8.7	2.27	100	2.00	10.00	2	10	4548.36	22741.8
						Self-tanning	2.5	0.65	200	2.00	10.00	4	20	2614.00	13070
						Baby sun care	1.7	0.44	200	2.00	10.00	4	20	1777.52	8887.6
BHA	DC	Lip products	4710	235	4.99	Lip moisturisers	37.4	1.87	5	0.10	1.60	0.005	0.08	9.33	149.2824
						Lipstick	26.8	1.34	3	0.10	1.60	0.003	0.048	4.01	64.19136
						Lip gloss	17.9	0.89	6	0.10	1.60	0.006	0.096	5.36	85.74816
						Lip liner/pencil	2.2	0.11	1.2	0.10	1.60	0.0012	0.0192	0.13	2.107776

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
		Eye products	3846	119	3.09	Mascara	35.6	1.10	8	0.10	1.60	0.008	0.128	8.81	140.993
						Eye shadow	19	0.59	1.5	0.10	1.60	0.0015	0.024	0.88	14.0904
						Eye liner/pencil	6.2	0.19	1.2	0.10	1.60	0.0012	0.0192	0.23	3.678336
	Skin care	Face care products	9111	175	1.92	Facial moisturisers	36.8	0.71	50	0.10	1.60	0.05	0.8	35.34	565.4703
						Nourishers /anti-agers	34.1	0.65	50	0.10	1.60	0.05	0.8	32.74	523.776
						Face masks	5.4	0.10	50	0.10	1.60	0.05	0.8	5.18	82.944
DEP	DC	Lip products	4710	715	15.18	Lip moisturisers	37.4	5.68	5	0.20	0.40	0.01	0.02	56.77	113.5499
						Lipstick	26.8	4.07	3	0.20	0.40	0.006	0.012	24.41	48.81888
						Lip gloss	17.9	2.72	6	0.20	0.40	0.012	0.024	32.61	65.21328
						Lip liner/pencil	2.2	0.33	1.2	0.10	0.40	0.0012	0.0048	0.40	1.603008

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
	Skin care	Face care products	9111	1343	14.74	Facial moisturisers	36.8	5.42	50	0.20	0.50	0.1	0.25	542.45	1356.119
						Nourishers /anti-agers	34.1	5.03	50	0.20	0.50	0.1	0.25	502.63	1256.585
						Face masks	5.4	0.80	50	0.20	0.50	0.1	0.25	79.60	198.99
		Face cleansers, toners & make up removers	2351	1029	43.77	Liquid/cream/ gel/bar cleansers	38.3	16.76	200	0.10	0.20	0.2	0.4	3352.78	6705.564
						Facial cleansing wipes	26.3	11.51	10	0.10	0.20	0.01	0.02	115.12	230.2302
						Toners	3.9	1.71	200	0.10	0.20	0.2	0.4	341.41	682.812
		Hand care products	1628	1628	100.00	Hand care	16.9	16.90	100	0.10	0.30	0.1	0.3	1690.00	5070
		Body creams and lotions	3806	1840	48.34	Firming/anti-cellulite body care	6.8	3.29	200	0.10	0.20	0.2	0.4	657.49	1314.976
						General purpose body care	74.6	36.06	200	0.10	0.20	0.2	0.4	7212.33	14424.66

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
		Sun care & tanning products	3343	1756	52.53	Sun protection	28.9	15.18	100	0.10	0.20	0.1	0.2	1518.12	3036.234
						Aftersun	8.7	4.57	100	0.10	0.20	0.1	0.2	457.01	914.022
						Self-tanning	2.5	1.31	200	0.10	0.20	0.2	0.4	262.65	525.3
						Baby sun care	1.7	0.89	200	0.10	0.20	0.2	0.4	178.60	357.204
		Baby care products	411	219		Baby skin care	12.4	6.61	300	0.00	0.10	0	0.3	0.00	1982.19
	Hair care	Shampoos and Conditioners	3811	3234	84.86	Shampoo	146.8	124.57	250	0.30	0.50	0.75	1.25	93430.86	155718.1
						Conditioners	74.6	63.31	400	0.30	0.50	1.2	2	75966.67	126611.1
						2-in-1 products	25.8	21.89	250	0.30	0.50	0.75	1.25	16420.41	27367.35
		Hair styling agents	1847	1036	56.09		121.7	68.26	150	0.10	0.20	0.15	0.3	10239.40	20478.81
		Colouring shampoos, hair dyes,	2370	2194	92.57		36.4	33.70	50	0.10	0.40	0.05	0.2	1684.84	6739.376

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
		bleaches													
		Perms and relaxants	117	117	100.00		0.8	0.80	80	0.10	0.50	0.08	0.4	64.00	320
	Tlt	Toilet soaps	4992	1029	20.61	Bar soap	397.7	81.97	125	0.10	0.90	0.125	1.125	10245.75	92211.72
						Liquid soap	124.6	25.68	250	0.10	0.90	0.25	2.25	6420.02	57780.14
		Shaving products	943	581	61.61	Pre-shave	31.9	19.65	200	0.60	1.20	1.2	2.4	23585.03	47170.05
						Men's post-shave	5.7	3.51	100	0.60	1.20	0.6	1.2	2107.06	4214.124
		Talcum powder	236	236	100.00		15	15.00	500	0.10	0.20	0.5	1	7500.00	15000
		Bath & shower products	2571	1299	50.53	Baby bath products	36.6	18.49	300	0.80	1.50	2.4	4.5	44385.55	83222.91
						Bath foam/gel/oil/pearls	59	29.81	500	0.80	1.50	4	7.5	119250.80	223595.3
						Bath salts/powder	4	2.02	400	0.80	1.50	3.2	6	6467.84	12127.2

CEC	Product Category		Sample size	Prod. with CEC	% prod with CEC[1]	Products	Units sold (mu)	Units with CEC (mu)[2]	Avg. vol. /unit (ml)[3]	CEC conc. in product (% weight)[4]		CEC vol/unit (ml)[5]		Total vol CEC in products sold (L)[6]	
										Min	Max	Min	Max	Min	Max
						Body wash/shower gel	229.9	116.17	250	0.80	1.50	2	3.75	232336.94	435631.8
		D&A	941	773	82.15	Deodorant sprays	232	190.58	200	0.70	1.90	1.4	3.8	266812.33	724204.9
						Deodorant roll-ons/cream	90.5	74.35	50	0.70	1.90	0.35	0.95	26021.01	70628.46
						Deodorant sticks	20.9	17.17	50	0.70	1.90	0.35	0.95	6009.27	16310.88
						Men's deodorants	74.1	60.87	250	0.70	1.90	1.75	4.75	106528.01	289147.5
		Depilatories	200	128	64.00		11.8	7.55	100	0.10	0.30	0.1	0.3	755.20	2265.6
	Fra	Parfum & Fragrance	1716	939	54.72		43.9	24.02	50	0.10	9.10	0.05	4.55	1201.10	109300.5

DC – Decorative cosmetics; mu – million units; Tlt – Toiletries; D&A – Deodorants and antiperspirants; Fra - Fragrances

To quantify CECs in cosmetics the following was done:

1. To derive the quantity of CECs used in cosmetics per annum, it was necessary to estimate the percentage of products actually contain the CEC, as not all products will contain the same CEC for a given functionality. Different brands of products on the market will contain different chemicals with the same function.
2. The % calculated was used to estimate the number of products containing CEC in the UK based of products sold in the UK per annum
3. The average volume of cosmetic products within each product category was determined using surveys carried out in retail outlets in the UK. Where product contents differed in volume for the same type of products, an average size was estimated using the mode of the products surveyed. At least 10 different products were surveyed to determine the mode when the different products were surveyed.
4. The concentration range of each CEC within each product category were derived from existing scientific literature as well as from Euromonitor International database ingredient listings, safety data sheets for specific products, US skin deep database and the US Department of Health and Human Services on 'Household Products Database'.
5. Both minimum and maximum % concentrations of the CEC determined in '4' were multiplied by the volume determined in '3' to give the minimum and maximum concentrations of the CEC in each product.
6. The minimum and maximum concentrations of CEC per product were multiplied by the number of cosmetic units sold per annum containing the CEC to estimate the total amount of CEC used in the different groups of cosmetic products yearly.

APPENDIX C

PEC calculations

Table C-1: Detailed PEC calculations for CECs in cosmetics

DOSEai calculations						
CECs	**Maximum CEC consumed in PCPs (Tonnes/yr)**	**Maximum CEC consumed in PCPs (kg/yr)**	**Maximum CEC consumed in PCPs (mg/yr)**	**Maximum CEC consumed in PCPs (mg/day)**	**DOSEai [CEC consumption per capital] (mg/day/ inh)**	
BHA	1.800	1800.154	1800153532.53	4931927.486	0.081	
BHT	39.496	39495.509	39495509449.19	108206875.203	1.776	
BP	229.191	229191.449	229191448797.73	627921777.528	10.303	
BP3	54.970	54970.315	54970315158.57	150603603.174	2.471	
D5	1364.868	1364867.936	1364867935690.0	3739364207.370	61.357	
DEP	62.447	62446.566	62446566353.36	171086483.160	2.807	
Nano TiO_2	2986.884	2986884.000	2986884000432.8	8183243836.802	134.275	
Nano ZnO	1820.763	1820762.745	1820762745445.9	4988391083.414	81.852	
OMC	133.627	133627.292	133627292016.82	366102169.909	6.007	
Triclosan	51.436	51435.593	51435592547.44	140919431.637	2.312	
Corrected Fpen						
CECs	**Total PCPs sold per yr (mu)**	**No. of PCPs sold per yr containing CEC (mu)**	**UK Population for 2008**	**No. of inhabitants using PCPs with CEC per year**	**Proportion of population using CEC per year (%)**	**Corrected Fpen [Proportion of population using CEC daily] (%)**

BHA	2600	221.4	60943912	5189608.506	8.515384615	0.02
BHT	2600	1443.3	60943912	33830903.15	55.51153846	0.15
BP	2600	1604.7	60943912	37614113.69	61.71923077	0.17
BP3	2600	186.5	60943912	4371553.688	7.173076923	0.02
D5	2600	1325.4	60943912	31067331.14	50.97692308	0.14
DEP	2600	2165.3	60943912	50754558.71	83.28076923	0.23
Nano TiO_2	2600	1077.2	60943912	25249531.54	41.43076923	0.11
Nano ZnO	2600	452.4	60943912	10604240.69	17.4	0.05
OMC	2600	391.6	60943912	9179090.746	15.06153846	0.04
Triclosan	2600	1784.2	60943912	41821587.61	68.62307692	0.19
PEC calculations						
	DOSEai (mg/L/inh)	**Corrected Fpen (%)**	**Daily wastewater flow per inhabitant (L/day)**	**Dilution factor**	**PECinitial (mg/L)**	**PECinitial (ug/L)**
BHA	0.080925679	0.02	200	10	9.43991E-07	0.001
BHT	1.775515743	0.15	200	10	0.000135016	0.135
BP	10.30327324	0.17	200	10	0.00087111	0.871
BP3	2.47118372	0.02	200	10	2.42822E-05	0.024
D5	61.35746926	0.14	200	10	0.004284678	4.285
DEP	2.807277668	0.23	200	10	0.000320263	0.320

Nano TiO_2	134.2750009	0.11	200	10	0.007620708	7.621
Nano ZnO	81.85216406	0.05	200	10	0.001950997	1.951
OMC	6.007198388	0.04	200	10	0.000123942	0.124
Triclosan	2.312280702	0.19	200	10	0.000217364	0.217

APPENDIX D

Criteria evaluation and weighting assignment for MCA

Environmental effects

The environmental effects were assessed based on 2 indicators: average PEC for the NMOs reaching surface water, sediment and soil from the use and disposal of cosmetics products and the average RCR to indicate the overall risk to both the aquatic and terrestrial organisms, as outlined in Table D-1.

Table D-1: Average PECs and RCR for NMOs in cosmetics

	Maximum PEC				RCRs			
NMOs	PEC_{sw} (ug/l)	PEC_{sed} (ug/l)	PEC_{soil} (ug/l)		RCR_{sw}	RCR_{sed}	RCR_{soil}	Average RCR
TiO2	16.343	5643.92	1497.6		1.634	3.561	4.724	
ZnO	5.991	6532.54	633.4		3.524	7.667	3.717	
Average	**11.167**	**6088.23**	**1065.5**		2.579	5.614	4.2205	**4.14**

The average PECs and the RCRs for NMOs were generated for the UK's population in 2008 (approximately 61 million people), with approximately 4800 tonnes of NMOs used and disposed per annum. For each alternative investigated (based on a different scenario), the quantity of NMOs used and disposed varied taking into consideration population increase (Office for National Statistics) and the increase demand for cosmetics at 3% per annum (COLIPA, 2008), deriving different PECs and RCR estimates for each RMO as illustrated in Table D-2.

Table D-2: Calculated PECs and RCR for RMOs

RMOs	Average quantity of NMOs (tonnes/yr)	PEC_{sw} (ug/l)	PEC_{sed} (ug/l)	PEC_{soil} (ug/l)		Average RCR
Scenario 1: Do nothing	4800	11.17	6088.23	1065.50		4.14
Scenario 2: Substitution	2900	6.75	3678.31	643.74		2.50
Scenario 3: Temporary restriction (5 years)	5000	11.63	6341.91	1109.90		4.31
Scenario 4: Total restriction with a 2 year phase out	4900	11.40	6215.07	1087.70		4.22

A survey conducted by Which? (2008) indicated that over 60% of the UK population are unclear as to what are NMOs and the products that contain them. The thesis used 'worst case' scenario to assume that a maximum of 60% of the population will therefore continue to use products with NMOs and not use or invest in 'all natural' or organic products. Hence, a maximum of 36.6 million people will continue to use products containing NMOs without substitution, resulting in approximately 2880tonnes of NMOs potentially reaching the environment (Table D-2).

Economic importance

A comparative methodology for estimating the economic value of innovation in nanotechnologies

In 2010, the Department of Environment, Food and Rural Affairs (DEFRA) produced a report 'A comparative methodology for estimating the economic value of innovation in nanotechnology' to perform a comparative valuation between a nano enabled product and an incumbent product on the market. The methodology estimates the value over a set timeframe, exploring the benefits of products containing NMOs to the consumer, producer as well as the wider benefits to society.

The valuation methodology used in this study was adopted from DEFRA (Walsh et al., 2010) and was tested and validated through a series of case studies, by a stakeholder workshop involving government departments, academia and the industry, and a steering group comprising policy makers and economists from a number of UK government departments (Walsh et al., 2010). Three main stages were used to calculate the value of a nano-enabled product as outlined in Figure D-1.

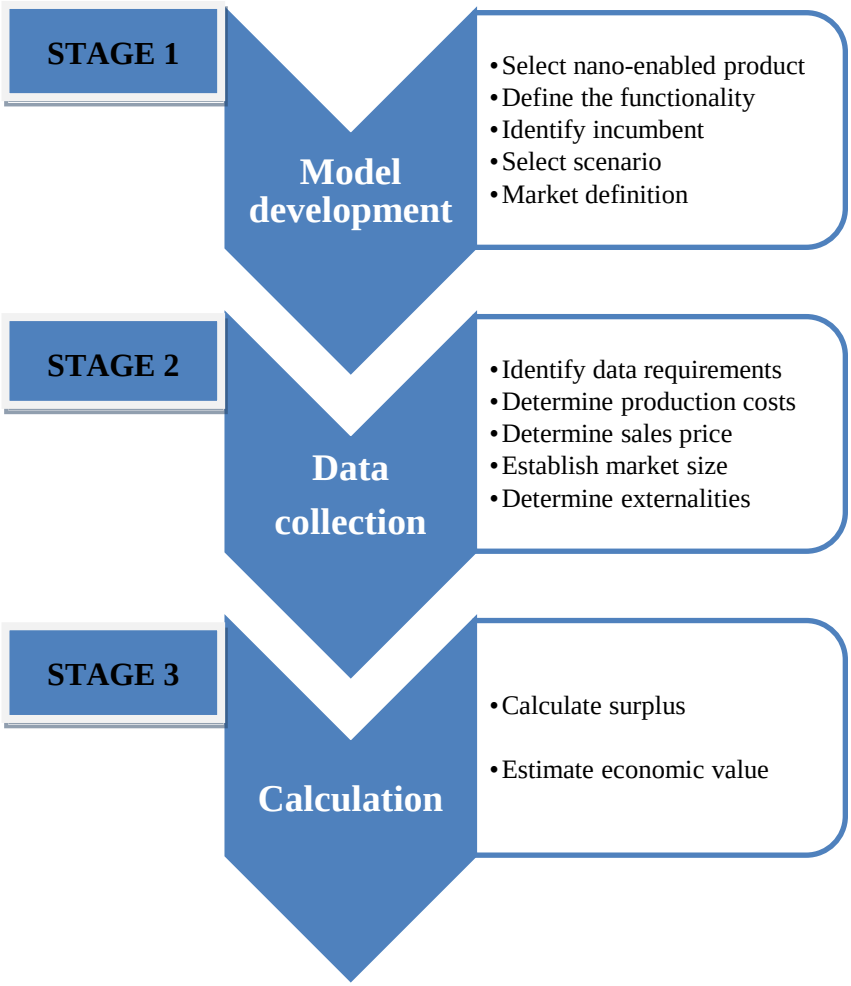


Figure D-1: Methodology for estimating the economic evaluation of nano-enabled cosmetic products

Stage 1 Model development

This stage defined the structure of the calculation. It identified the nano-enabled product to ensure that the product group is neither focused on a single product nor covered too wide an area. If the selection is too narrow, normal market variations may lead to a specific product, technology or company failing or performing considerably better than expected, thereby reducing the accuracy of the calculation. Conversely, an area that is too broad is difficult to define as the products will be very diverse, so determining the value of particular parameters may prove extremely challenging. The functionality of the nano-

enabled product is then defined using a decision matrix to ensure that the correct incumbent technology is selected (Table D-3). This also allows the removal of consumer valuation (CV) from the estimation of economic value. Consumer valuation is defined as being the consumers' willingness and ability to pay for a particular product. This is subjective and given the limited availability of these data for emerging nanotechnologies, the methodology assumed that such data is not available and functionality of the incumbent technology matches that of the nano-enabled product. The result of this is that CV is eliminated from the calculation.

An incumbent product that best matches the functionality of the nano-enabled product was defined and a specific scenario was selected to simplify the number of variables needed to calculate the value of the nano-enabled product. This assessed the effect of the nano-enabled product and its functionalities on the market size. One of the four scenarios identified was chosen to determine the correct scenario for the type of nano-enabled product innovation below. The geographic location and the timeframe over which the value of the nano-enabled product was assessed were then selected to define the market to specify whether the nano-enabled product captured the entire market of the incumbent.

Table D-3: Decision matrix to determine functionality of nano-enabled products

		FUNCTIONALITY	
		Single	Multiple
MARKET	Increased	Nano-enabled product increases the size of the market compared to the incumbent	Nano-enabled product enhances performance over the incumbent and increases the market size
	Fixed	Nano-enabled product does not extend the market of the incumbent	Nano-enabled product provides enhanced performance over that of the incumbent

Stage 2 Data collection

Stage 2 identified the data requirements for the model and described the methods used to collect data. Where data were readily available from manufacturers and suppliers, these were used and where data were a series of proxies are described to help determine values. The parameters required to estimate the valuation of nano-enabled cosmetic products for the model is described in Table D-4.

Table D-4: Parameters for evaluation of nano-enabled products

Parameter	Description
Q_0	Initial market quantity of incumbent - quantity of products sold in the UK containing sunscreen active agents
P_0	Incumbent price - retail price of each unit of cosmetic containing the incumbent
C_A	Incumbent unit production cost – the unit cost for producing the incumbent product
C_N	Nano-enabled product unit production cost – the unit cost for producing the nano-enabled product
P_N	Nano-enabled product price
β	Price elasticity - sensitivity of the market to changes in price. β = -1 as price of a product falls, there is a proportional increase in the number of sales
%A	% of production of the incumbent product located in the UK
%N	% of production of the nano-enabled product located in the UK
T	Timeframe for evaluation, set at 20 years

Q_0 and P_0 were derived from market research data by Euromonitor International (Euromonitor International, 2009a). C_A was estimated using the average sector margin approach (Equation D.1).

$$C_A = Sales\ price \times \mu \ where\ \mu = {}^{COGS}/_{sales} \quad \textbf{(D.1)}$$

μ represents the proxy COGS/sales ratio and COGS is the total production costs for the company or the 'cost of goods sold'. The sales price was estimated by dividing the total sales figure per annum by the number of cosmetic products sold in the UK based on market research from Euromonitor International. The proxy margin was developed using publicly available corporate sales data from annual reports from a group of companies that collectively represent the incumbent market. The COGS were derived from company's total profits/losses minus their sales figures averaged over a 3 year period. The companies chosen were the major manufacturing and production companies for cosmetics in the UK. They included Procter & Gamble Co., Unilever, L'Oréal Groupe, Estée Lauder Cos Inc, Alliance Boots Plc, Johnson & Johnson Inc and Beiersdorf AG.

The unit production cost of the nano-enabled product (C_N) is calculated on the assumption that the nano-enabled product is replacing an incumbent technology by reducing the amount of material required (replacement of bulk sunscreen agents by the nano metal oxides) but otherwise uses the same production process, thereby changing the efficacy of the product, but leaves the other constituents of production cost fairly constant. Therefore the production costs for the nano-enabled product are proportional to the change in efficacy, and are given by Equation D.2. It is assumed for this study that the production costs of both the nano-enabled product and the incumbent are assumed to be fixed over the lifetime of the study. %A and %A was estimated based on existing scientific literature.

$$C_N = \left(\frac{F_A}{F_N}\right) \times C_A \qquad \textbf{(D.2)}$$

Where F_A and F_N are the volumes of material needed to perform the function.

Once the initial parameters have been established, this data is then used to determine the sales price for the nano-enabled product over time and the market size for the nano-

enabled product at the launch of the product, and throughout the time period of the evaluation using demand analysis based upon knowledge of the current market. Assumptions were made on the price elasticity and the functional form of demand. This approach is used because knowledge of the actual demand for NMOs as a UV filter is unavailable. The sales price for the nano-enabled product over 20 years is calculated using Equation D.3 and the linear trend in price reduction over the lifetime of the product is calculated in Equation D.4

$$P_{20} = {C_N}/{\mu_0} \quad where\ \mu_0 = \frac{C_A}{P_0} \qquad \textbf{(D.3)}$$

Where μ_0 is the cost to sales price ratio for the incumbent product

$$PRT = \left(\frac{P_0 - P_{20}}{T}\right) \qquad \textbf{(D.4)}$$

Where PRT is price reduction trend

The market size was derived using Equation D.5. It was assumed that the size of the market will increase with a corresponding decrease in sales price. The market quantity was calculated for the 20 year period based on the linear trend in price reduction.

$$Q_0 = \alpha P_t^{\beta} \quad where \quad \alpha = Q_0 \times P_0^{-\beta} \qquad \textbf{(D.5)}$$

%A and %N was estimated based on market research data. Externalities were not considered for this study as environmental concerns were assessed in Chapter 6 and R&D expenditure was expected to be similar for both nano enabled and incumbent products due to the continuous levels of R&D in the cosmetic industry (COLIPA, 2008).

Stage 3 Calculation

The data gathered from Stage 2 was used to calculate the benefits (producer and consumer surplus) of the nano-enabled product as compared to the incumbent. The

producer surplus was calculated using Equation D.6. When direct replacements of nano-enabled products resulted in increased sales, the increasing market size over time meant that the additional profit made by the producers from additional sales needed to be considered (Equation D.7)

$$PS_t = (P_t - C_t)Q_t \quad \textbf{(D.6)}$$

$$\Delta PS_{(t.0)} = (P_t - C_N)Q_t - (P_0 - C_A)Q_A \quad \textbf{(D.7)}$$

Where PS is producer surplus

Consumer surplus was calculated in Equation D.8. The equation considered that consumers get the product for a lower price and additional consumers bought the product. To accurately estimate the change in consumer surplus it is necessary to perform integration due to the non-linear nature of demand.

$$CS_{(t,0)} = \alpha \times \ln\frac{P_0}{P_t} \quad \textbf{(D.8)}$$

where CS is consumer surplus

The overall change in surplus is then calculated to provide a comparative calculation of nano-enabled product against an incumbent alternative. The overall change in mean value added per period is given by Equation D.9.

$$\Delta S_{(t,0)} = \Delta PS_{(t,0)} + \Delta CS_{(t,0)} \quad \textbf{(D.9)}$$

Where $\Delta S_{(t,0)}$ is the change in total surplus at time t.

The overall surplus value was then modified taking into account diffusion of the product into the market place (time it takes for the nano-enabled product to displace the incumbent) to estimate the economic valuation of the nano-enabled product (Equation D.10). The risk associated with these developing technologies is taken into account through the use of empirical discount rates, which reduced the value of a technology in proportion to its distance from market (Equation D 11).

$$\Delta S^{D}_{(t,0)} = \Delta S_{(t,0)} \times D_t \quad \textbf{(D.10)}$$

Where $\Delta S^{D}_{(t,0)}$ is the diffusion adjusted change in surplus at time t and D_t is the fraction of market share afforded by the nano-enabled product at time t.

An additional calculation was performed that gives the total value of the technology, the Net Present Value (NPV). This is represented by Equation D.11. In most stages of this methodology, assumptions were required for the calculation. All calculations were done in Excel using the spreadsheet application.

$$NPV = \sum_{(t=1)}^{\infty} \Delta S_{(t,0)} \times R_t \quad \textbf{(D.11)}$$

Results

Stage 1 Model development

Selecting nano-enabled product

Cosmetics using NMOs were used as the nano-enabled products. Traditional sunscreens are cosmetically unappealing as they consist of thick formulations that do not blend well into the skin. In recent years, manufacturers have started replacing bulk TiO2 and ZnO commonly used in cosmetics for NMOs. Cosmetics represent a group of products with a well-defined single market, for which data on both the incumbent and nano enabled products are available.

Determining functionality

The functionality of sunscreens in cosmetics is to protect the skin from harmful UV radiation, thus reducing aging/wrinkles of the skin. The benefit of using nano enabled sunscreen resolved the problem of the unsightly white film of traditional sunscreens and created a vehicle that is more transparent, less viscous, and blends into the skin more easily. Products containing these NMOs need a less amount of material requirement to

generate the same functionality. However, this defined functionality does not capture the whole value of the nano-enabled products for all products. Some products such a facial moisturisers and washes have multiple functions such as softening and cleansing, hence, the overall benefit is likely to be underestimated.

Identifying incumbent

The incumbent products used in this study were cosmetics which use sunscreen active ingredients but not in its nanoform. This included sunscreens, facial moisturiser, anti-aging creams, face wash and body lotion.

Selecting scenario

The introduction of NMOs is a direct substitution of the existing larger scale ZnO and TiO_2 particles used in cosmetics as sunscreen ingredients. The nano-enabled product replaces and over time gains the entire market share of the existing product (because of its lower production costs). Additionally the product will have increased sales over the incumbent product as the sales price falls over time. The magnitude of this increase in sales is determined by the magnitude of the "price elasticity" (sensitivity of consumer demand to a change in price). It is expected that as consumers becomes increasingly aware of the harmful effects of UV radiation, there will be increased demand for products containing UV filters. Therefore, the scenario used will be that the nano-enabled products directly replace the incumbent products, with increased sales in the entire market share over a period of time.

Market definition

The study was conducted for the UK market using data sourced and analysed from Euromonitor International (Euromonitor International, 2008) and the calculations were done annually for a 20 year period, since this is the life of a patent.

Stage 2 Identifying data requirement

According to Appendix B, approximately 73.4% of the cosmetics make up the initial incumbent market. Since approximately 1099.4 million units of cosmetics are sold annually, it is estimated that the initial market quantity of incumbent (Q_0) is estimated at 806.66 million units per annum. The retail price of each unit of cosmetic containing the incumbent (P_0) is averaged by the total sales per annum divided by the total number of units sold in the UK (Euromonitor International, 2009a).

P_0 = £9406.2 million/2600million units = £3.62

Determining production costs

Table D-5: Average margins from company's reports

Company	2007	2008	2009	2010	Average
Procter & Gamble Co.		84.8%	82.5%	83.9%	83.7%
Unilever	89.7%	87.0%	90.8%		89.2%
L'Oréal Groupe		88.9%	89.7%	88.5%	89.0%
Estée Lauder Cos Inc	93.6%	94.0%	97.0%		94.9%
Alliance Boots Plc		99.9%	99.4%	96.8%	98.7%
Johnson & Johnson Inc	82.7%	79.7%	80.2%		80.9%
Beiersdorf AG		90.5%	93.4%	94.7%	92.9%
AVERAGE (μ value)					**89.9%**

Incumbent product cost (C_A) = £3.62 * 89.9% = £3.25

Nano-enabled product cost (C_N) = (30% cheaper to produce than C_N) = £2.28

Determining sales price

The nano-enabled sales price is assumed to be equal to that of the incumbent since where there is no additional functionality of the nano enabled product. Both products function to reduce UV radiation from the skin.

P_N = £3.62

Establishing market size

The market size is expected to increase over the 20 year period as the nano enabled products are direct substitutes for the incumbent products. The nano-enabled product replaces and over time gains the entire market share of the existing product (because of its lower production costs). Additionally the product will have increased sales over the incumbent product as the sales price falls over time. The magnitude of this increase in sales is determined by the magnitude of the "price elasticity" (how sensitive consumer demand is to a change in price). Table D-6 illustrates that the market size would increase to1149.84 million units as the unit price of nano enabled product fall to £2.54 over the next 20 years.

Table D-6: Predicted changes in market size over a 20 year period

Year	Price of the nanotech (£)	Market size (mu)
2008	3.62	806.66
2009	3.57	818.88
2010	3.51	831.48
2011	3.46	844.47
2012	3.40	857.87
2013	3.35	871.70

2014	3.30	885.99
2015	3.24	900.75
2016	3.19	916.02
2017	3.13	931.81
2018	3.08	948.15
2019	3.03	965.08
2020	2.97	982.63
2021	2.92	1000.82
2022	2.86	1019.70
2023	2.81	1039.30
2024	2.76	1059.68
2025	2.70	1080.87
2026	2.65	1102.92
2027	2.59	1125.89
2028	2.54	1149.84

A report generated by DEFRA entitled 'A scoping study into the manufacture and use of nanomaterials in the UK' estimated that 55% of production of the nano-enabled product using NMOs was located in the UK (%N) (Department for Food and Rural Affairs, 2005). (Cosmetic Toiletry and Perfumery Association, 2009) estimated that approximately 70% of cosmetic production is located in the UK based on sales and import data (%A).

Stage 3 Calculation

Table D-7- gives details for the calculation of consumer, producer and overall surplus yearly over the 20 year period. As the nano enabled product is already on the market a discount rate of 4% is assumed. Over 20 years, the use of NMOs in cosmetics will provide benefits worth £5 942 000.00 and the net present value to the UK economy is predicted at £11 374 000.00.

Table D-7: Market value added from nano-enabled products

	Surplus				Diffusion Rate		Discounted value	
Year	Producer surplus	Consumer Surplus	$\Delta S_{(t,0)}$		%	$\Delta S_{(t,0)}{}^{D}$	Year	MVA (£million)
2008	385.583	0.00	385.583		0.2	0.7711	1	0.742
2009	370.259	43.91	414.165		0.7	2.899	2	2.680
2010	354.464	88.48	442.945		2.0	8.859	3	7.876
2011	338.175	133.75	471.922		5.0	23.596	4	20.170
2012	321.368	179.73	501.096		10.9	54.619	5	44.893
2013	304.020	226.44	530.463		20.5	108.745	6	85.943
2014	286.103	273.92	560.020		34.0	190.407	7	144.694
2015	267.589	322.18	589.765		50.0	294.883	8	215.468
2016	248.448	371.25	619.694		66.0	408.998	9	287.357
2017	228.646	421.15	649.801		79.5	516.592	10	348.991
2018	208.150	471.93	680.082		89.1	605.953	11	393.616
2019	186.922	523.61	710.529		95.0	675.003	12	421.605
2020	164.923	576.21	741.136		98.0	726.313	13	436.205
2021	142.108	629.78	771.893		99.3	766.489	14	442.629
2022	118.433	684.36	802.790		99.8	801.185	15	444.869
2023	93.848	739.97	833.816		100.0	833.816	16	445.181
2024	68.298	796.66	864.959		100.0	864.959	17	444.047
2025	41.727	854.47	896.201		100.0	896.201	18	442.390
2026	14.071	913.46	927.528		100.0	927.528	19	440.244
2027	-14.736	973.65	958.918		100.0	958.918	20	437.638
2028	-44.770	1035.12	990.349		100.0	990.349	21	434.599
							Value over 20yrs	**5,942**
							Terminal value	**11,374**

MVA-market value added

The NMOs in the cosmetic industry are used as substitutes for sunscreen agents due to their ease of application on the skin and aesthetic value, hence the alternative to NMOs

are the use of naturally occurring NMOs or other 'all natural', organic ingredients containing UV absorbing properties. This methodology was redone to estimate the current value of using 'all natural' alternatives for NMOs in cosmetics. The number of products sold in the UK containing the NMOs was estimated at 292.74 million per annum from the product survey conducted. The incumbent products were considered to be cosmetics containing nano-enabled products and a discount rate of 1.08 was used as cosmetics containing 'all natural' alternatives to NMOs are not currently on the market. The amount of products produced in the UK for both the incumbent and the alternatives were estimated to be equal as it is assumed that the alternatives would directly replace the nano enabled products (55%).

Market competition (Porter's 5 Forces Analysis)

Porter's 5 Forces Analysis deals with factors outside an industry that influence the nature of competition within it, the forces inside the industry (microenvironment) that influence the way in which firms compete, and so the industry's likely profitability is conducted in Porter's five forces model. In general terms, the greater the competitive forces in the industry, the more pressure you are likely to find on prices. Whereas, the weaker the competitive forces in the industry, the less pressure you are likely to have on prices (Porter, 1980).

Five Forces Analysis assumes that there are five important forces that determine competitive power in a business situation as outlined in Table D-8. The forces were brainstormed for the cosmetic industry and checked against the criteria for each force and given a score. A '--/++' scale was used to quantitatively determine the effects of market competition of the different RMOs. A score of "++" meant strongly favours the economy (less competition, hence greater profits), "+" moderately favours the economy, "0" sign

for no effect, "--" strongly against the economy (more competition, hence less profits) and "-" for a force moderately against the economy.

Table D-8: Analysis of market competition using Porter's 5 forces theory

Porter's 5 Forces	Description		Option 1: Do nothing	Option 2: Substitution	Option 3: Temporary restriction	Option 4: Total restriction
Supplier Power	Ease for suppliers to drive up prices due to limited supply and uniqueness of NMOs which increases strength and control over buyer. Cost of switching from one supplier to another.	Fewer supplier choices imply increased demand for goods and more powerful suppliers. Many supplier choices imply reduced demand for goods and less powerful suppliers.	++	++	-	- -
Buyer Power	Ease for buyers to drive prices down for cosmetics containing NMOs. This is driven by the number of buyers, the importance of	Few powerful buyers, then the consumers are often able to dictate terms to the cosmetic industry. Many buyers, then the cosmetic industry are often able to dictate	++	- -	-	-

	each individual buyer to your business and the cost to switch from your products and services to others	terms to consumer.				
Competitive Rivalry	Number and capability of your competitors.	Many competitors, equally attractive products, hence little power as suppliers and buyers will go elsewhere if the price is not satisfactory. If the cosmetic industry is a monopoly, then tremendous strength.	- -	++	+	0
Threat of Substitution	Ability of your customers to find a substitute	Substitution is easy and substitution is viable, then this weakens power Substitution is difficult and substitution non-viable, then this strengthens power	-	- -	++	++
Threat of	Ability of people to enter	Little costs, time or money to enter	++	- -	0	0

New Entry	your market	market and compete effectively, fewer economies of scale in place (no patents), then new competitors can quickly enter your market and weaken your position. Strong and durable barriers to entry, then preserve a favourable position and take fair advantage of it				
Total scores	Market competition		++	- -	+	-

Stakeholder preferences

Surveys carried out on public perception on NMOs were used for this criterion since surveys specific to NMOs in cosmetics were inadequate for the purpose of this study. A survey carried out by Gaskell et al., (2005), sampling over 1000 people in the UK (confidence limits of ± 0.8%) asked "Do you think nanotechnology will improve our way of life in the next 20 years?" 61% of adults did not know what nanomaterials were which indicated that 61% of the UK population may continue to use nanomaterials unaware of potential concerns. 24% of the population sampled in the UK agrees that nanomaterials will improve the way of life and represented the maximum population that may encourage further research in this area. 5% believed that nanomaterials will make things worse and thus represented the maximum population which may support the total restriction of the use of nanomaterials in products.

An article in Cosmetic Business stated that the market for organic non-food products such as cosmetic products has increased by approximately 33% over the last year indicating that a maximum of 33% of the population may be willing to purchase an alternative to NMOs in cosmetics. Hence, a maximum of 66% of population will still be willing to use cosmetics containing NMOs. This represented a vague estimate based on the US market (Cosmetics business, 2006)

The flexibility of implementing each RMO based on conformity to legislation and policy as well as research and development were assessed using an ordinal scale and ranked. A scale of 1-4 was used with 1 being the easiest to conform (do nothing) and 4 the most difficult (total restriction). Since limited data are available for alternatives and more R&D is needed, substitution was given a score of 3. Temporary restriction was given a score of

2 as this is a gradual process and within the next 5 years the implementation of REACH legislation on chemicals can influence the use of CECs in products.

Assignment of weightings

Weightings were assigned using the pairwise comparison method also known as the Analytical Hierarchy Process (AHP). This procedure supported the MCA by assigning quantitative weightings to each sub-criterion. Each pair of sub-criteria is compared and the more important of the two sub-criteria is selected. Subsequently, the two sub-criteria are quantified in terms of what extent the first sub-criterion is more important than the other. The method then converted these comparisons for all pairs of sub-criteria to quantitative weightings for all criteria.

The appropriate weighting for each sub-criterion, that is, the importance of the sub-criteria investigated for this thesis was determined by investigating which sub-criterion was most important to consumers when purchasing cosmetics containing NMOs. A survey conducted by Which?, (2008) indicated that over 60% of the UK population are unclear as to what are NMOs and the products that contain them, whilst a survey conducted by Ling et al., (2003) showed that 66% of the participants purchase sunscreens every year, even though these products contain the highest concentrations of NMOs in cosmetics (2-25% of formulation). Additionally, the potential environmental impacts of these nanoparticles are not completely understood scientifically, which suggests that limited information of the concerns of the NMOs are passed on to the consumer. The weighting used for the thesis is listed in Table D-9. A scale of 1-8 was used where 8 denoted the most heavily weighted or most important sub-criterion, to account for differing levels of importance of each sub-criterion.

Table D-9: Weighting criteria for MCA

Criterion	Sub-criterion	Weight	Averaged weighting
Environmental effects	Water quality impairment	5	4
	Soil quality impairment	2	
	Sediment quality impairment	3	
	Ecological impairment	6	
Economic importance	MVA	7	5.5
	Market competition	4	
Stakeholder preference	Public perception	8	4.5
	Flexibility	1	

APPENDIX E

MCA report for the management of the use and disposal of NMOs in cosmetic products

This report was created by DEFINITE for Windows version 3.0.0.3.

Session: MCA for managing CECs in products [C:\Definite3.0\Software\MCA for managing CECs in products (old).]

Problem Definition

To determine the best RMO for the use and disposal of CECs in cosmetics.

Alternatives:

Option 1 - Do Nothing Option: Continue the manufacturing, marketing and use of NMOs in cosmetic products in the UK.

Option 2 – Substitution: Substitute the NMOs used in cosmetics with naturally occurring NMOs or other all natural ingredients.

Option 3-Temporary Restriction: Temporarily restrict the use of NMOs in cosmetic products for a maximum of 5 years.

Option 4- Total Restriction: Prohibit the manufacture, marketing and use of NMOs in cosmetic products at a community-wide level with phase out of the substance within 24 months

Effects

Table E-1: Effects table for environmental effects, economic importance and stakeholder preferences

Environmental effects		**Type of scale**	**Type of effect**	**Unit**
Water quality impairment	Changes in concerns over surface water quality in freshwater aquatic environments	Interval scale	Costs	ug/l
Sediment quality impairment	Changes in concerns over sediment quality in freshwater aquatic environments	Interval scale	Costs	ug/l
Soil quality impairment	Changes in concerns over soil quality in a terrestrial environments	Interval scale	Costs	ug/l
Ecological impairment	Changes in concerns over aquatic and terrestrial flora and fauna	Ratio scale	Costs	%
Economic importance		**Type of scale**	**Type of effect**	**Unit**
MVA	Market value added to the economy from the final benefits accrued from producer and consumer surplus	Monetary scale	Benefits	£
Market	The potential for profitability of the cosmetic industry due to market	--/++ scale	Benefits	-/+

competition	competition			
Stakeholder preference		**Type of scale**	**Type of effect**	**Unit**
Public preferences	Population in the UK willing to support each RMO	Ratio scale	Costs	%
Political preferences	Ease of implementing each RMO based on conformity to legislation and policy	Ordinal scale	Costs	ordinal

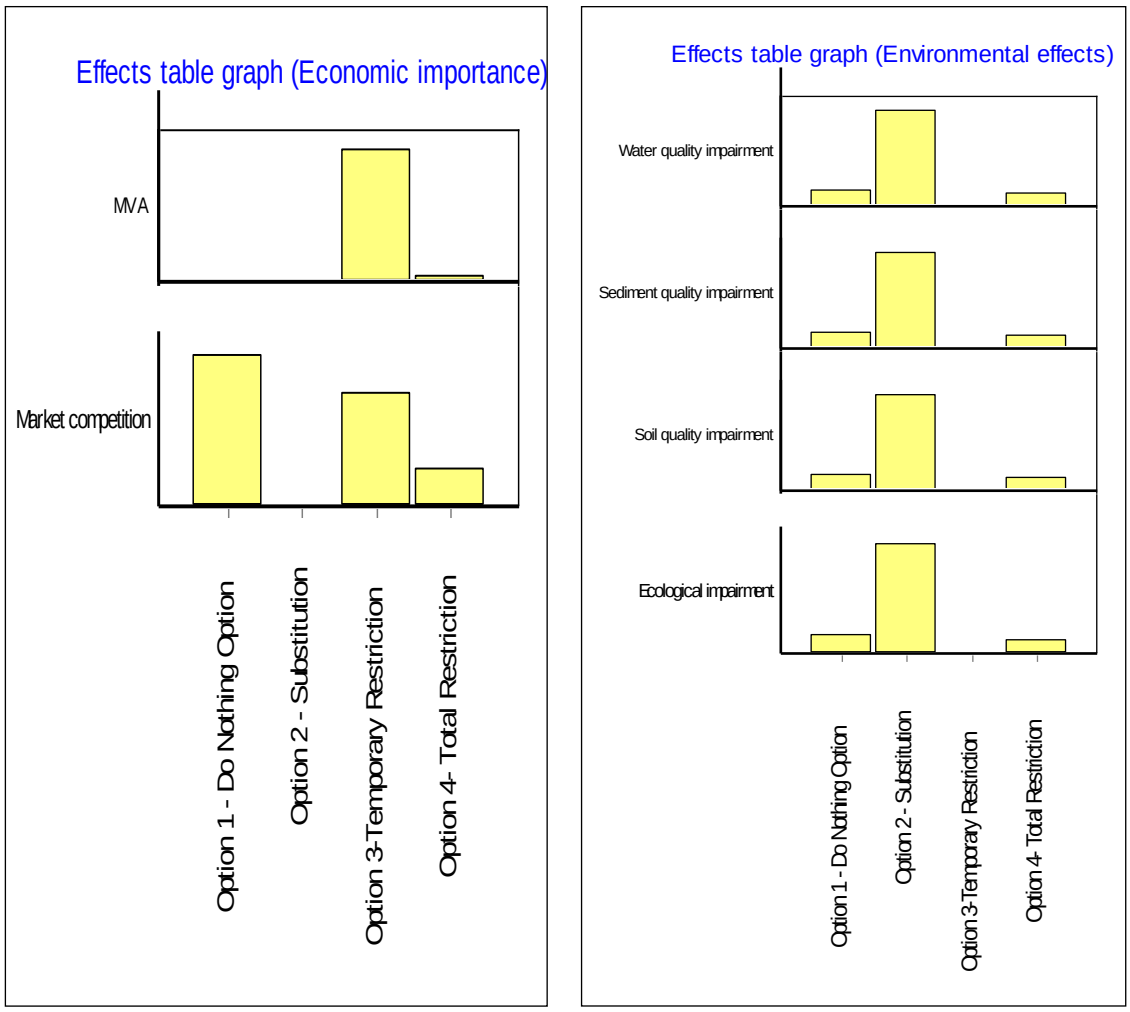


Figure E-1: Effects graph for environmental effects and economic importance

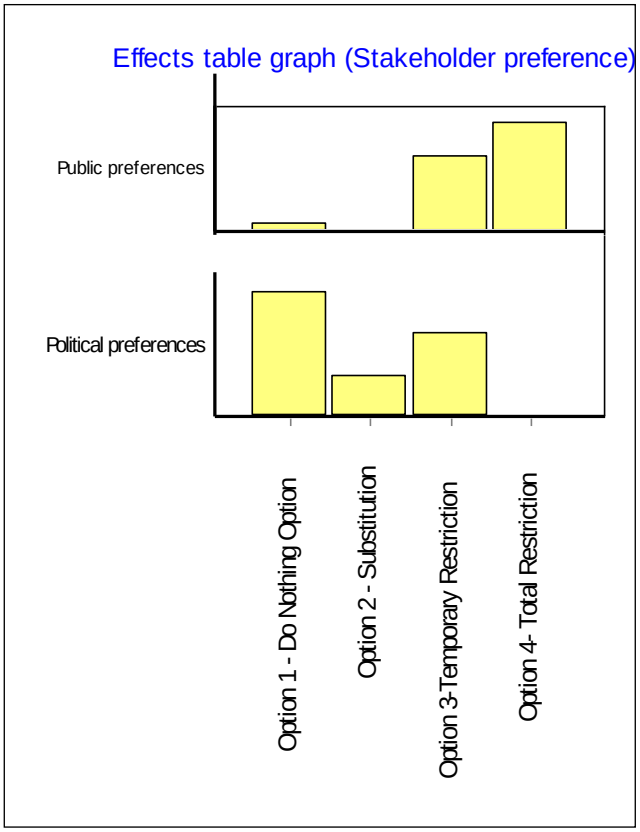


Figure E-2: Effects graph for stakeholder preferences

Multicriteria analyses

Multicriteria analysis: MCA 1: Weighted summation {maximum (convex, interval); Pairwise Comparison (Economic importance: 0.637)}

Method:

Weighted summation

Standardization:

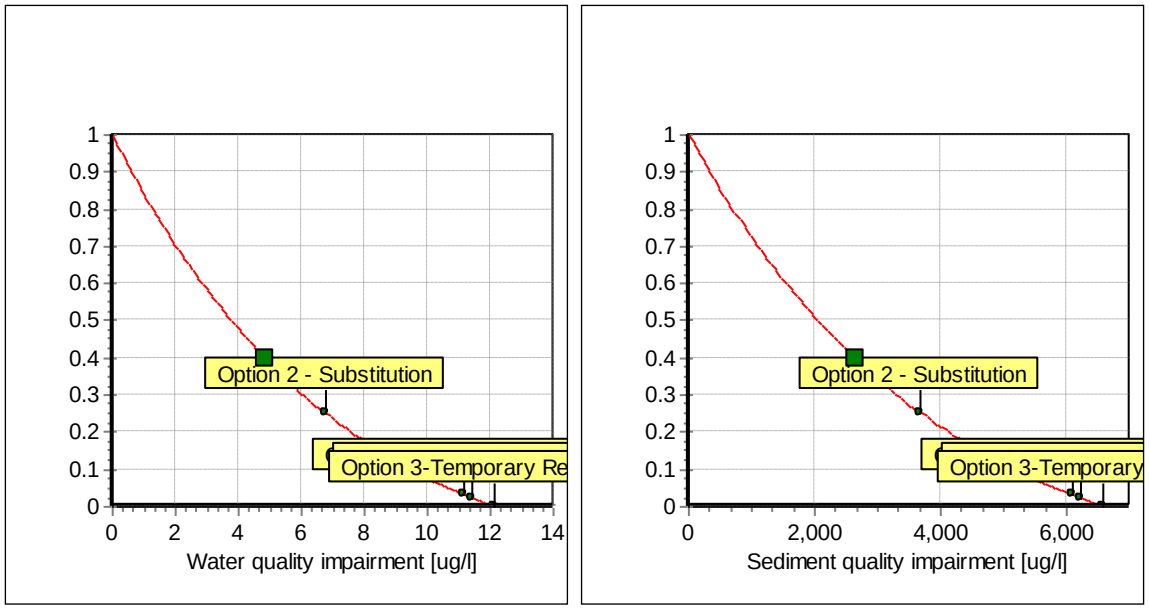


Figure E-3: Standardization graphs for water quality impairment and sediment quality impairment

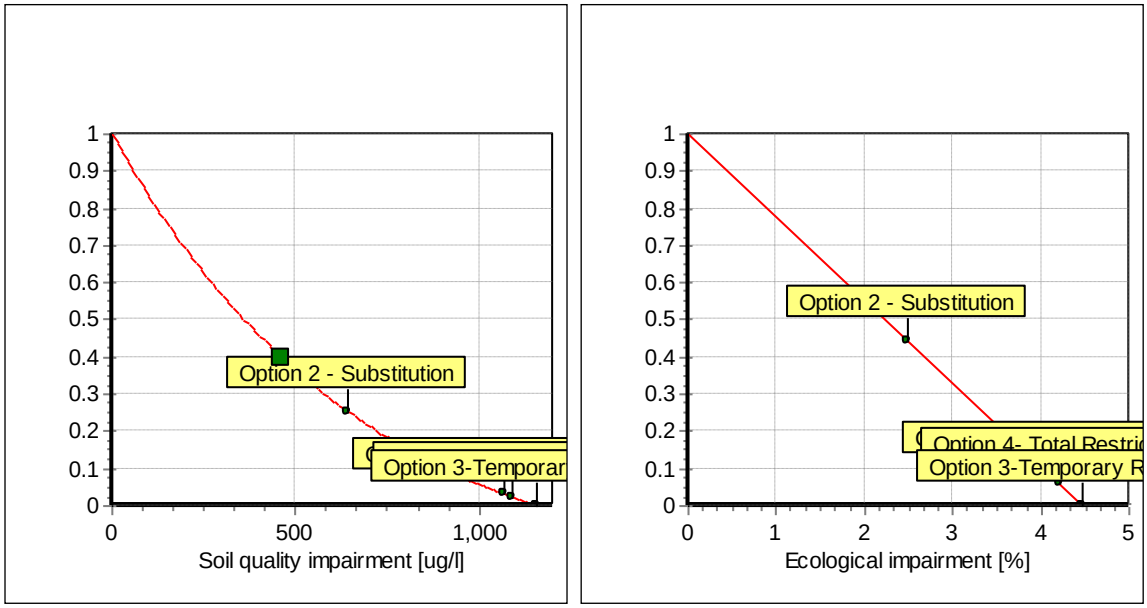


Figure E-4: Standardization graphs for soil quality impairment and ecological impairment

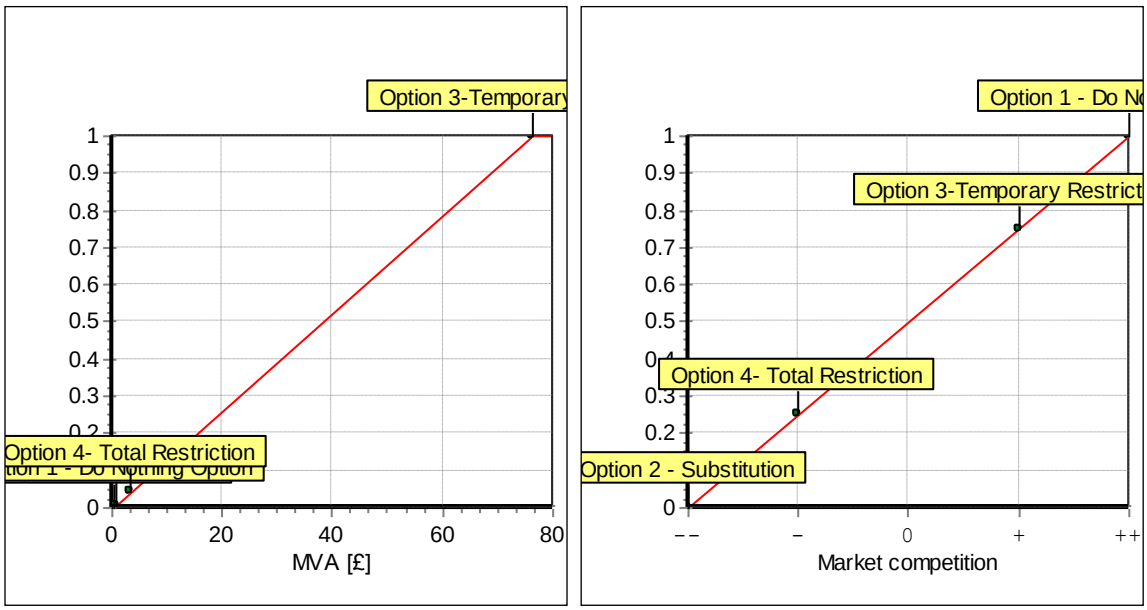


Figure E-5: Standardization graphs for MVA and market competition

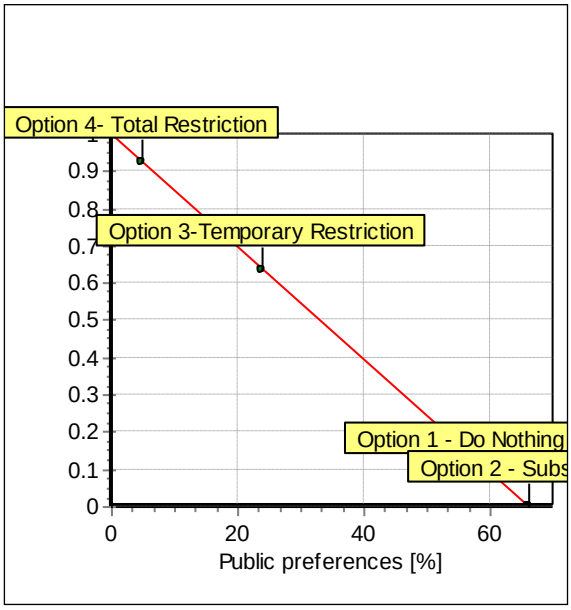


Figure E-6: Standardization graphs for public preferences

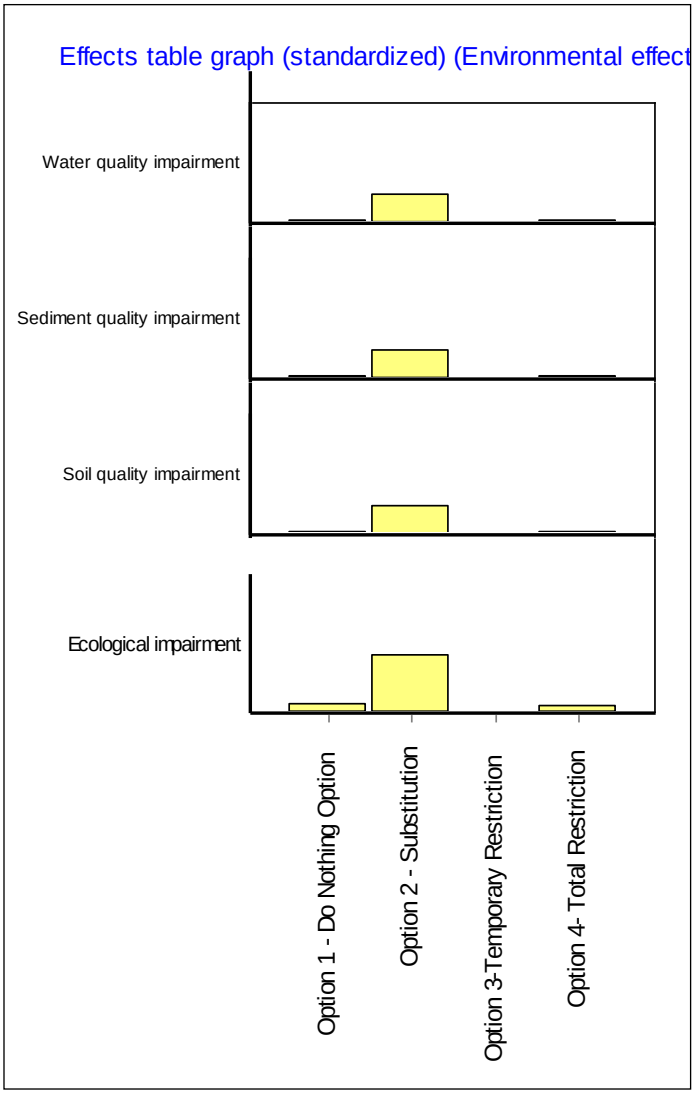


Figure E-7: Effects graph (standardized) for environmental effects

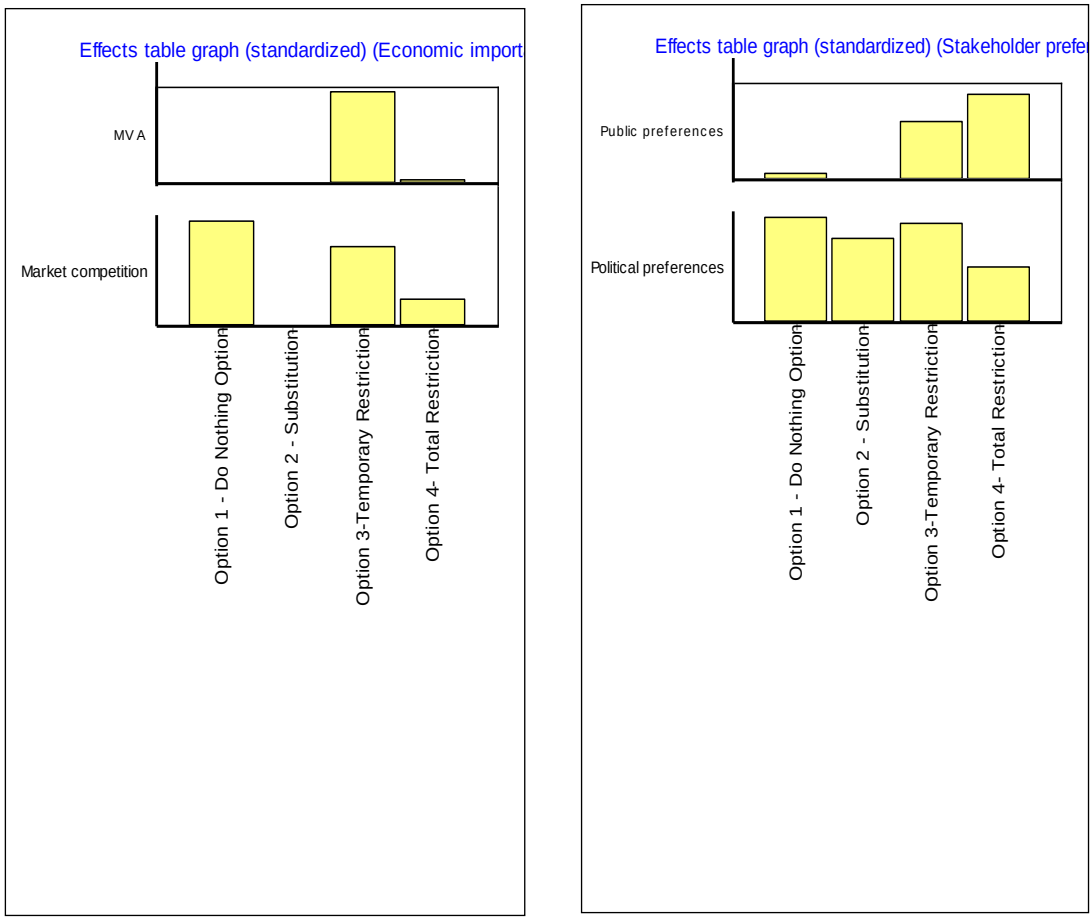


Figure E-8: Effects graph (standardized) for economic importance and stakeholder preference

Weightings:

Weights settings: Pairwise comparison

Table E-2: Actual weights

	Weighting level 1	Weighting level 2	Actual weighting
Environmental effects	0.105		
Water quality impairment		0.288	0.030
Sediment quality impairment		0.143	0.015
Soil quality impairment		0.064	0.007
Ecological impairment		0.505	0.053
Economic importance	0.637		
MVA		0.75	0.478
Market competition		0.25	0.159
Stakeholder preference	0.258		
Public preferences		0.875	0.226
Political preferences		0.125	0.032

Table E-3: Weights perspectives

	Total	Perspective: Environmental effects	Perspective: Economic importance	Perspective: Stakeholder preference
Environmental effects	0.105	0.66	0.17	0.17
Economic importance	0.637	0.17	0.66	0.17
Stakeholder preference	0.258	0.17	0.17	0.66

Results:

Table E-4: MCA 1: Weighted summation {maximum (convex, interval); Pairwise Comparison (Economic importance: 0.637)}

	Total	Perspective: Environmental effects	Perspective: Economic importance	Perspective: Stakeholder preference
Option 3-Temporary Restriction	0.77	0.27	0.73	0.60
Option 4- Total	0.29	0.19	0.22	0.60

Restriction				
Option 1 - Do Nothing Option	0.22	0.11	0.21	0.18
Option 2 - Substitution	0.06	0.25	0.08	0.12

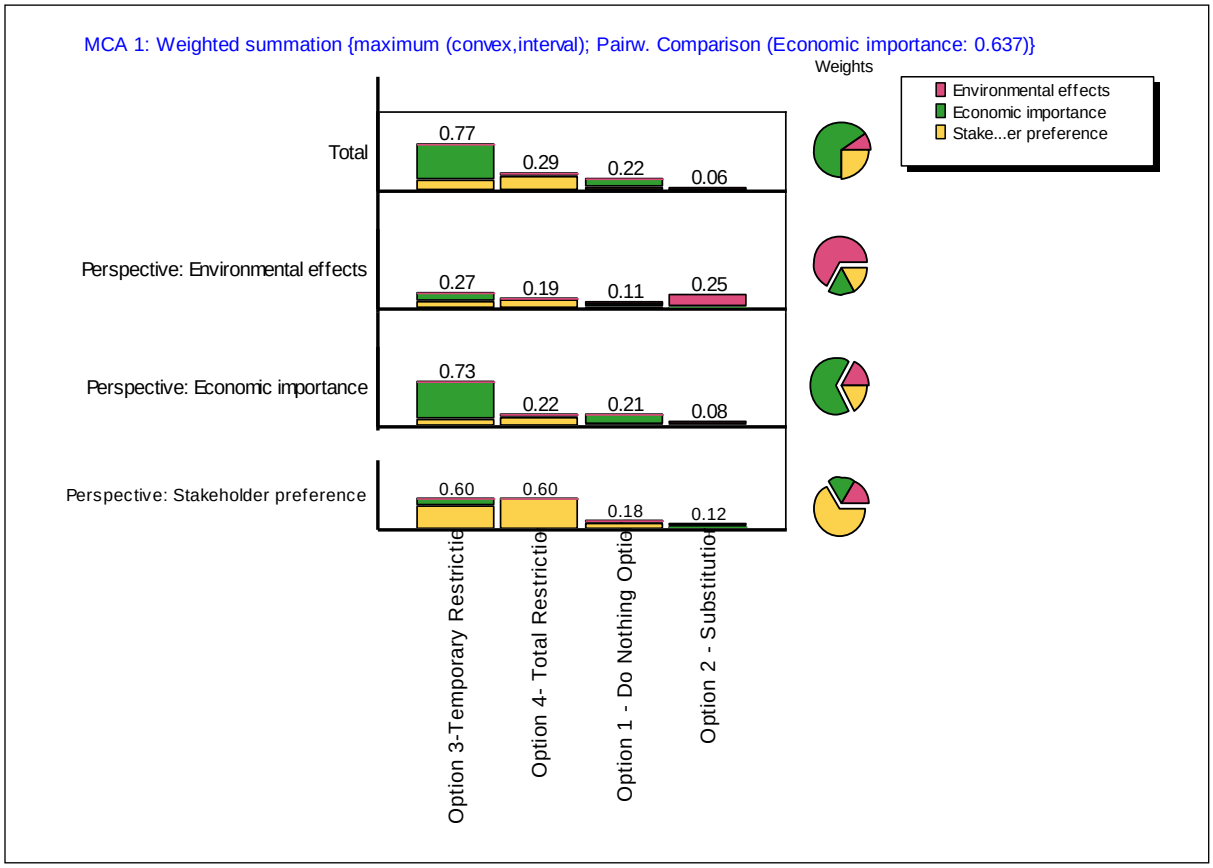


Figure E-9: Weighted summation {maximum (convex, interval); Pairwise Comparison (Economic importance: 0.637)}

Sensitivity analyses

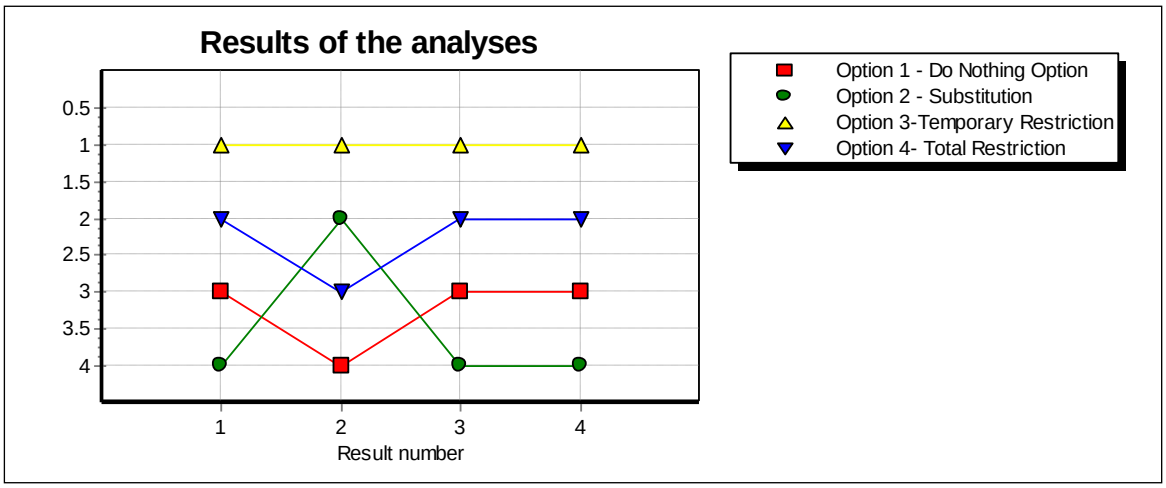


Figure E-10: Results of the analyses

Table E-5: Comparison of results

1	MCA 1: Weighted summation {maximum (convex, interval); Pairwise Comparison (Economic importance: 0.637)}	Total
2	MCA 1: Weighted summation {maximum (convex, interval); Pairwise Comparison (Economic importance: 0.637)}	Perspective: Environmental effects
3	MCA 1: Weighted summation {maximum (convex, interval); Pairwise Comparison (Economic importance: 0.637)}	Perspective: Economic importance
4	MCA 1: Weighted summation {maximum (convex, interval); Pairwise Comparison	Perspective: Stakeholder preference

	(Economic importance: 0.637)}	

Uncertainty Analysis

[ScorUnc.: 0.00, 25.00, 25.00, 25.00...]

Table E-6: Results of Uncertainty Analysis

Alternatives	Total	Score (sens.anal.)	Conclusion
Option 3-Temporary Restriction	0.77	4.00	1
Option 4- Total Restriction	0.29	2.90	2
Option 1 - Do Nothing Option	0.22	2.10	3
Option 2 - Substitution	0.06	1.00	4

Table E-7: Settings

	Score Unc. [%]
Environmental effects	
Water quality impairment	25
Sediment quality impairment	25
Soil quality impairment	25
Ecological impairment	25
Economic importance	
MVA	25
Market competition	50
Stakeholder preference	
Public preferences	50
Political preferences	50

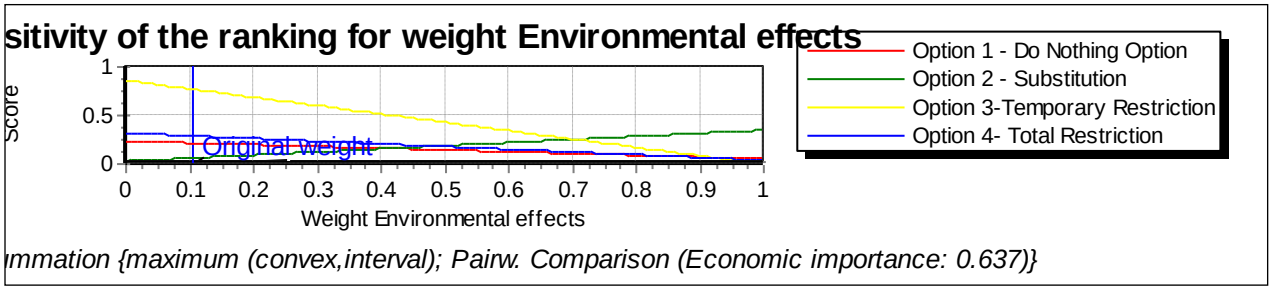


Figure E-11: Sensitivity of the ranking for weight Environmental effects

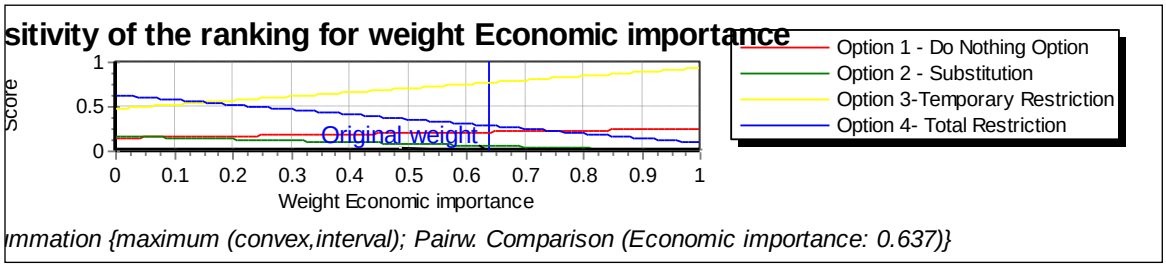


Figure E-12: Sensitivity of the ranking for weight Economic importance

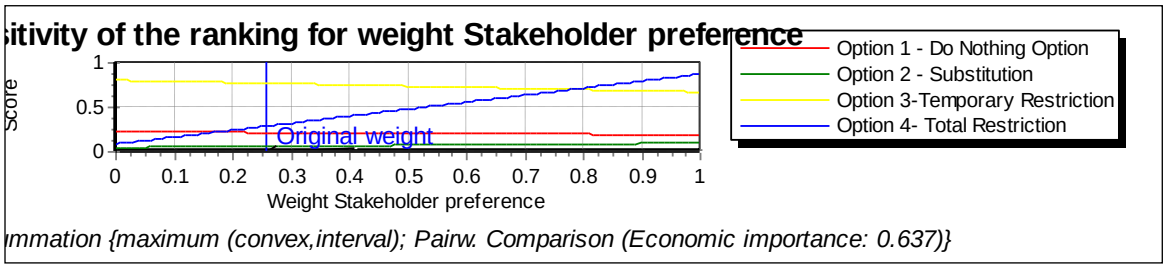


Figure E-13: Sensitivity of the ranking for weight Stakeholder preference

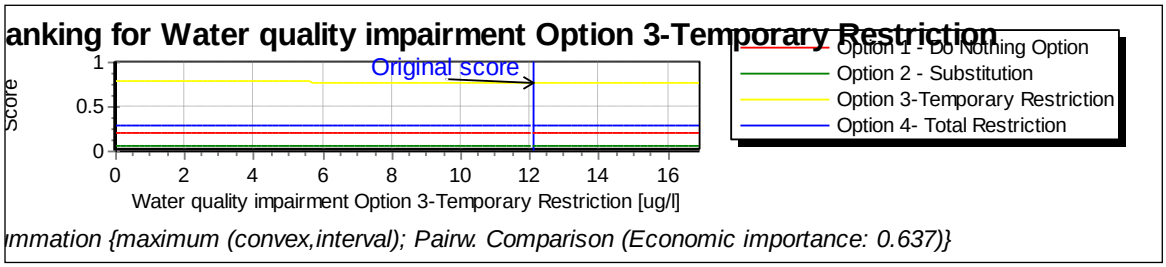


Figure E-14: Sensitivity of the ranking for Water quality impairment Option 3-Temporary Restriction

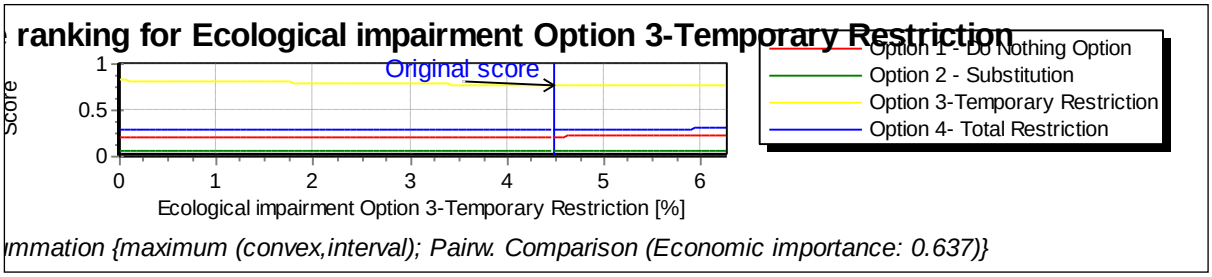


Figure E-16: Sensitivity of the ranking for Ecological impairment Option 3-Temporary Restriction

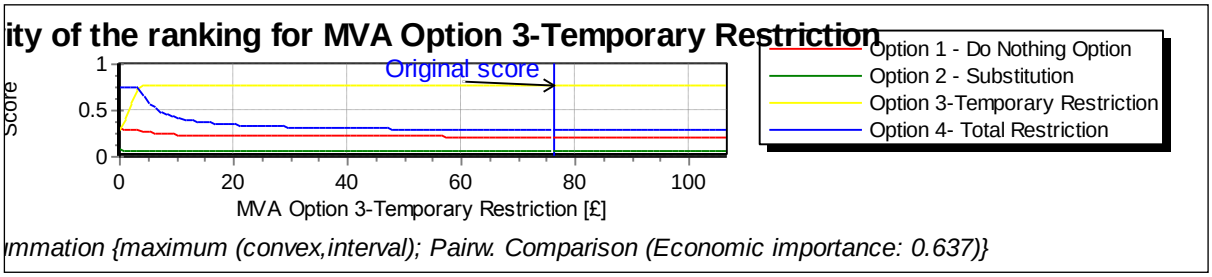


Figure E-17: Sensitivity of the ranking for MVA Option 3-Temporary Restriction

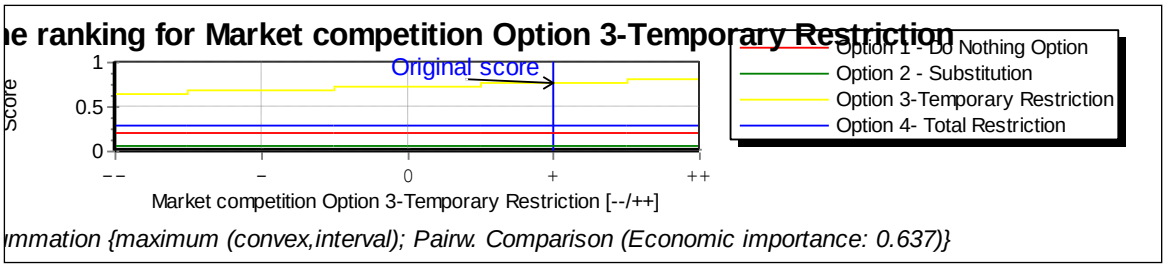


Figure E-18: Sensitivity of the ranking for Market competition Option 3-Temporary Restriction

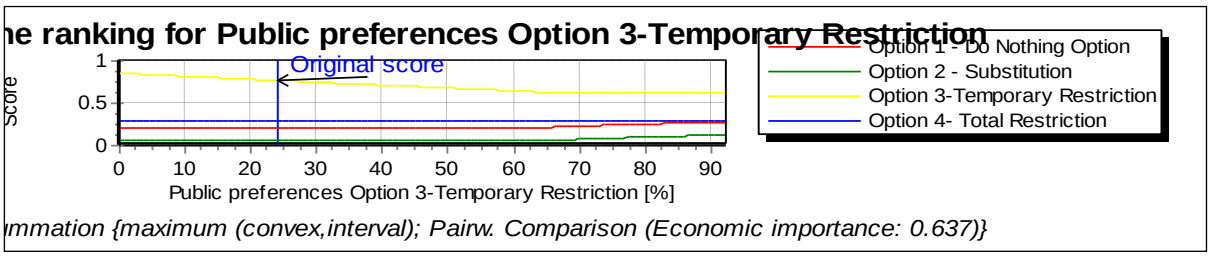


Figure E-19: Sensitivity of the ranking for Public preferences Option 3-Temporary Restriction

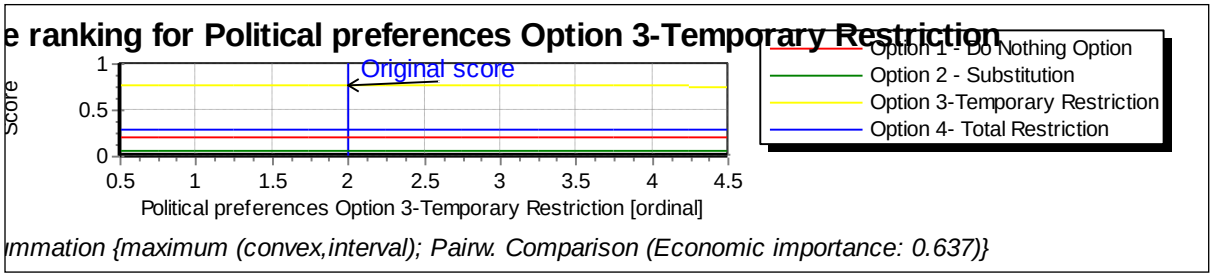


Figure E-20: Sensitivity of the ranking for Political preferences Option 3-Temporary Restriction

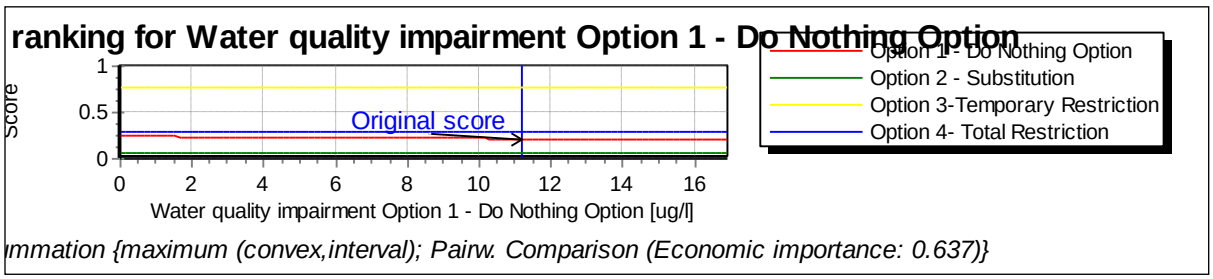


Figure E-21: Sensitivity of the ranking for Water quality impairment Option 1 - Do Nothing Option

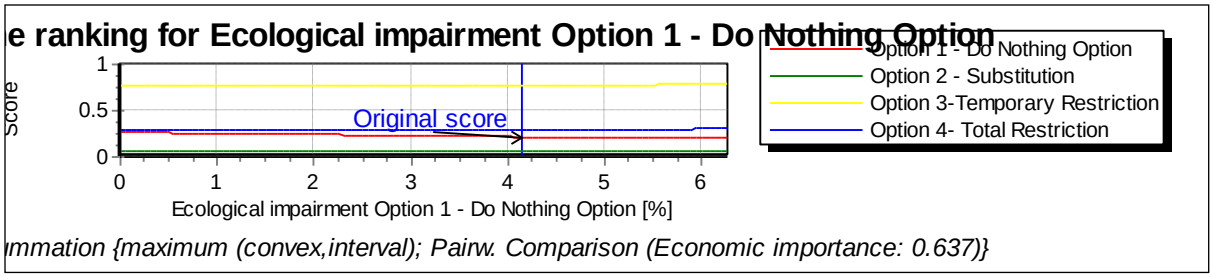


Figure E-22: Sensitivity of the ranking for Ecological impairment Option 1 - Do Nothing Option

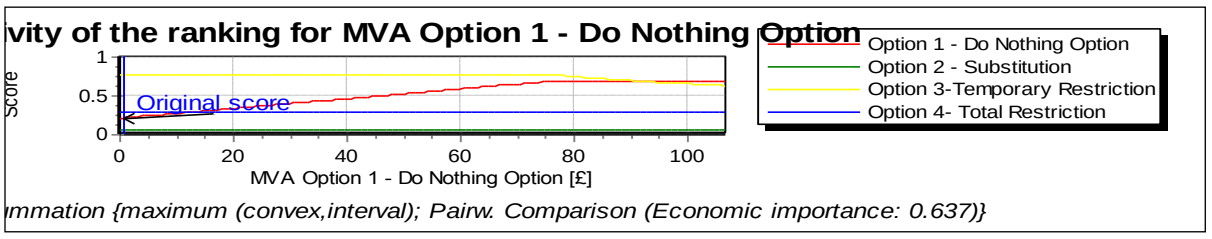
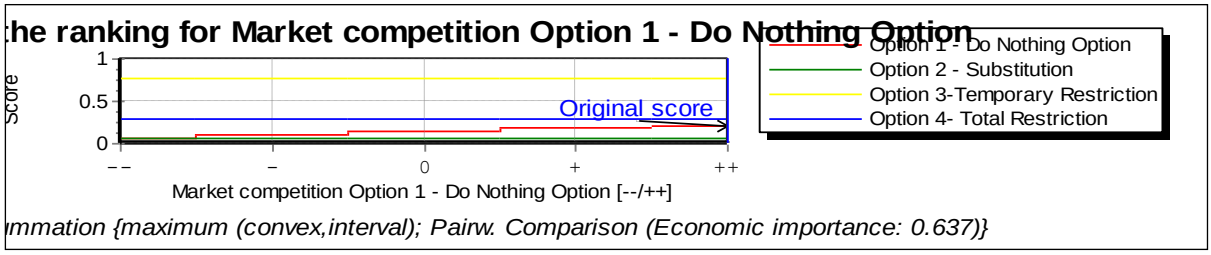


Figure E-23: Sensitivity of the ranking for MVA Option 1 - Do Nothing Option



FigureE-24: Sensitivity of the ranking for Market competition Option 1 - Do Nothing Option

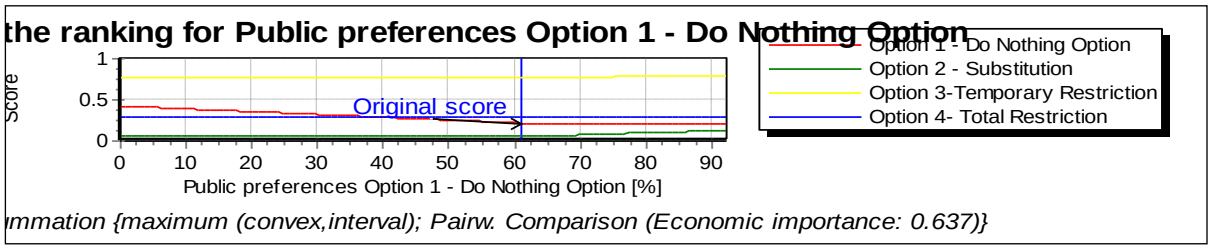


Figure E-25: Sensitivity of the ranking for Public preferences Option 1 - Do Nothing Option

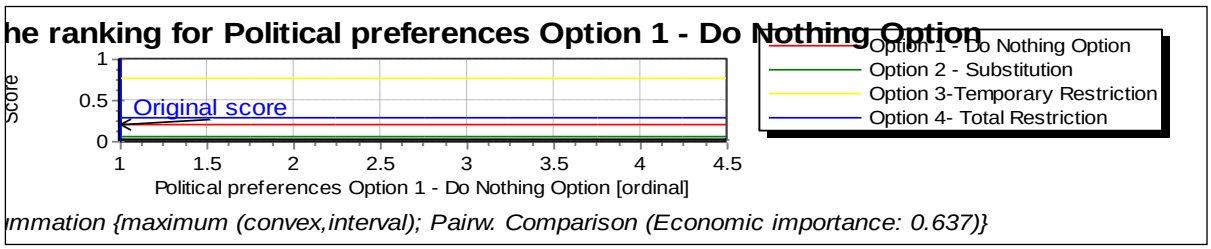


Figure E-26: Sensitivity of the ranking for Political preferences Option 1 - Do Nothing Option

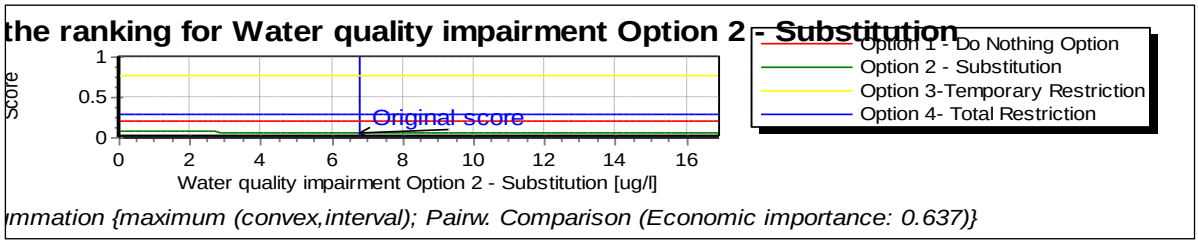


Figure E-27: Sensitivity of the ranking for Water quality impairment Option 2 - Substitution

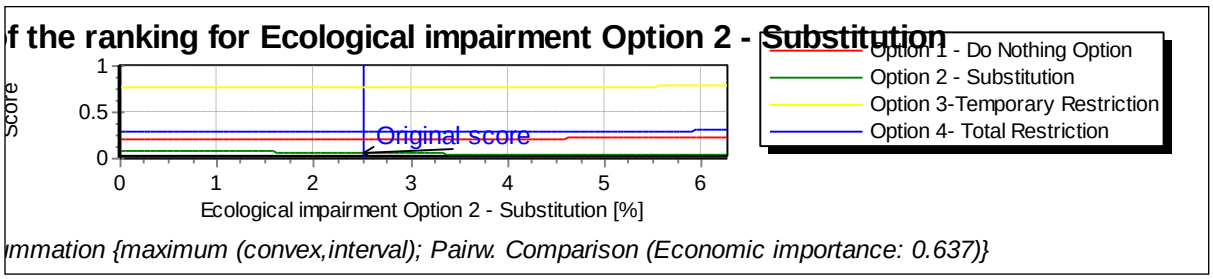


Figure E-28: Sensitivity of the ranking for Ecological impairment Option 2 - Substitution

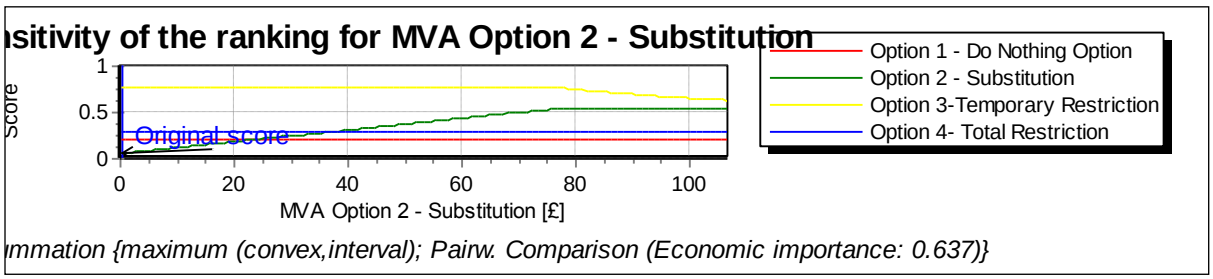


Figure E-29: Sensitivity of the ranking for MVA Option 2 - Substitution

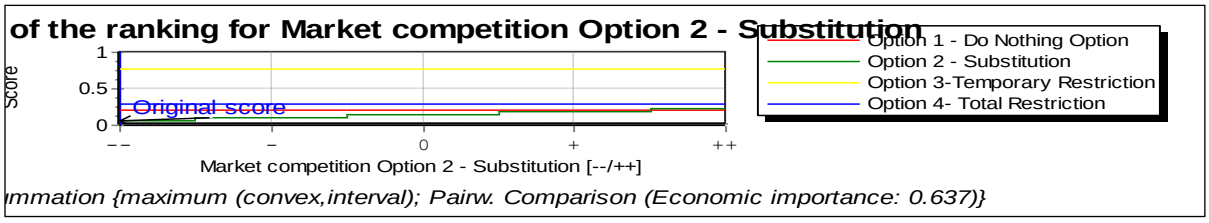


Figure E-30: Sensitivity of the ranking for Market competition Option 2 - Substitution

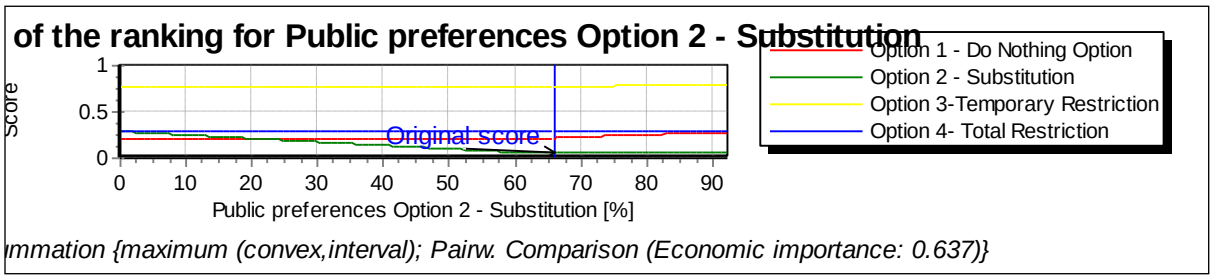


Figure E-31: Sensitivity of the ranking for Public preferences Option 2 - Substitution

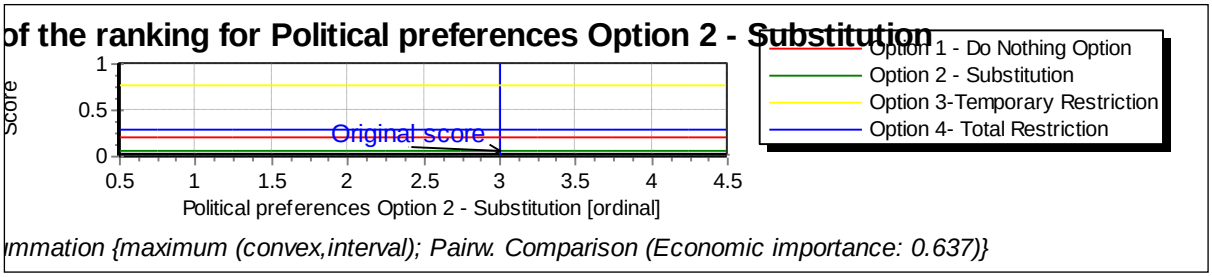


Figure E-32: Sensitivity of the ranking for Political preferences Option 2 - Substitution

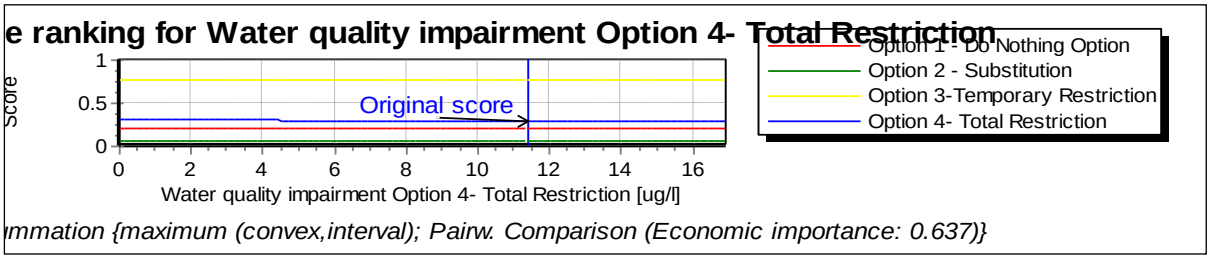


Figure E-33: Sensitivity of the ranking for Water quality impairment Option 4- Total Restriction

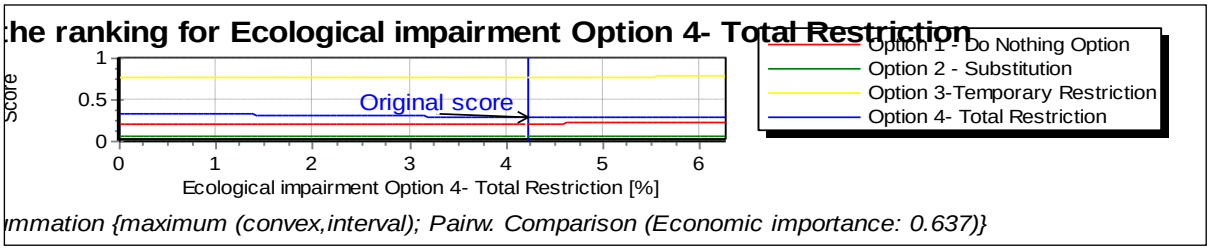


Figure E-34: Sensitivity of the ranking for Ecological impairment Option 4- Total Restriction

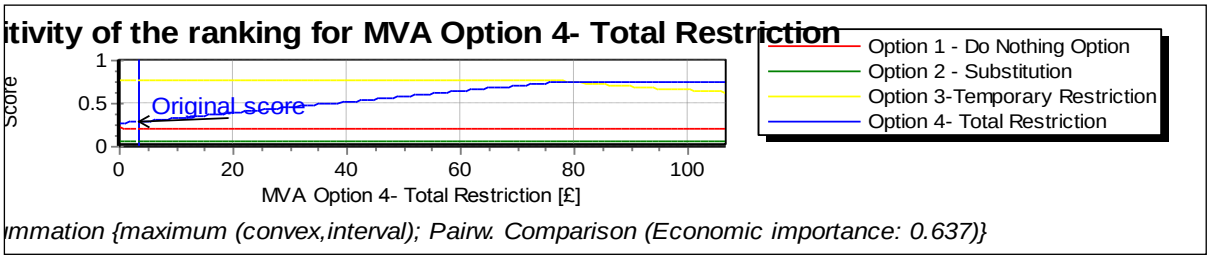


Figure E-35: Sensitivity of the ranking for MVA Option 4- Total Restriction

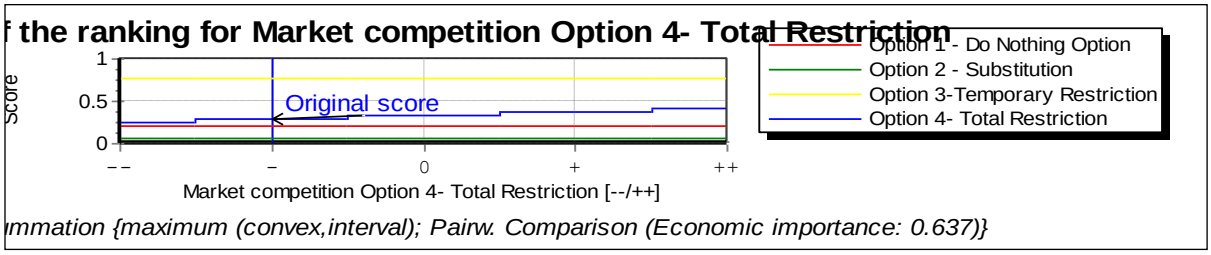


Figure E-36: Sensitivity of the ranking for Market competition Option 4- Total Restriction

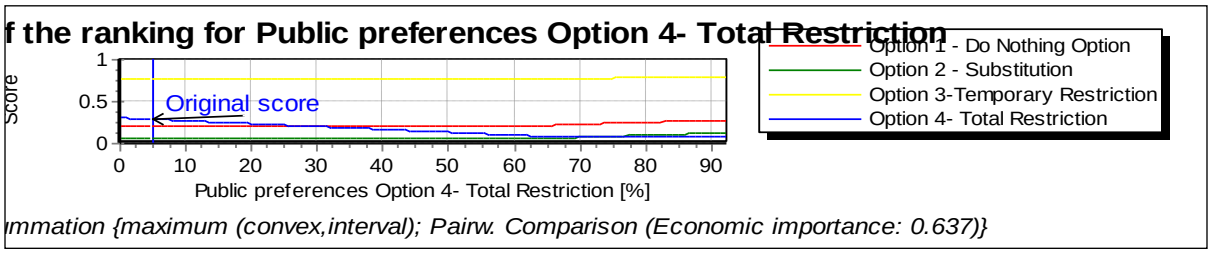


Figure E-37: Sensitivity of the ranking for Public preferences Option 4- Total Restriction

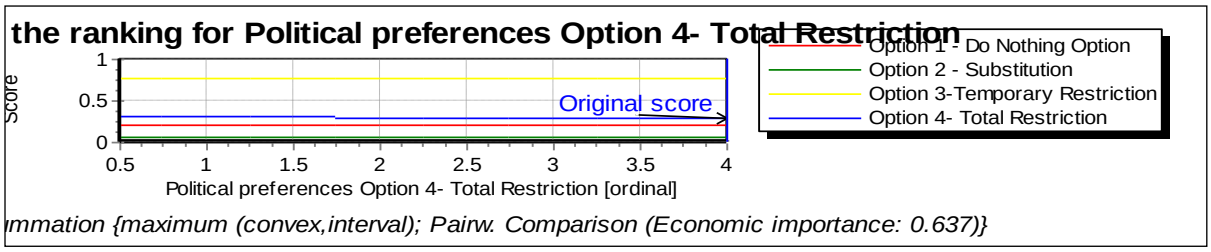


Figure E-38: Sensitivity of the ranking for Political preferences Option 4- Total Restriction

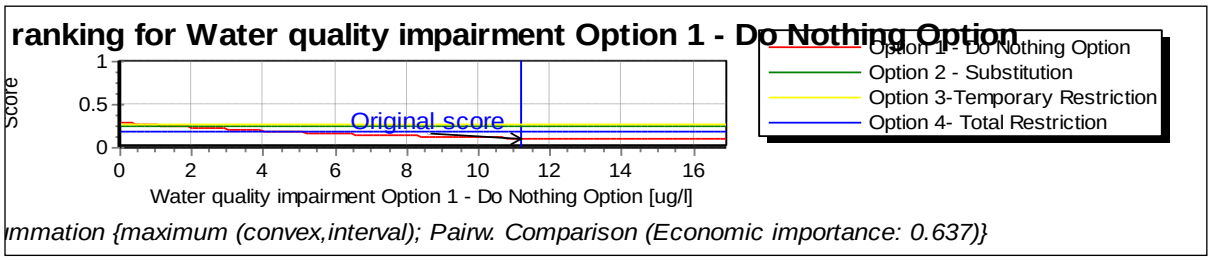


Figure E-39: Sensitivity of the ranking for Water quality impairment Option 1 - Do Nothing Option

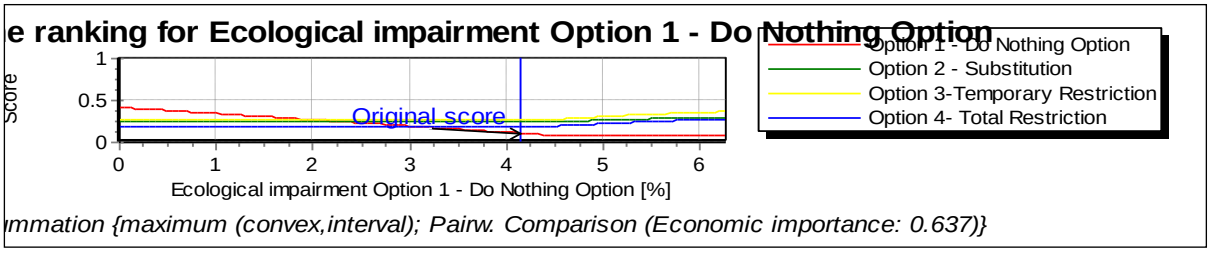


Figure E-40: Sensitivity of the ranking for Ecological impairment Option 1 - Do Nothing Option

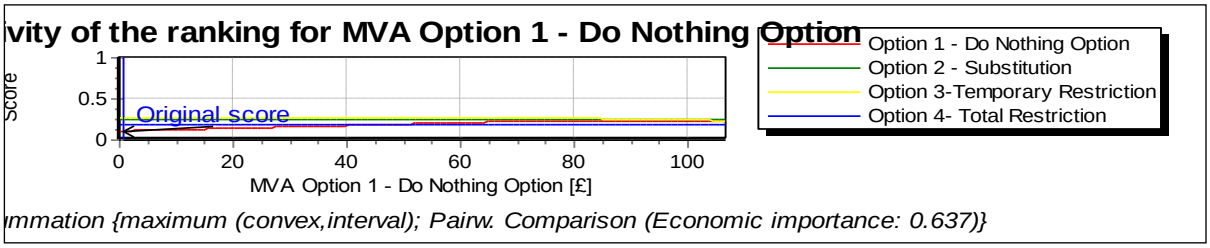


Figure E-41: Sensitivity of the ranking for MVA Option 1 - Do Nothing Option

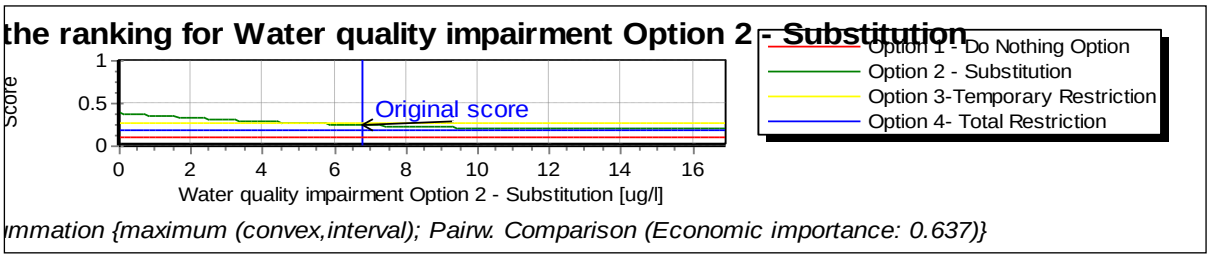


Figure E-42: Sensitivity of the ranking for Water quality impairment Option 2 - Substitution

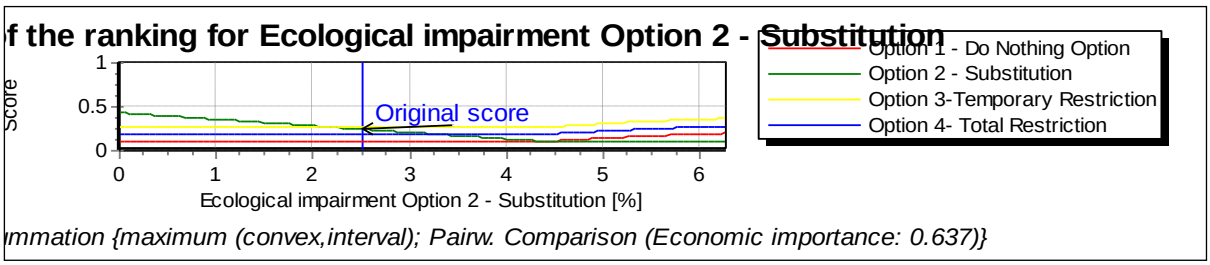


Figure E-43: Sensitivity of the ranking for Ecological impairment Option 2 - Substitution

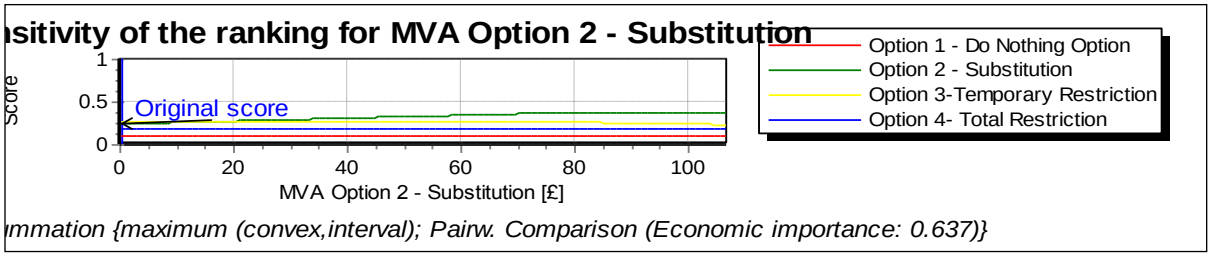


Figure E-44: Sensitivity of the ranking for MVA Option 2 - Substitution

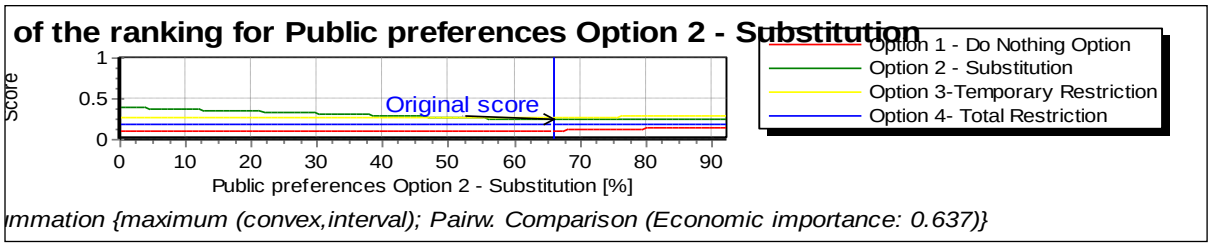


Figure E-45: Sensitivity of the ranking for Public preferences Option 2 - Substitution

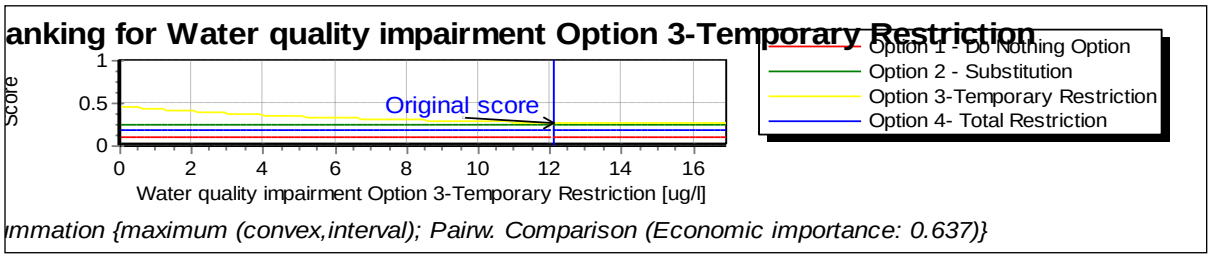


Figure E-46: Sensitivity of the ranking for Water quality impairment Option 3-Temporary Restriction

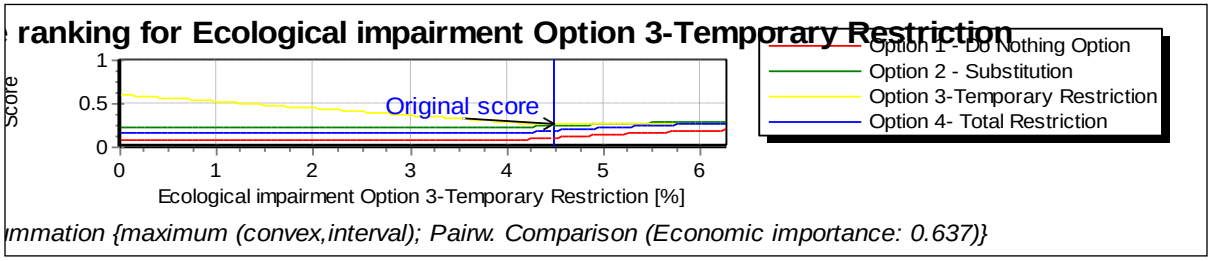


Figure E-47: Sensitivity of the ranking for Ecological impairment Option 3-Temporary Restriction

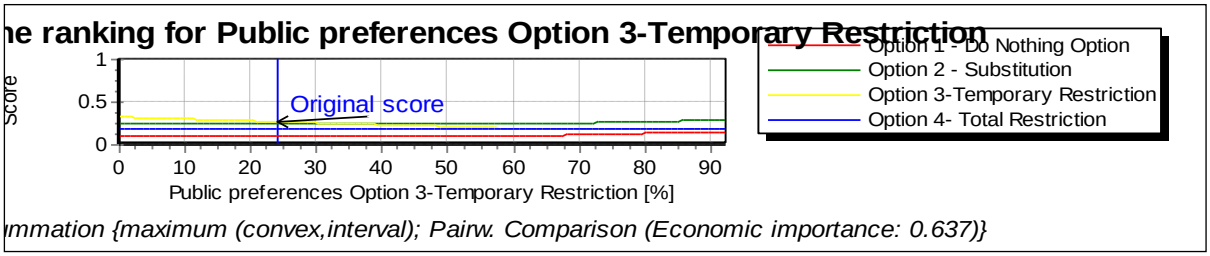


Figure E-48: Sensitivity of the ranking for Public preferences Option 3-Temporary Restriction

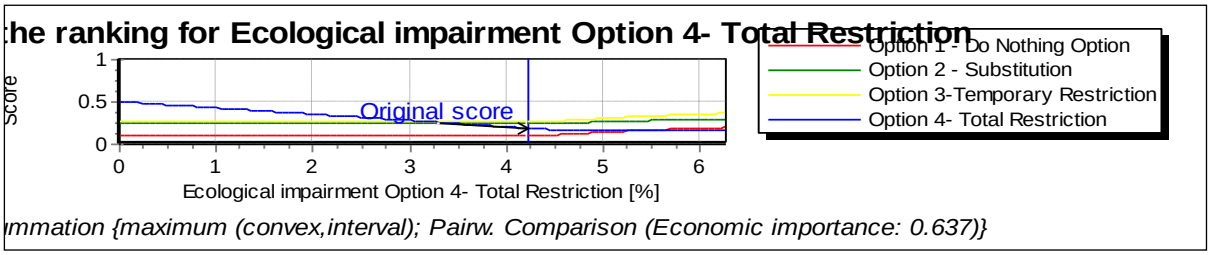


Figure E-49: Sensitivity of the ranking for Ecological impairment Option 4- Total Restriction

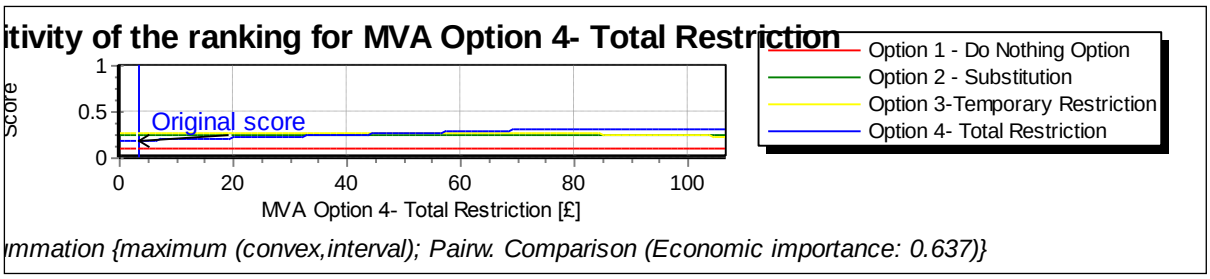


Figure E-50: Sensitivity of the ranking for MVA Option 4- Total Restriction

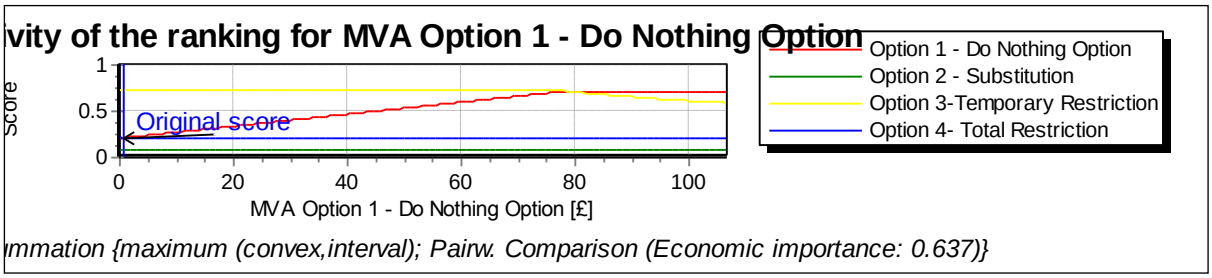


Figure E-51: Sensitivity of the ranking for MVA Option 1 - Do Nothing Option

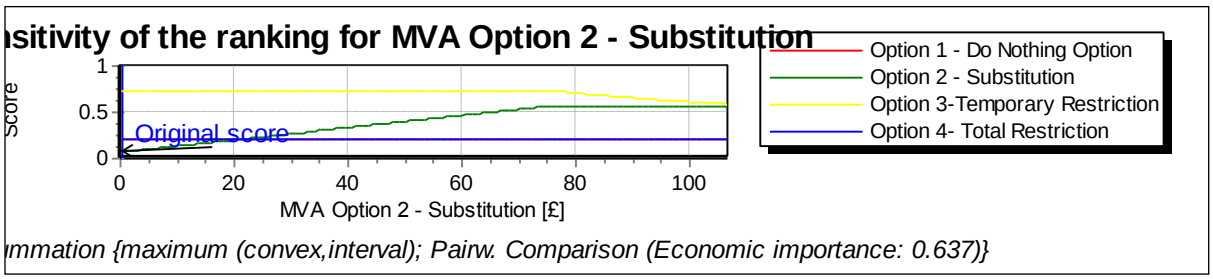


Figure E-52: Sensitivity of the ranking for MVA Option 2 - Substitution

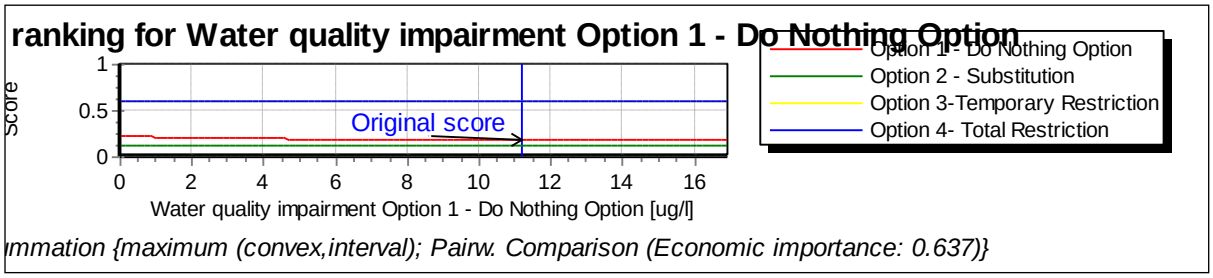


Figure E-53: Sensitivity of the ranking for Water quality impairment Option 1 - Do Nothing Option

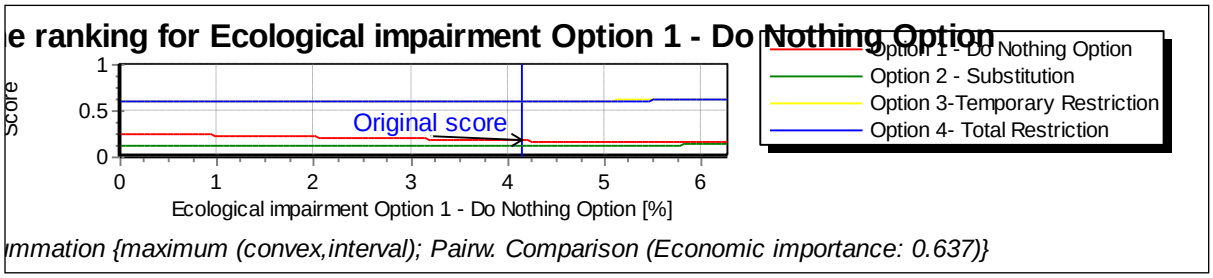


Figure E-54: Sensitivity of the ranking for Ecological impairment Option 1 - Do Nothing Option

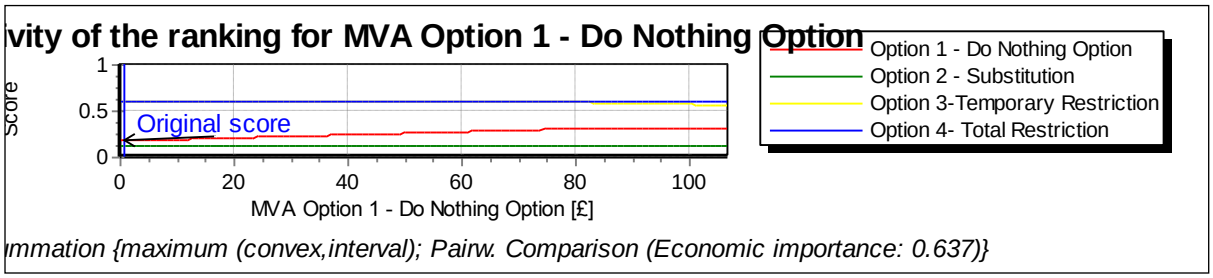


Figure E-55: Sensitivity of the ranking for MVA Option 1 - Do Nothing Option

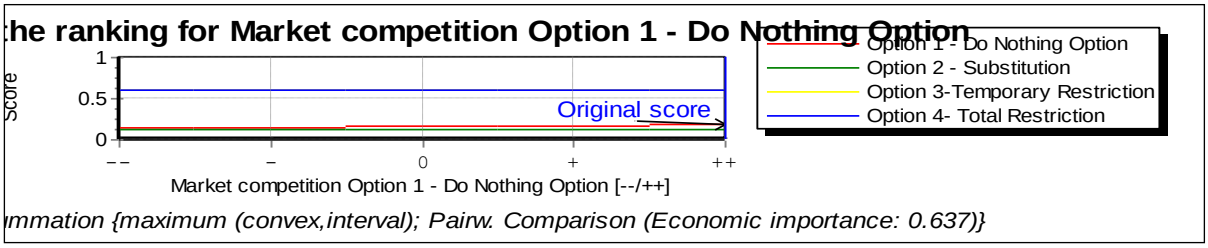


Figure E-56: Sensitivity of the ranking for Market competition Option 1 - Do Nothing Option

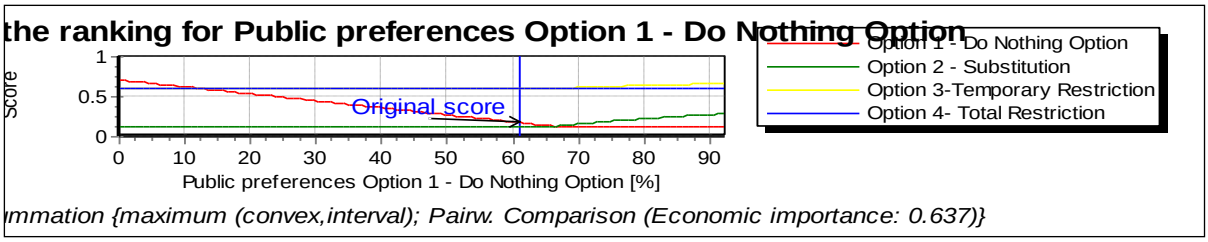


Figure E-57: Sensitivity of the ranking for Public preferences Option 1 - Do Nothing Option

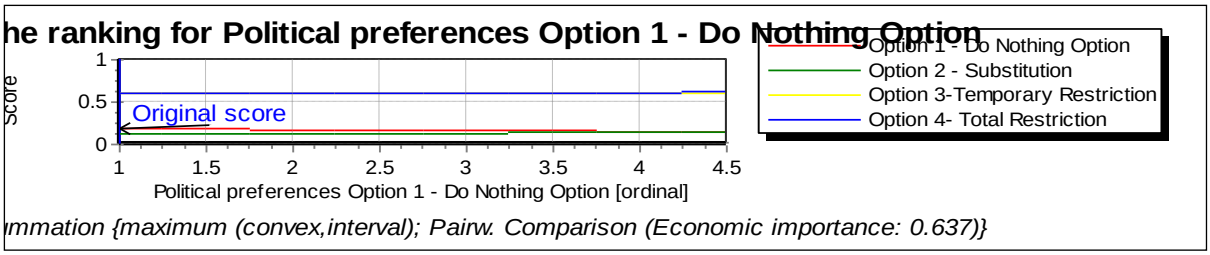


Figure E-58: Sensitivity of the ranking for Political preferences Option 1 - Do Nothing Option

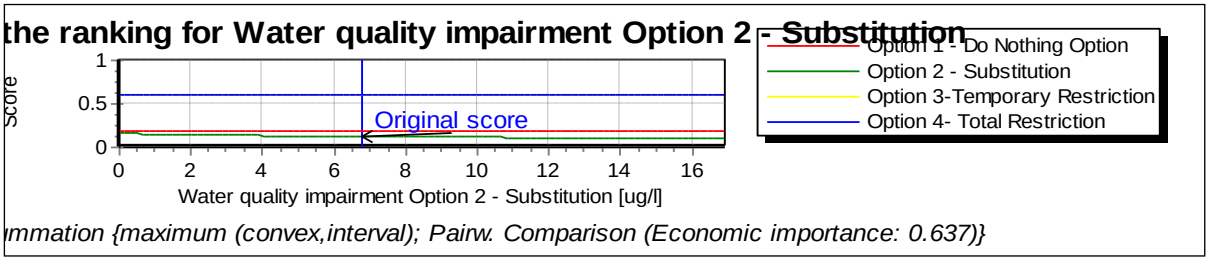


Figure E-59: Sensitivity of the ranking for Water quality impairment Option 2 - Substitution

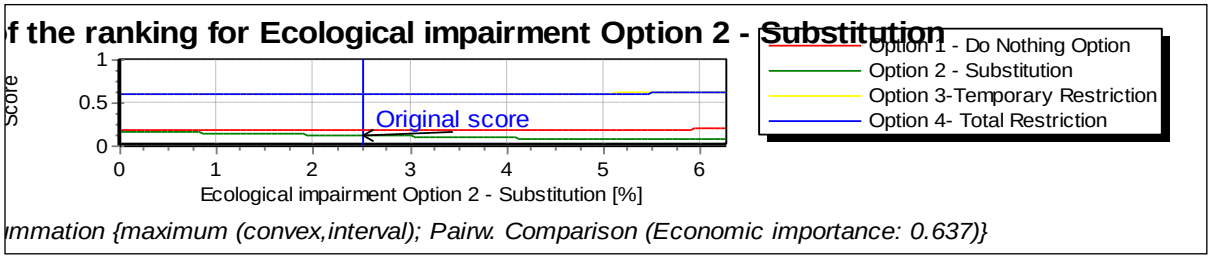


Figure E-60: Sensitivity of the ranking for Ecological impairment Option 2 - Substitution

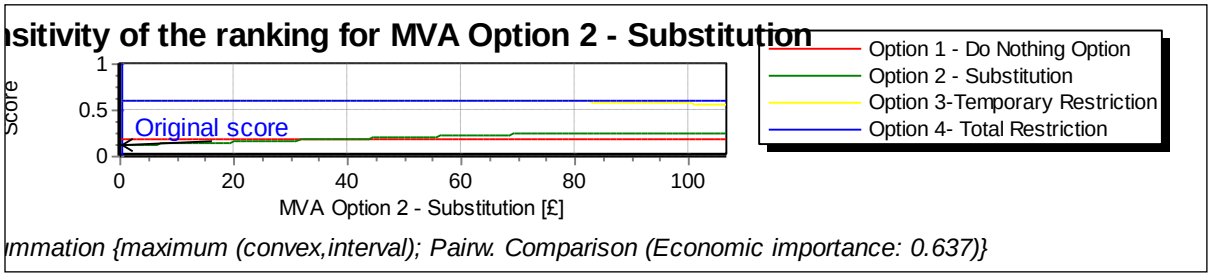


Figure E-61: Sensitivity of the ranking for MVA Option 2 - Substitution

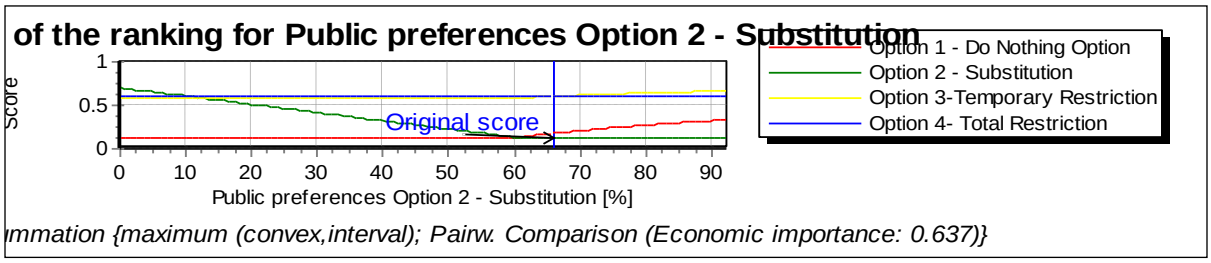


Figure E-62: Sensitivity of the ranking for Public preferences Option 2 - Substitution

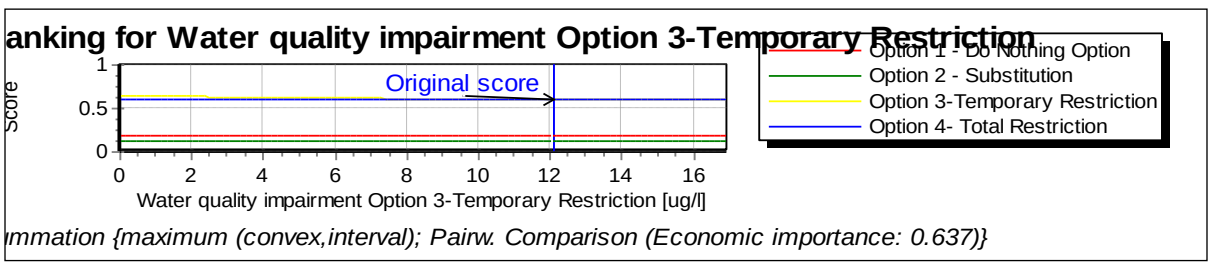


Figure E-63: Sensitivity of the ranking for Water quality impairment Option 3-Temporary Restriction

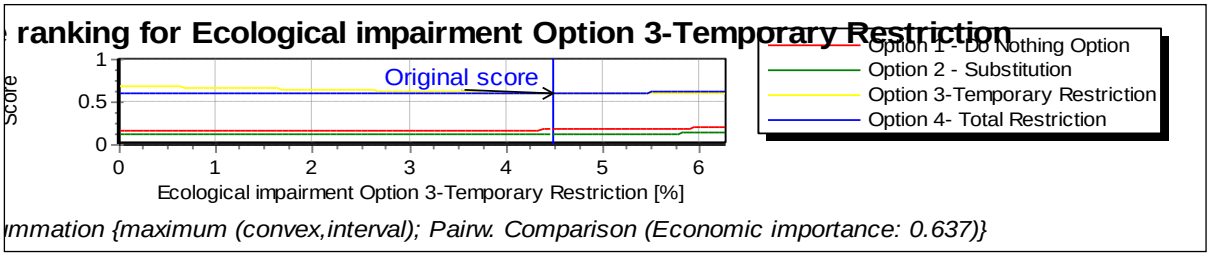


Figure E-64: Sensitivity of the ranking for Ecological impairment Option 3-Temporary Restriction

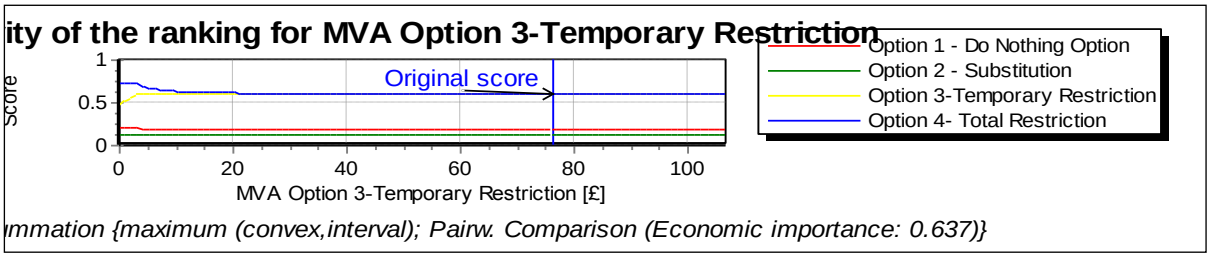


Figure E-65: Sensitivity of the ranking for MVA Option 3-Temporary Restriction

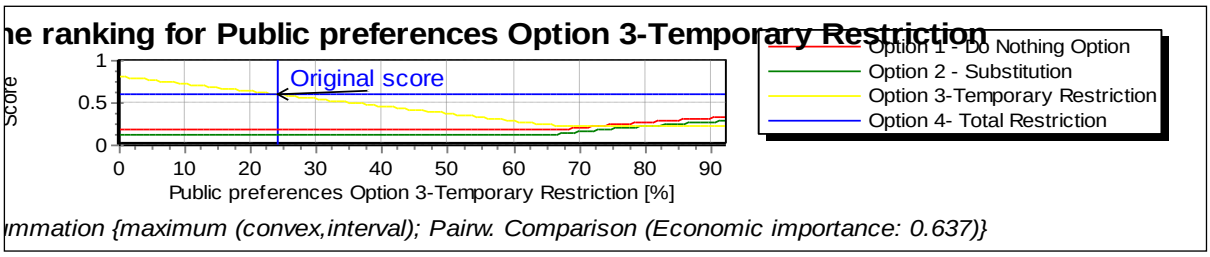


Figure E-66: Sensitivity of the ranking for Public preferences Option 3-Temporary Restriction

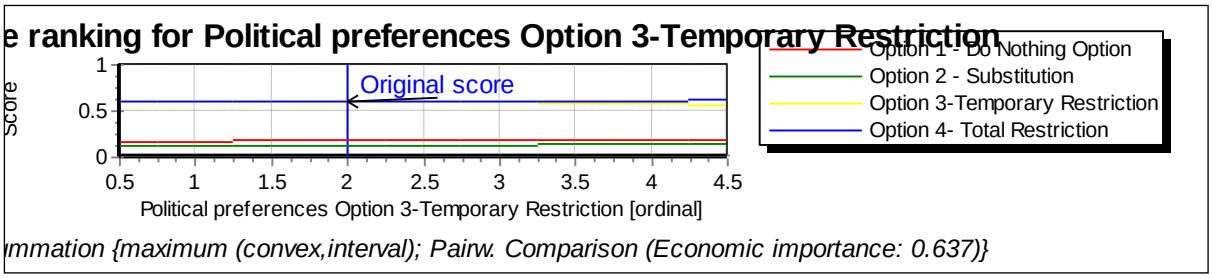


Figure E-67: Sensitivity of the ranking for Political preferences Option 3-Temporary Restriction

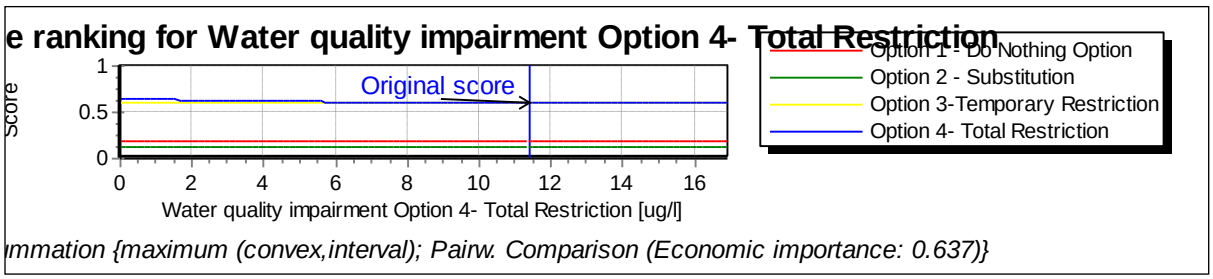


Figure E-68: Sensitivity of the ranking for Water quality impairment Option 4- Total Restriction

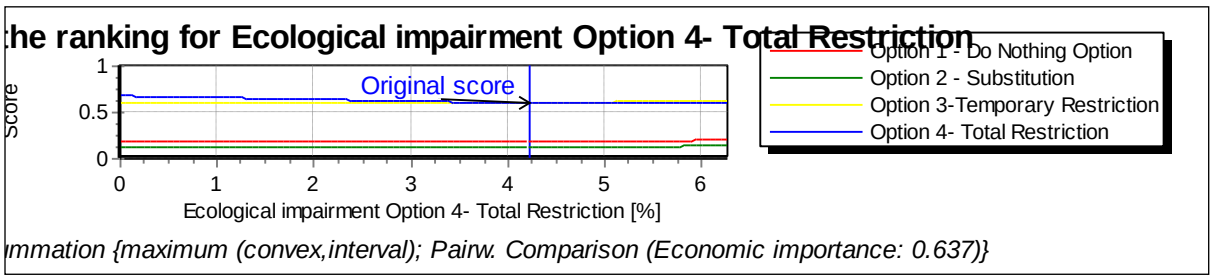


Figure E-69: Sensitivity of the ranking for Ecological impairment Option 4- Total Restriction

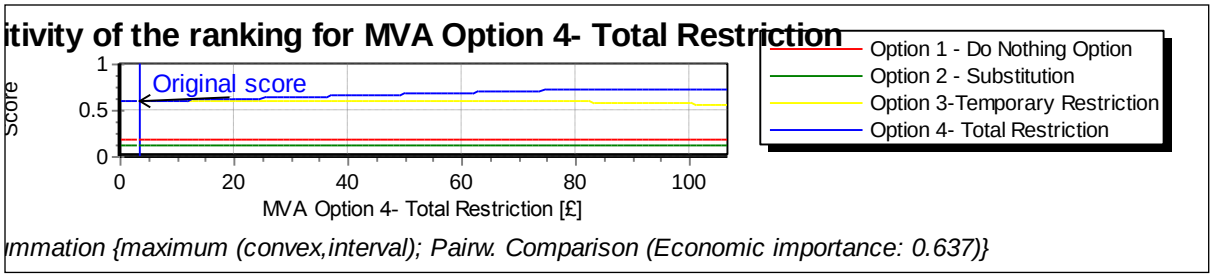


Figure E-70: Sensitivity of the ranking for MVA Option 4- Total Restriction

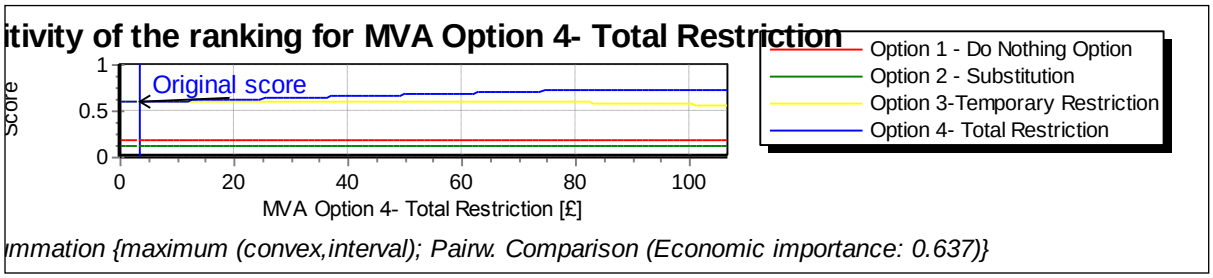


Figure E-71: Sensitivity of the ranking for MVA Option 4- Total Restriction

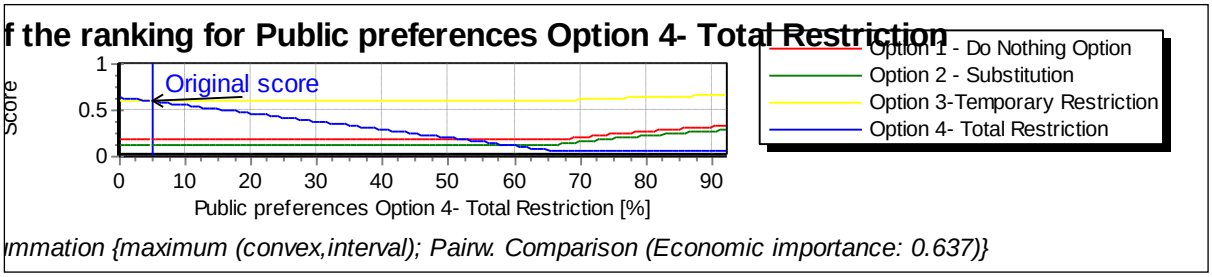


Figure E-72: Sensitivity of the ranking for Public preferences Option 4- Total Restriction

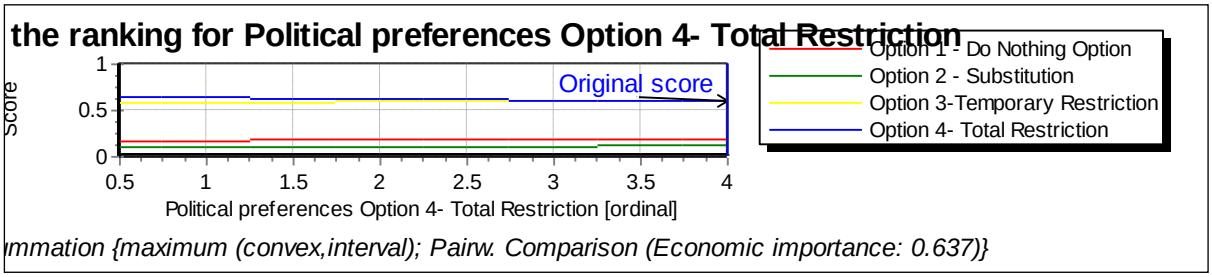


Figure E-73: Sensitivity of the ranking for Political preferences Option 4- Total Restriction