REVIEW OF REACH WITH REGARD TO THE REGISTRATION REQUIREMENTS ON POLYMERS

070307/2011/602175/SER/D3

Final Report
Part A: Polymers

Prepared for

European Commission
DG Environment

December 2012

RPA

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ENVIRONMENTAL LAW & POLICY

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by

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1. INTRODUCTION

1.1 Background to the Study

1.1.1 Introduction to REACH

Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH[1]) came into force on 1 June 2007. REACH aims to provide a high level of protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemicals and their uses, while at the same time enhancing the innovative capability and competitiveness of the EU chemicals industry. Furthermore, REACH aims to ensure the free movement of substances and the promotion the development of alternative methods for the assessment of hazards of substances (Recital 1).

The regulation applies to substances manufactured, placed on the market and used in the EU either on their own, in mixtures or in articles (Article 1). Furthermore, REACH is based on the principle that it is for industry *to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle* (Article 1(3)).

The four key elements in REACH are:

1. **Registration:** of substances manufactured or imported in amounts starting at 1 tonne per year (per manufacturer or importer) (Title II). Notifications of substances by companies under Directive 67/548/EEC are considered to be registrations under REACH (Article 24);

2. **Evaluation** (Title VI): of which there are two types – dossier evaluation and substance evaluation;

3. **Authorisation:** of substances of very high concern (SVHC), assuring that the risks of SVHC are properly controlled and that these substances are progressively replaced, while ensuring the good functioning of the internal market (Title VII); and

4. **Restriction:** aimed at addressing risks not adequately controlled on a Community wide basis (Title VIII).

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 200/21/EC (REACH).

1.1.2 Reviews under Article 138

Obligations were placed on the Commission to undertake a range of reviews of the operation of REACH, with these set out in Article 138, and summarised in Table 1.1.

Table 1.1: Summary of Reviews Required under Article 138 of REACH

Section	Summary of Review	Deadline
1	Chemical Safety Assessment/Report exemptions for substances manufactured/ imported in quantities less than 10 tonnes per company. CMRs Cat. 1 or 2 under Directive 67/538/EEC (Cat 1A or Cat 1B under Regulation (EC) No 1272/2008)	1 June 2019 1 June 2014
2	Consider registration of polymers	As soon as practicable
3	Registration requirements for substances manufactured/ imported in quantities less than 10 tonnes per company	Every 5 years, starting 1 June 2012 (deadline for Article 117(4) report)
4	Annexes I, IV and V	1 June 2008
5	Annex XIII	1 December 2008
6	Scope of REACH regarding overlaps with other EU legislation	1 June 2012
7	Endocrine disrupting chemicals	1 June 2013
8	Communication on additional dangerous substances in articles	1 June 2019
9	Promotion of non-animal testing	1 June 2019

The reviews of specific concern for this element of the study are those required under Article 138 section 2, as described below:

> *The Commission may present legislative proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established, and after publishing a report on the following:*
>
> *(a) The risks posed by polymers in comparison with other substances;*
>
> *(b) The need, if any, to register certain types of polymer, taking account of competitiveness and innovation on the one hand and the protection of human health and the environment on the other.*

1.2 Study Objectives

The Specifications state that:

> *The objective of the contract is to provide technical, scientific and policy support to the Commission to undertake the reviews described in Articles 138(1), (2) and (3) of REACH.*

In particular, this element of the study (Task A) is to review the exemption from registration requirements for polymers.

1.3 Organisation of Report

The remainder of this report has been organised as follows:

- **Section 2** sets out the current requirements with regard to the registration of polymers, monomers, and other polymer constituents under REACH;
- in **Section 3,** polymers are described, along with the industry that manufactures and uses them;
- the hazards posed by polymers are assessed in **Section 4**, and compared with the those posed by monomers and other substances;
- **Section 5** sets out the current approaches to the control of risks posed by polymers;
- **Section 6** summarises previous impact assessment conclusions on the registration of polymers;
- **Section 7** lists the assumptions being taken forward for the Impact Assessment from the information set out in the previous sections;
- **Section 8** details the policy options for the future registration of polymers that have been examined here;
- **Section 9** presents the estimated costs of the different policy options, while **Section 10** provides estimates of the numbers of new hazardous properties that may be identified and an indication of the cost-effectiveness of the different options; and
- **Section 11** provides a summary of the key study findings.

In addition, references are given in Section 12 while Annex 1 provides details of the current approaches to managing the risks posed by polymers, as summarised in Section 5.

2. POLYMERS AND REACH

2.1 Definitions

2.1.1 REACH Definitions

It is important to note that this study is concerned with polymer substances rather than polymer materials or products, where:

- **Monomers**: are defined in REACH Article 3(6) as, *a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process*. In 2009, the European Court of Justice ruled that 'monomer substances' as defined by Article 6(3) *relates only to reacted monomers which are integrated in polymers* (ECJ, 2009). However, ECHA Guidance on Monomers and Polymers (2012) includes unreacted monomers within its list of impurities, and thus as constituents of the polymer. ECHA (2012) also states that *substances exclusively involved in the catalysis, initiation or termination of the polymer reaction are not monomers*.

- **Additives**: Article 3.1, provides the only definition of an additive within the legal text of REACH, within its definition of a substance as, *a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any **additive** necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition*.

- **Polymer substances**: are defined in REACH Article 3(5), *as a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:*

  (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
  (b) less than a simple weight majority of molecules of the same molecular weight.
  In the context of this definition, a 'monomer unit' means the reacted form of a monomer substance in a polymer.

- **Polymer materials/products**: are mixtures of polymer substances and other additive substances, such as plasticisers. It is only the polymer substance contribution to the risks from these mixtures that are of relevance to this study.

A further clarification of the definition of a polymer substance is provided in ECHA (2012), which states that:

- *a "polymer molecule" is a molecule that contains a sequence of at least 3 monomer units, which are covalently bound to at least one other monomer unit or other reactant;*

- *a "monomer unit" means the reacted form of a monomer substance in a polymer (for the identification of the monomeric unit(s) in the chemical structure of the polymer the mechanism of polymer formation may, for instance, be taken into consideration);*

- *a "sequence" is a continuous string of monomer units within the molecule that are covalently bonded to one another and are uninterrupted by units other than monomer units. This continuous string of monomer units can possibly follow any network within the polymer structure;*

- *"other reactant" refers to a molecule that can be linked to one or more sequences of monomer units but which cannot be regarded as a monomer under the relevant reaction conditions used for the polymer formation process; and*

- *impurities deriving from the manufacturing process*, are considered to form a part of the polymer substance.

2.1.2 IUPAC Definitions

It is the REACH definitions that are of direct relevance to this study. However, the IUPAC definitions provided here are widely used by those in the polymer industry and these are not always consistent with the REACH definitions provided above. For example, the description of a "polymer molecule" provided by ECHA (2012) as *a molecule that contains a sequence of at least 3 monomer units,* would incorporate oligomers as described below as molecules consisting of *a small plurality of units*. The IUPAC definitions have therefore been reproduced here for completeness and to clarify potential differences[2]:

- **Monomer molecule:** A molecule which can undergo polymerization thereby contributing constitutional units to the essential structure of a macromolecule.

- **Polymer:** A molecule of high relative molecular mass, the structure of which essentially comprises the multiple repetition of units derived, actually or conceptually, from molecules of low relative molecular mass.

- **Oligomer:** A molecule of intermediate relative molecular mass, the structure of which essentially comprises a small plurality of units derived, actually or conceptually, from molecules of lower relative molecular mass.

[2] Definitions published on the IUPAC Internet site:
(http://old.iupac.org/reports/1996/6812jenkins/molecules.html#1.3).

2.2 Polymer Synthesis and Composition

2.2.1 Manufacture of Polymers

The information provided here summarises the situation for polymers overall, including polymers with specialist properties such as rubbers (elastomers), expanded foams, coatings, adhesives, etc.

Polymers are made by polymerising monomers into macromolecular chains. Besides monomers, other substances are often needed for polymerisation to occur, e.g. initiators, catalysts and, depending on the manufacturing process, solvents may also be used. Further additives may be used to modify the properties of the parent polymer including stabilisers, plasticisers, flame retardants, pigments and fillers. Some processing of polymers may also require process aids such as process stabilisers, viscosity modifiers and slip agents.

Many different polymer types exist but these are usually divided into two broad groups:

- thermoplastics (which soften when heated and can be remoulded); and
- thermosetting plastics (which are cross-linked, do not readily soften and cannot be remoulded).

The chemical process for the chain formation may be divided into chain-growth polymerisations (mainly addition polymerisation), and step-growth polymerisation (mainly condensation polymerisation, but also addition polymerisation) (Braun *et al*, 2005; McIntyre, 2005). In addition polymerisation, monomers are reacted by opening a double bond, but with no by-products being formed (Harper and Petrie, 2003). In condensation polymerisation, water or other simple molecules (e.g. ammonia, carbon dioxide, hydrochloric acid, methanol and hydrogen chloride) are formed during the reaction (Peacock and Calhoun, 2006; Alger, 1997).

Polymerisation reactions are rarely 100% complete and, thus, unreacted monomers (and, in the case of condensation, reaction by-products) and oligomers may be found in the polymer, which may be hazardous for human health and the environment and/or affect polymer properties (Matlack, 2001; Araújo *et al*, 2002). The proportion of unreacted monomers (or condensation by-products) can vary greatly depending on type of polymer, polymerisation technique and techniques for reducing the levels of these constituents (Araújo *et al*, 2002). In a review by Araújo *et al* (2002), the proportion of unreacted monomers (or condensation by-products) varied from no or very low levels (100 ppm; i.e. 0. 0001%) to up to 40,000 ppm (i.e. 4%). However, industry carefully controls polymerisation to ensure that the resultant polymer has the desired properties (Plastics Platform, *pers. comm.*). The minimisation of residual monomer content is also often a priority as residual monomers can result in increased hazards while representing decreased production efficiency and increased costs.

For example, great efforts are made to minimise the residual vinyl chloride monomer (VCM) content in polyvinyl chloride (PVC). The OECD SIDS programme identified

VCM concentrations in final PVC products to be very much below those figures quoted by Araújo *et al* (2002) (OECD, 2001; figures in brackets indicate the date to which these data relate):

- <1 ppm residual VCM in PVC products (1991) with data to suggest that by 1998 figures were a factor of 10 lower than this; and
- <10 ppb VCM in modern medical grade PVC (1992).

Other monomers, such as acrylates which are used to produce polyacrylates, are completely consumed in the polymerisation process and only contain trace levels of the polymerisation by-products acrylic acid and esters (OECD, 2005).

Besides the unreacted monomers (or condensation by-products), other polymerisation impurities can be present in a polymer, including oligomers, low molecular weight polymer fragments, catalyst remnants and polymerisation solvents, as well as a wide range of plastic additives including processing aids and end-product additives (Crompton, 2007). All these components are usually of low molecular weight and therefore, may, migrate from a plastic product or finished article (Crompton, 2007) to air, water or other contact media (e g. food and pharmaceuticals).

2.2.2 Polymer Types

Among the extremely large variety of existing polymers, the list of polymer types provided here is representative of a large number of the thermoplastic and thermosetting polymer types and families having a global production exceeding 10,000 tonnes/year (Lithner, 2011a and PlasticsEurope, 2011). The listing is aligned with the PRODCOM listing set out in Table 3.9, and where applicable the PRODCOM code is shown. Those polymer types in the PRODCOM list represent materials of commercial significance and which are supplied in larger tonnages.

For many entries the expression “primary form” is used but the precise form is not shown; however, in general, the primary forms will include:

- defined size pellets, powders (including moulding powders), granules, flakes and similar bulk forms including irregular shape lumps or blocks; and
- liquids and pastes, including dispersions (e.g. aqueous emulsions and suspensions) and solutions.

The listing in Table 3.1 is ordered first by overarching polymer type (i.e. thermoplastic or thermoset), then by polymer family (i.e. polymers sharing similar chemical characteristics, such as polymer backbone or reactive functional group) and finally as some specific examples which are not intended to be exhaustive just illustrative.

The order of each polymer type is broadly in-line with the market share or demand as reported in recent analysis for the European plastics industry (PlasticsEurope, 2011). In this analysis, many of the polymer families are grouped together under the category

"other" and so the ordering in regard to demand is only applicable for thermoplastics and thermosets.

Natural polymers, with the exception of cellulosics, are not included in Table 2.1, as they are outside of the scope of this study.

Table 2.1: Polymers in Global Production in Quantities Greater Than 10,000 Tonnes per Year	
Polymer	**PRODCOM Code**
Thermoplastic Polymers	
Polyethylenes	20161035, 20161039, 20161050
Polymers of ethylene in primary forms (excluding polyethylene and ethylene-vinyl acetate copolymers)	20161090
Low-density polyethylene (LDPE).	N/A
Linear-low-density polyethylene (LLDPE).	N/A
High-density polyethylene (HDPE)	N/A
Ultra High Molecular Weight Polyethylene	N/A
Polypropylenes	N/A
Polymers of propylene (or other olefins) in primary forms	20165150
Polypropylene (PP) – atactic, isotactic and syndiotactic	20165130
Ethylene/Propylene Copolymers	N/A
Ethylene-propylene copolymers	N/A
Ethyelene-propylene-diene monomer rubbers	N/A
Ethylene-propylene based thermoplastic elastomers	N/A
Styrenic Resins	N/A
Polymers of Styrene in primary forms	20162090
Expansible Polystyrene in primary forms	20162035
Polystyrene (PS).	N/A
Expanded polystyrene (EPS).	N/A
High-impact polystyrene (HIPS).	N/A
Acrylonitrile-butadiene-styrene (ABS) terpolymer.	20162070
Styrene-acrylonitrile (SAN) copolymer	20162050
Chlorinated Polymers	N/A
Polyvinyl chloride (PVC)	20163010
Non plasticised PVC mixed with any other substance in primary forms	20163023
Plasticised PVC mixed with any other substance in primary forms	20163025
Polyvinylidene chloride (PVDC).	N/A
Vinyl chloride-vinyl acetate copolymers and other vinyl chloride copolymers in primary forms	20163040
Polyesters	20164090
Polyethylene terephthalate (PET)	20164062
Polycarbonates (PC).	20164040
Polylactic acid (PLA).	N/A
Polybutylene terephtalate (PBT).	N/A
Other PET	20164064
Polycaprolactone (PCL)	N/A
Polyglycolide (PG)	N/A
Liqid crystalline polymers (aromatic)	N/A
Polyethylene adipate (PEA)	N/A
Polytrimethylene terephthalate (PTT)	N/A
Polyethylene naphthalate (PEN)	N/A
Vectran	N/A
Alkyd resins	20164050
Acrylic Resins	N/A
Polyacrylonitrile (PAN) and copolymers	N/A

Table 2.1: Polymers in Global Production in Quantities Greater Than 10,000 Tonnes per Year	
Polymer	**PRODCOM Code**
Polymethyl methacrylate (PMMA)	N/A
PMMA in primary forms	20165350
Acrylic polymers in primary forms	20165390
Fluoropolymers	20163040
Polytetrafluorethylene (PTFE)	N/A
Polyvinylidene fluoride (PVDF)	N/A
Polyamides (PA) aliphatic, Nylons	20165450
Polyamide 6 – Nylon 6	N/A
Polyamide 6,6 – Nylon 6,6	N/A
Polyamide 6. 6 – Nylon 6,6	N/A
Polyamide 6. 9 – Nylon 6.9	N/A
Polyamide 6. 10 – Nylon 6,10	N/A
Polyamide 6. 12 – Nylon 6.12	N/A
Polyamide 11 – Nylon 11	N/A
Polyamide 12 – Nylon 12	N/A
Other aliphatic polyamides	20165490
Polyamides (aromatic), Aramides	N/A
Poly(m-phenyleneisophtalamide) (MPD-I) (Nomex®)	N/A
Poly(p-phenyleneterephtalamide) (PPD-T) (Kevlar® and Twaron®)	N/A
Vinyl Polymers	N/A
Ethylene vinyl acetate (EVA) and ethylene vinyl alcohol (EVOH)	N/A
Poly vinyl actetate (PVAc)	N/A
Poly vinyl acetate in primary forms	N/A
Poly vinyl alcohol (PVA)	N/A
Poly vinyl acetate in aqueous dispersion in primary forms	N/A
Poly acrylonitrile	N/A
Polymers of vinyl esters or other vinyl polymers in primary forms	20165270
Polyacetals	N/A
Polyacetals in primary forms	20164013
Polyoxymethylene (POM) and copolymers	N/A
Thermoplastic Elastomers	N/A
Thermoplastic polyurethanes (TPU) (linear polyurethanes)	N/A
Styrenic block copolymers	N/A
Polyolefin blends,	N/A
Elastomeric alloys (TPE-v or TPV)	N/A
Thermoplastic copolyesters	N/A
Thermoplastic polyamides	N/A
Polyether block amide PEBA	N/A
Ion exchange polymers	20165970
PolyAPTAC, (poly (acrylamido-N-propyltrimethylammonium chloride)	N/A
PolyMAPTAC,)poly[(3-(methacryloylamino)-propyl] trimethylammonium chloride)	N/A
Nafion[3]	N/A
Petroleum resins	N/A
C5 petroleum resin	20165920
C9 petroleum resin	N/A
C5/C9 Copolymer	N/A
Coumarone-indene	N/A
Polyterpenes	N/A
Polysulphides	N/A

[3] Nafion is formed by the copolymerization of tetrafluoroethylene (TFE) (the monomer in Teflon) and a derivative of a perfluoro (alkyl vinyl ether) with sulfonyl acid fluoride

Table 2.1: Polymers in Global Production in Quantities Greater Than 10,000 Tonnes per Year	
Polymer	**PRODCOM Code**
Polysulphones	N/A
Conjugated and conductive polymers	N/A
Polyacetylene	N/A
Polyaniline	N/A
Polypyrrole	N/A
Polydiacetylenes	N/A
Graphene (already subject to registration under REACH)	N/A
Carbon Nanotubes (already subject to registration under REACH)	N/A
Amorphous carbon (already subject to registration under REACH)	N/A
Other Thermoplastics	N/A
Polyphenylene ether (PPE), also called Polyphenylene oxide (PPO)	N/A
Polyphenylene sulphide (PPS)	N/A
Other polymers of halogenated olefins in primary forms	20163090
Thermosetting Polymers	
Polyurethanes	N/A
(PUR) (three-dimensional)	N/A
Polyurethanes in primary forms	20165670
Polyisocyanurates	N/A
Synthetic rubbers	20171090
Synthetic latex rubber	20171050
Polybutadiene	N/A
Polychoroprene (Neoprene)	N/A
Butyl rubber	N/A
Styrene butadiene rubber (SBR)	N/A
Nitrile butadiene rubber	N/A
Fluoroeleastomers	N/A
Unsaturated Polyesters	N/A
Unsaturated liquid polyester in primary forms	20164070
Unsaturated polyester in primary forms	20164080
Amino Resins	N/A
Amino resins in primary forms	20165630
Melamine resins	N/A
Melamine-formaldehyde resins (MF)	N/A
Melamine resins in primary forms	20165570
Urea and Thiourea resins	N/A
Urea-formaldehyde resin (UF)	N/A
Urea and thiourea resins in primary forms	20165550
Phenolic resins	N/A
Bakelite	N/A
Phenol formaldehyde resins (PF)	N/A
Phenolic resins in primary forms	20165650
Polyimides	N/A
Polyimides	N/A
Bismaleimides (BMI)	N/A
Epoxy and epoxide resins	N/A
Diglycidyl Ether of Bisphenol-A (DGEBA)	N/A
Phenolic (Novolac) Epoxy Resins	N/A
Epoxide resins in primary forms	20164030
Polyelectrolyte	N/A
Polyacrylic acid (PAA), superabsorbent polymer	N/A
Cellulose and Cellulosics	N/A
Cellulose and its chemical derivatives in primary forms	20165940
Cellulose acetate	N/A

Table 2.1: Polymers in Global Production in Quantities Greater Than 10,000 Tonnes per Year	
Polymer	**PRODCOM Code**
Inorganic Polymers	
Silicones (polyorganosiloxanes)	N/A
Polydimethysiloxanes (PDMS)	N/A
Organomodified siloxanes (OMS)	N/A
Polymethylhydrosiloxane (PMHS)	N/A
Silicones in primary forms	20165700
Silicone rubber	N/A
Phosphates	N/A
Polyphosphazenes	N/A
Polyphosphoric acid	N/A
Organic-Inorganic Hybrids	N/A
Polyhedral Oligomeric Silsesquioxane (POSS)	N/A

As a further complication, it is understood that some polymers are themselves manufactured from the polymerisation of two or more polymers[4], rather than directly from their constituent monomers. Polymer blending may also produce a polymer with properties different from the constituent polymers, however, such a polymer blend is considered to be a mixture under REACH.

Table 2.2 provides common examples of the wide range of synthetic polymeric elastomers (synthetic rubbers) produced, as an addition to the list provided in Table 2.1.

Table 2.2: Common Synthetic Rubbers	
Technical Name	**ISO 1629 Code**
Polyacrylate Rubber	ACM
Ethylene-acrylate Rubber	AEM
Polyester Urethane	AU
Bromo Isobutylene Isoprene	BIIR
Polybutadiene	BR
Chloro Isobutylene Isoprene	CIIR
Polychloroprene	CR
Chlorosulphonated Polyethylene	CSM
Epichlorohydrin	ECO
Ethylene Propylene	EP
Ethylene Propylene Diene Monomer	EPDM
Polyether Urethane	EU
Perfluorocarbon Rubber	FFKM
Fluoronated Hydrocarbon	FKM
Fluoro Silicone	FMQ
Fluorocarbon Rubber	FPM
Hydrogenated Nitrile Butadiene	HNBR

[4] Polymers may be synthesized by the polymerization of monomers or by chemical post-modification of a polymer. Examples of post-modification reactions include polymer end group modification, polymer functionalization via grafting, and controlled polymer degradation such as vis-breaking. It's also possible to further polymerise short-chained polymers. *Source:* http://www.cefic.org/Documents/IndustrySupport/Position_on_Polymers_20081218.pdf

Table 2.2: Common Synthetic Rubbers	
Technical Name	**ISO 1629 Code**
Polyisoprene	IR
Isobutylene Isoprene Butyl	IIR
Acrylonitrile Butadiene	NBR
Polyurethane	PU
Styrene Butadiene	SBR
Styrene Ethylene Butylene Styrene Copolymer	SEBS
Polysiloxane	SI
Vinyl Methyl Silicone	VMQ
Acrylonitrile Butadiene Carboxy Monomer	XNBR
Styrene Butadiene Carboxy Monomer	XSBR
Thermoplastic Polyether-ester	YBPO
Styrene Butadiene Block Copolymer	YSBR
Styrene Butadiene Carboxy Block Copolymer	YXSBR

2.2.3 Monomers

Fifty five common monomers identified as being present in the forty one types of polymer listed above, are set out in Table 2.3.

Table 2.3: Common Monomers				
Monomer	**Common Synonyms**	**CAS Number**	**EC Number**	**Example Polymers (No. from list above)**
1,3,5-trioxane	Trioxymethylene, metaformaldehye & trioxin	110-88-3	203-812-5	POM
1,3-dioxolane	Dioxolane	646-06-0	211-463-5	POM copolymer
1,4-dichlorobenzene	p-dichlorobenzene	106-46-7	203-400-5	PPS
11-aminoundecanoic acid	None	2432-99-7	219-417-6	Nylon 11
1-chloro-2,3-epoxypropane	Epichlorohydrin & chloromethyloxirane	106-89-8	203-439-8	Epoxy
2,6-xylenol	2,6-dimethylphenol, cresylic acid, dimethylphenol, 1,2,6-xylenol, 1,3-dimethyl-2-hydroxybenzene, 1-hydroxy-2,6-dimethylbenzene & 2,6-DMP	576-26-1	209-400-1	PPO
4,4'-methylenedianiline	MDA	101-77-9	202-974-4	PU foams
4,4'-methylenediphenyl diisocyanate	MDI	101-68-8	202-966-0	PUR & TPU
4-methyl-m-phenylene diisocyanate	Toluene diisocyanate, TDI & 2,4-diisocyanato-1-methyl-benzene	584-84-9	209-544-5	PUR

Table 2.3: Common Monomers				
Monomer	**Common Synonyms**	**CAS Number**	**EC Number**	**Example Polymers (No. from list above)**
Acrylamide	Prop-2-enamide & vinyl amide	79-06-1	201-173-7	PAN
Acrylic acid	Prop-2-enoic acid	79-10-7	201-177-9	PAA
Acrylonitrile	2-propenenitrile, cyanoethene & vinylcyanide	107-13-1	203-466-5	PAN, SAN, & ABS
Adipic acid	Hexanedioic acid & hexane-1,6-dioic acid	124-04-9	204-673-3	Nylon 6,6 & TPU
Bisphenol A	BPA, 4,4'-isopropylidenediphenol, 4,4'-(propane-2,2-diyl)diphenol & 2,2-bis(4-hydroxyphenyl)propane	80-05-7	201-245-8	Epoxy & PC
But-1-ene	1-butene, butene (mixed-1-and-2-isomers), 2-methylpropene, (Z)-but-2-ene & (E)-but-2-ene	106-98-9	203-449-2	LLDPE
Buta-1,3-diene	1,3-butadiene, butadiene, biethylene, divinyl, erythrene, pyrrolylene & vinylethylene	106-99-0	203-450-8	ABS & HIPS
Butane-1,4-diol	1,4-butanediol & tetramethylene glycol	110-63-4	203-786-5	TPU & PBT
ε-caprolactam	Azepan-2-one	105-60-2	203-313-2	Nylon 6
Cyanoguanidine	Dicyandiamide	461-58-5	207-312-8	Epoxy
Dapsone	4,4'-diamino diphenyl sulfone & DDS	80-08-0	201-248-4	Epoxy
D-glucitol	Sorbitol, D-sorbitol & glucitol	50-70-4	200-061-5	PUR
Dimethyl terephthalate	1,4-Dimethyl benzene-1,4-dicarboxylate	120-61-6	204-411-8	PET & PBT
Dimethyldichloro silane	dichloro(dimethyl)silane	75-78-5	200-901-0	PDMS & OMS
Diphenyl carbonate	Phenyl carbonate	102-09-0	203-005-8	PC
Dodecane-12-lactam	Lauryl lactam	947-04-6	213-424-8	Nylon 12
Ethane-1,2-diol	Ethylene glycol & ethanediol	107-21-1	203-473-3	TPU & PET
Ethylene	Ethene	74-85-1	200-815-3	HDPE, LDPE, LLDPE & EVA
Ethylene oxide	Oxirane	75-21-8	200-849-9	PUR & POM copolymer
Formaldehyde	Methanal	50-00-0	200-001-8	POM, PF, MF & UF
Hex-1-ene	1-hexene, hexene-1;1-n-hexene,1-C6H12, butylethylene, hexane, UN 2370, hexylene & neodene 6	592-41-6	209-753-1	LLDPE
Hexamethylenediamine	Hexane-1,6-diamine	124-09-4	204-679-6	Nylon 6,6

Table 2.3: Common Monomers				
Monomer	**Common Synonyms**	**CAS Number**	**EC Number**	**Example Polymers (No. from list above)**
Isophthaloyl dichloride	Isophthaloyl chloride	99-63-8	202-774-7	MPD-I
Lactic acid	2-hydroxypropanoic acid	50-21-5	200-018-0	PLA
Maleic anhydride	Furan-2,5-dione	108-31-6	203-571-6	UP
Melamine	1,3,5-Triazine-2,4,6-triamine	108-78-1	203-615-4	MF
Methenamine	Hexamethylenetetramine & 1,3,5,7-Tetraazatricyclo[3.3.1.13,7]decane	100-97-0	202-905-8	PF
Methyl methacrylate	MMA, methyl 2-methylpropenoate	80-62-6	201-297-1	PMMA & UP
Methyloxirane	Epoxypropane, propylene oxide, propylene epoxide	75-56-9	200-879-2	PUR
m-phenylenediamine	MPD & 1,3-diaminobenzene	108-45-2	203-584-7	MPD-I
Oct-1-ene	1-octene, caprylene, Neodene 8 & octylene	111-66-0	203-893-7	LLDPE
Phenol	Carbolic acid, monohydrobenzene & phenylalcohol	108-95-2	203-632-7	PF
Phosgene	Carbonyl chloride	75-44-5	200-870-3	PC
Phthalic anhydride	2-benzofuran-1,3-dione	85-44-9	201-607-5	UP
p-phenylene-diamine	PPD & 1,4-diaminobenzene	106-50-3	203-404-7	PPD-T
Propane-1,2-diol	Propylene glycol, methyl ethyl glycol, MEG & methylethylene glycol	57-55-6	200-338-0	UP
Propene	Propylene	115-07-1	204-062-1	PP
Styrene	Phenylethene & ethenylbenzene	100-42-5	202-851-5	PS, EPS, HIPS, SAN, ABS & UP
Terephthalic acid	Benzene-1,4-dicarboxylic acid & TPA	100-21-0	202-830-0	PET
Terephthaloyl chloride	Terephthaloyl dichloride	100-20-9	202-829-5	PPD-T
Tetrafluoro-ethylene	TFE & perfluoroethylene	116-14-3	204-126-9	PTFE
Urea	Carbamide, carbonyl diamide & diaminomethanal	57-13-6	200-315-5	UF
Vinyl acetate	Ethenyl acetate, ethenyl ethanoate & acetic acid vinyl ester	108-05-4	203-545-4	PAN, EVA & PVA
Vinyl chloride	Chloroethene & chloroethylene	75-01-4	200-831-0	PVC
Vinylidene chloride	,1-dichloroethylene	75-35-4	200-864-0	PVDC
Vinylidene fluoride	1,1-difluoroethylene	75-38-7	200-867-7	PVDF

When the monomers listed in Table 2.3 were compared to the list of registered substances provided by ECHA, it was found that 95% had been registered by 19 July 2012 (ECHA, 2012c). This is not surprising as they are the most common monomers and thus are likely to be registered at high volumes.

Since at this time it is not possible to search for monomers in the registered substances database on the ECHA website[5], alternative sources of information have been searched on the Internet. For example, in its assessment of the hazards posed by polymers undertaken by the polymer industry, over 350 monomers and other reactants were considered (PSG, pers. comm.).

In order to develop an estimate of the total number of potential monomers, we carried out our own searches. As a starting point, we considered the list of authorised monomers based on the Council of Europe Resolution AP (2004)1[6] on coatings intended to come into contact with foodstuffs: the technical document[7] reports that over 500 monomers (plus an additional list of additives) have already been evaluated by the European Food Safety Authority (EFSA) or have already been authorised at national level.

In addition, the portfolio of specialty monomers and polymers of individual manufacturers can provide insight into likely numbers. For example, one manufacturer consulted for this study offers over 500 acrylate/methacrylate monomers, and further sets of fluorinated monomers and silicone containing monomers for a total of almost 700 monomers. A second manufacturer produces a portfolio of over 500 monomers covering a range of functional groups.

Moreover, different monomers and polymers databases were found, listing basic and specialty monomers and polymers by their properties. The Material Information Station database called "PolyInfo" compiled by the Japanese National Institute for Materials Science[8] reports over 22,000 monomers, with Table 2.4 listing the numbers of monomers by class and providing a description for each class.

Table 2.4: Number of Monomers by Class

Class	Description	No.
Carbon multibonding monomers (addition polymerization type)		
Acetylenes	Compound that has one triple bond or more.	324
Acrylic acids (acrylics)	Compound that has C=C-CO-Z (Z=O or S or N) or C=C-CN structure.	2,919
Dienes	Compound that has two double bonds C=C or more.	905

5 http://echa.europa.eu/information-on-chemicals/registered-substances

6 http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/food_contact/Resolution%20AP%20_2004_1%20on%20coatings.pdf

7 http://www.cepe.org/epub/easnet.dll/GetDoc?APPL=1&DAT_IM=02091C&TYPE=PDF

8 http://polymer.nims.go.jp/index_en.html#database

Table 2.4: Number of Monomers by Class		
Class	**Description**	**No.**
Halo-olefins	Compound that has only one double bond C=C, and doesn't contain elements other than C, H, and halogen(X). (X=F, Cl, Br, I)	163
Olefins	Compound that has only one double bond C=C, and consists only of C and H.	262
Styrenes	Compound that has structure of C=C-Ar (Ar=aromatic rings and aromatic heterocyclic rings).	1,116
Vinyl compounds	Compound that has vinyl group C=C-, and has atom or aromatic rings other that C and H.	5,315
Ring monomers (ring-opening polymerization type / polycondensation type)		
Cyclic acid anhydrides	Cyclic compound that has CO-O-CO- bond in the ring.	136
Cyclic amines	Cyclic compound in the ring that has NH- bond. However, exclude the case where it is included in the atom group where this parital structure characterizes the following monomer system.	175
	-NH- in Lactams -NH-CO-	
	-NH- in Cyclic imides -CO-NH-CO-	
Cyclic carbonates	Cyclic compound that has O-CO-O- bond in the ring.	15
Cyclic ethers	Cyclic compound that has O- bond in the ring.	448
Cyclic imides	Cyclic compound that has -CO-NH-CO- group (imide), -NH-CO-O- group (urethane) or -NH-CO-NH- group (urea) in the ring.	100
Cyclic iminoethers	Cyclic compound that has N=C-O- bond in the ring.	80
Cyclic olefins	Cyclic compound that has ring consists of carbon or carbon multiple bond.	180
Cyclic sulfides	Cyclic compound that has S atom in the ring.	331
Lactams	Cyclic compound that has NH-CO- bond in the ring.	157
Lactones	Cyclic compound that has CO-O- bond in the ring.	148
Amino-acid N-carboxy anhydrides	Cyclic compound that has O-CO-NH-C(R)-CO- bond in the ring.	56
Phosphorus containing cyclic compounds	Cyclic compound that has P atom in the ring.	47
Silicon containing cyclic compounds	Cyclic compound that has Si atom in the ring.	92
Bifunctional monomer (polycondensation type / polyaddition type)		
Aldehydes	Compound that has aldehyde -CH=O function.	117
Amino acids (amino carboxylic acid)	Amino carboxylic acid (H_2N-Y-COOH, H_2N-Y-COOR) (ester) derivatives.	217
Aromatic ethers	Compound with which aromatic hydrocarbon radicals are united with oxygen mutually.	13
Carbonates (carbonic acid derivatives)	Carbonic acid derivatives.	58

Table 2.4: Number of Monomers by Class		
Class	**Description**	**No.**
Diamines	Diamine (H_2N-Y-NH_2) derivatives and Polyamines.	1,532
Dicarboxylic acids	Dicarboxylic acid (HOOC-Y-COOH, ROOC-Y-COOR)(ester) derivatives.	1,984
Dihalides (dihalogenated compound)	Dihalogenated compounds that don't correspond.	655
Diisocyanates	Iso(thio)cyanate (-N=C=O) derivatives.	350
Diketones	Diketones compounds.	19
Diols	Polyol that has two free OH radicals or more.	1,902
Hydroxy acids (oxy carboxylic acid)	Oxy carboxylic acid (HO-Y-COOH, HO-Y-COOR)(ester) derivatives.	118
Melamines & Ureas	Melamines and Urea (H_2N-CO-NH_2) derivatives.	79
Phenols	Compound that has an aromatic hydroxyl ArOH structure.	1,290
Phosphorus containing compounds	Phosphorus (P) containing compounds.	124
Sulfur containing compounds	Sulfur (S) containing compounds.	475
Others		
Anilines	Anilines except diamines.	276
Silane compounds	Silane derivatives except silicon containing cyclic compounds.	99
Other monomers	Other compounds whose reaction sites don't correspond.	723
	Total	22,825
Source: PolyInfo database		

A second database[9], provided by CHEMnetBASE, and that can be partially consulted online, lists over 11,200 monomers.

It has to be recognised though that not all these monomers may be placed on the EU market, and/or not all may be being manufactured or imported at greater than 1 tonne.

2.2.4 Additives to Polymers

Additive Types

Besides monomers, many other chemical substances may be needed during the polymerisation process. Additives are substances added to a material to improve or change its properties or to function as diluents, e.g. fillers to reduce cost (Harper and Petrie, 2003). An extremely large variety of additives exist, with each additive type being named after its particular function (Harper and Petrie, 2003; Flick, 2004; Zweifel, 2009). In general these are not within the scope of this study (see Section

[9] http://www.polymersdatabase.com/dictionary-search.do?method=view&id=6887650&si=POLY

2.3.4), however the principle functions of additives have been listed in Table 2.5 for completeness.

Table 2.5: Principle Additive Functions		
Acid scavengers	Coupling agents	Melt strength improvers
Adhesion promoters	Crosslinking agents	Mould release agents
Antiblocking agents	Curing agents	Pigments
Antifogging agents	Defoamers	Plasticisers
Antimicrobials	Dispersants	Processing aids
Antioxidants	Fillers	Release agents
Antislip agents	Flame retardants	Slip agents
Antistatic agents	Heat stabilisers	Thickeners (viscosity regulators)
Bactericidal agents	Impact modifiers	UV-protective agents and
Blowing and foaming agents	Light stabilisers	UV-stabilisers
Brighteners and whiteners	Low-profile additives	Wetting agents.
Colorants	Lubricants	

Additives as Mixtures with Polymers

The types of additive listed here are generally combined with a polymer substance to form a mixture with the particular mechanical and other properties needed for the formation of articles. **Additives used in this way <u>fall outside</u> of the scope of this** study unless they are reactive with the polymer.

Additives as part of the Polymer

Some additives become part of the polymer (e.g. cross linking agents, curing agents, inhibitors, initiators), or are necessary to preserve the stability of the polymer. **Additives used in this way are <u>within</u> the scope of this study.** Some additives are incorporated into a polymer matrix to produce a polymer additive which may then be incorporated into the final polymer matrix. An example is the development of both additive and reactive polymeric fire retardants that are polymers in their own right but are used as additives in other polymers. In this example the additive polymer FR would be assessed as a polymer in its own right and, when the reactive polymer FR is used, it will modify the polymer to which it is attached and be deemed a new polymeric substance (Lein *et al*, 2010 & Stevens *et al*, 2010).

2.3 Polymers and Registration

2.3.1 Introduction

The REACH provisions set out in Title II (Registration) and Title VI (Evaluation) do not apply to polymers (Article 2(9)). However, the manufacturer/importer of a polymer needs to register the monomer substance(s) or any other substance(s) that has not already been registered by an actor up the supply chain, if both the following conditions are met (Article 6(3)):

- the polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);
- the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.

Therefore, the manufacturer/importer of a polymer will not need to register the monomer substance, or any other substance chemically bound to the polymer, provided these have already been registered by the supplier or another actor up their supply chain.

It is important to note that outside of the legislative framework of REACH, the word 'polymer' can refer to a polymer substance, a mixture of a polymer substance(s) with other substances (additives), and/or a polymer article.

2.3.2 Registration of Monomers and Constituent Substances

Article 6 sets out the general obligation to register substances on their own or in mixture(s). Under this Article a manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of 1 tonne or more per year shall submit a registration to ECHA, unless expressly exempted from some or all of the registration requirements under other Article(s) of REACH.

Although monomers often meet the definition of isolated intermediates under REACH, the use of these substances to produce polymers cannot be registered in accordance with the provisions which normally apply to on-site or transported isolated intermediates (Article 6(2)). REACH does not provide an explanation or justification for why more information is required for the registration of monomers than is required for other isolated intermediates, but by inference it would seem that this provision may have been included to ensure that some assessment of polymers under REACH occurs during the registration of their monomers.

However, for the other substances used in the manufacture of the polymer that are used as on-site isolated intermediates or transported isolated intermediates, Article 17 (Registration of on-site isolated intermediates) and Article 18 (Registration of transported isolated intermediates) apply, provided that those other substances meet the conditions specified in these Articles, e.g. initiators, terminators, chain-transfer agents, post-reactants.

Where a manufacturer/importer uses a substance both as a monomer and as a non-monomeric intermediate, a "standard" registration dossier in accordance with Article 10 is required. In this situation, the registrant can still submit one registration dossier covering the total tonnage of monomer and non-monomer. However, the information requirements for this registration dossier are based on the tonnage of the substance used as a monomer or other uses that do not meet the requirements set out in Articles 17 or 18, while including details of the volume manufactured/imported for use as an intermediate.

2.3.3 Registration and Oligomers

Oligomers are very short chain fragments that are not explicitly defined under REACH. Oligomers may contain more than three monomer units and meet the other criteria for a polymer set out in Article 3(5); in which case, were they to be separated from the polymer they would be considered polymers in their own right. However, oligomers may also not meet the criteria set out in Article 3(5); in which case, they would need to be registered were they to be separated from polymer and placed on the market. Indeed, some oligomers (e.g. dimers of maleic anhydride) may be used as monomers and others may be considered as polymers in their own right.

2.3.4 Registration and Additives

(ECHA, 2012) makes it clear that, ***stabilisers*** *and* ***impurities*** *are considered to be part of the substance and do not have to be registered separately.* Stabilisers include, *heat stabilisers, anti-oxidants (both useful during extrusion) and light stabilisers (e.g. for preservation during use). Impurities are unintended constituents of the polymer such as catalysts residue*s. Other substances are often added to polymers to improve their performance and termed "additives" which are not necessary for preserving the stability of the polymer such as pigments, lubricants, thickeners, antistatic agents, antifogging agents, nucleating agents and flame retardants. ECHA (2012) makes it clear that w*hen a polymeric material contains such substances it should be considered as a mixture or an article, as the case may be,* and that *substances' normal registration requirements apply*.

Additives as Mixtures with Polymers

Additives are generally combined with a polymer substance to form a mixture with the particular mechanical and other properties needed for the formation of articles. **Additives used in this way <u>fall outside</u> of the scope of this study** unless they are reactive with the polymer.

Additives as part of the Polymer

Some additives become part of the polymer (e.g. cross linking agents, curing agents, inhibitors, initiators), or are necessary to preserve the stability of the polymer. **Additives used in this way are <u>within</u> the scope of this study.** It is also understood that some additives are incorporated into a polymer matrix to produce a polymer additive which may then be incorporated into the final polymer matrix (PSG, *pers.*

comm.). An example is the development of both additive and reactive polymeric fire retardants that are polymers in their own right but are used as additives in other polymers.

2.3.5 Registration and Polymers

Polymers in General

In considering potential registration requirements for polymers, it is important to recognise that they differ in many ways, including in terms of the:

- identity of monomer units;
- proportion of different monomer units;
- distribution of monomer units or groups of monomer units;
- chain length mean and distribution (a number count or spatial length - note that transport properties are chain length dependent particularly Guassian length);
- average distribution of molecular weight of polymer chains (expressed as number or weight based molecular weight);
- degree and position of cross-linking;
- identity, quantity and proportions of constituents of relevance to this study (e.g. catalyst residues, stabilisers, covalently bonded flame-retardants, and unreacted monomers);
- manufacturing process used, including post reaction of polymers;
- permeability to gases and liquids;
- solubility in different media, including water;
- variability of polymer structure following manufacture and processing;
- variability of the distribution and availability of other ingredients (e.g. catalyst residues, stabilisers, covalently bonded flame-retardants, and unreacted monomers) following manufacture and processing;
- the availability of monomeric functional groups for further chemical reaction or interaction with surrounding media;
- the availability of potentially hazardous monomers, monomeric functional groups, other ingredients of relevance to this study (e.g. residual products and stabilisers) and degradation products under differing environmental conditions
- the hazard properties of monomers, monomeric functional groups and other relevant ingredients (e.g. residual products/by-products (i.e. molecules split off during condensation) and stabilisers); and
- the stability of the polymer under differing environmental conditions. There are a large range of potential environmental and use phase exposure conditions. The leading stability areas include thermal, UV or photolytic, oxidative, hydrolytic and combinations. However, there are others including radiation, electrical, mechanical, etc.

Each of the factors listed above may alter the physical and hazard properties of a polymer. Therefore, for polymers to be registered, it would be necessary first to find a way (or ways) of grouping them that would do justice to their inherent variability in structural and hazard properties. Some of these properties will be relevant to the identification and grouping for registration of some polymers but not for others. The

polymer industry has indicated though that general harmonisation of polymer groups (PSG, *pers. comm.*) "should be possible based on discussion between industry, regulators etc. However, it was estimated that it might take of the order of ***two years*** to reach a consensus on the substance identification parameters that should be used to allow grouping of polymers for regulatory purposes".

Industry has further suggested that, for the purposes of registration under REACH, a limited number of factors, or scientific qualifiers, would be sufficient in most cases for the purposes of polymer substance identification and grouping (PSG, *pers. comm.*). The qualifiers suggested by industry as potentially being sufficient for this purpose are set out in Table 2.5.

Post-reacted Polymers

In addition to being manufactured through the polymerisation of monomers, a polymer can also be subjected to a chemical reaction to form covalent or ionic bonds between itself and other substances including post-reacted polymers. No definition for a post-reacted polymer is given either in REACH or in the ECHA Guidance (ECHA, 2012). Industry has indicated that a significant proportion of polymers placed on the market fall into this category (PSG, *pers. comm.*). For example, polymers are often manufactured so that only a proportion of the monomer is reacted; this polymer is then marketed for further polymerisation by the same company or another actor down the supply chain. Such a polymer may undergo a series of reactions by different actors down the supply chain, each time producing a polymer substance with different physicochemical properties.

A reactant used to modify a polymer would normally fall within the definition of an 'other reactant' (Article 3(5)a), rather than being considered to be an additional monomer. When used to modify the properties of a polymer, these 'other reactants' will often be considered to be intermediates under REACH and, where these substances do not have an additional non-intermediate use, they may have less information in their registration dossier than for other substances.

Table 2.6: Scientific Qualifiers Relevant for Substance ID for Polymers

Scientific Qualifier	**Description [Unit]**	**Remarks**
Polymer Identifier		
CAS number	CAS number [N/A]	In the EU, the regulatory focus is on the monomers. Therefore, not all polymers have a CAS number
Chemical Name	IUPAC Name [N/A]	Give the IUPAC name if available, or else the CAS definition, or else the best possible identifier
Common Name following an ISO standard where existing*	e.g. LDPE or HDPE [N/A]	-
General Technical Information		
Molecular weight	M_n (number averaged) [Da]	$\bar{M}_n = \frac{\sum_i N_i M_i}{\sum_i N_i}$ N_i = No. polymers with molar mass M_i
Molecular weight range	M_n (min) - M_n (max) [Da (min) - Da (max)]	

Table 2.6: Scientific Qualifiers Relevant for Substance ID for Polymers		
Scientific Qualifier	**Description [Unit]**	**Remarks**
Molecular Weight distribution	% of M_n (n = 1 - i)	The molar mass distribution (or molecular weight distribution) in a polymer describes the relationship between the number of moles of each polymer species (N_i) and the molar mass (M_i) of that species.
Monomers	Kind (for example acrylates)	Identification of monomer chemical group
	Type of monomer substance	monoconstituent, multi-constituent or UVCB (this may be an indicator for the complexity of the polymer and thus a potential issue for identification, e.g. if polymers are based on petroleum distillates)
	Identification and number of different monomers	CAS number of the monomers (and/or EC number)
	Sequence of Monomers	Isotactic, atactic, syndiotactic
Other reactants	Kind (for example aliphatic alcohol) including identification of chemical group	Initiator, terminator, chain-transfer agent, post-reactant
	Identification and number of different other reactants	CAS number of the monomers (and/or EC number)
Stabiliser	Identification and % of each stabiliser	CAS number of the monomers (and/or EC number)
Structural Details		
Degree of branching	% of linear polymer vs. % of branched polymer	-
3D Configuration	-	-
Functional groups	Identification of functional groups	Identifies the nature of any (side)group that gives the polymer a special functionality (e.g., the functional group in ion exchange resins)
End group modification	-	-
Un-reacted Monomer		
Intentional monomers present	Identification and % of each monomer	CAS number of the monomers (and/or EC number)
Unintentional monomer residues	Identification and % of each monomer	CAS number of the monomers (and/or EC number)

However, modifiers may sometimes be considered as monomers, for example when grafting polymer side-chains onto an existing polymer backbone, when reacting a polymer with monomers, and when reacting the functional group at the end of a polymer chain with different monomers to form block co-polymers of the structure: A-A-A-A-A-B-B-B-B-B).

A further group of post-reacted polymers includes those formed as part of a final article, e.g. acrylic paint coatings and many silicone sealants. These polymer products are made up of monomer, oligomer and/or short chain polymer preparations that will react to form the final polymer after use by an actor down the supply chain. These final polymers (e.g. cured sealant or dry paint coat) are considered to be articles, and thus would be exempt from any options for the registration of polymers.

Industry has indicated that only a small proportion of polymers manufactured for further polymerisation/reaction would meet the criteria for non-isolated intermediates and thus would be exempt from registration (Article 2(c)) (PSG, *pers. comm.*). A larger proportion of these polymers would meet the criteria for on-site or transported isolated intermediates, and so would be subject to very much reduced registration requirements (Article 17 and Article 18, respectively). However, it is understood that a significant proportion of polymers currently manufactured in the EU for further polymerisation/reaction would not meet the criteria for any form of intermediate, and could be considered for possible registration. Unfortunately, industry was not able to estimate the relative proportions of these polymers that are likely to be non-isolated intermediates, on-site isolated intermediates, transported isolated intermediates, and non-intermediates.

Naturally Occurring Polymers

A manufacturer or importer of a naturally occurring polymer can be exempted from any registration provisions under REACH provided that the polymer fulfils the definition of a naturally occurring substance (according to article 3(39)), has not been chemically modified, and does not meet the hazard criteria set out in Annex V(8).

Where such polymers have been chemically modified, ECHA (2012) states that the monomers making up these polymers would be considered as naturally occurring substances, and as such would only need registering if hazardous (the substances used to modify the polymer would need to be registered under REACH). Furthermore, where it proves impossible to identify and quantify the monomer building blocks of the polymer, the substance itself may be considered to be a UVCB substance for the purposes of registration (substance of unknown or variable composition, complex reaction products or biological materials).

Finally, there is further advice that indicates that even where the monomeric units of a natural polymer would otherwise be eligible for registration, these units may be considered to be non-isolated intermediates (FAQs published by ECHA):

> *monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s) in natural polymers can, for practical reasons, be treated as "non-isolated intermediates" and do not have to be registered.*

The discussion outlined above is complex but in summary neither naturally occurring polymers nor their monomers require registration, even when chemically modified. However, the substances used to modify these polymers will need to be registered. Naturally occurring polymers are not therefore considered further here.

Rubber

Synthetic rubber has the same registration requirements as any other form of synthetic polymer. The arguments made with regards to naturally occurring polymers apply equally to natural rubber.

2.4 Assumptions for the Impact Assessment

The assumptions presented in this section that have been carried forward to the assessment of options are set out in Section 7 of this report, including possible information requirements for the registration of polymers, and are not repeated here for brevity.

3. POLYMER SYNTHESIS AND INDUSTRY

3.1 The European Chemicals Industry

3.1.1 The Sector at the EU Level

The polymer industry is a subsector of the chemicals industry. Therefore, in order to provide context to the polymer industry, data are first presented on the European chemicals industry as a whole. These data are then supplemented in Section 3.3 by data specific to the polymer industry itself.

Data stored on the Eurostat database have been used to obtain information on employment and trade, and these data are grouped under NACE codes. However, the NACE codes used have changed over recent years and the data presented here are therefore grouped under both version 1.1 codes and version 2 codes. These two versions have different coding but similar (not identical) grouping. Where such data are presented, the NACE code version and accompanying description are provided for clarity.

The European chemicals industry produces 21% of the world's chemicals and created €491 billion for the economy of the European Union in 2010 (Cefic, 2011). Currently, eight Member States account for 90% of EU chemicals production, while the remainder of the market is divided between the other 19 Member States. Figure 3.1 illustrates the distribution of the EU chemicals market, showing that the eight largest chemicals producers in the EU collectively generated €437 billion in chemical sales in 2010, while the remaining 19 Member States generated €54 billion in sales (Cefic, 2011).

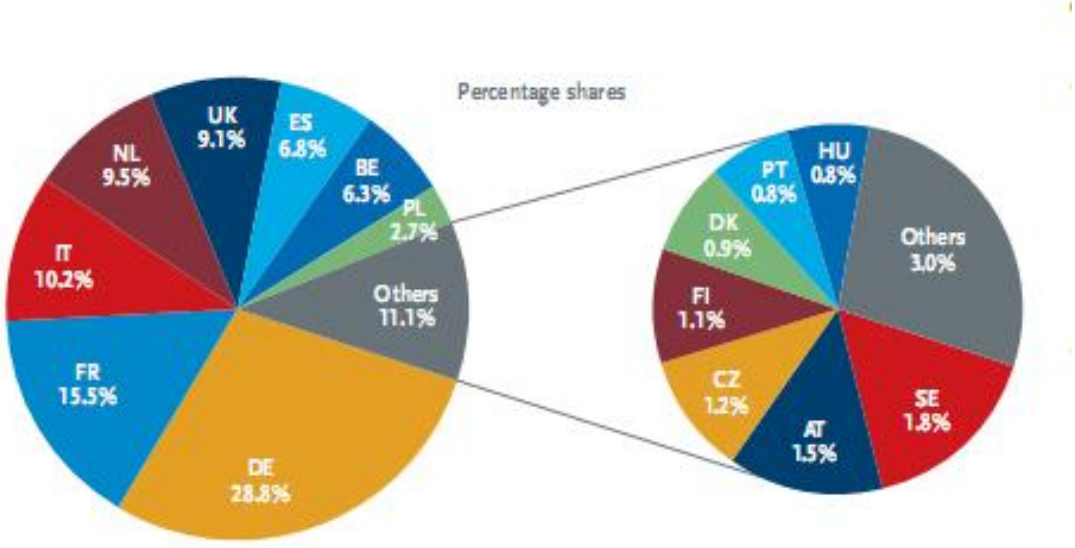


Figure 3.1: European Chemicals Market: Percentage Shares by Member States in 2010, reproduced from Cefic (2011)

EU chemical manufacturing includes the production of base chemicals, specialty chemicals and consumer chemicals and, according to Cefic (2011), total EU chemicals sales can be subdivided by value as follows:

- Specialty chemicals – 25.6%;
- **Polymers – 24%;**
- Petrochemicals – 24%;
- Base inorganics – 13.6%; and
- Consumer chemicals – 12.8%.

It is estimated that 27,000 companies (excluding pharmaceutical companies) are active within the EU chemicals industry and have approximately 1.2 million employees (Cefic, 2010). In terms of direct employment, based on data from 2007, the European chemicals industry accounts for 5.4% of the total employment generated by the EU manufacturing sector. Importantly, unlike other manufacturing sectors, the chemicals industry boasts a skilled and highly trained workforce; consequently the chemicals industry has the highest labour cost per employee in EU manufacturing sector (Cefic, 2011).

Irrespective of the high labour costs, companies with less than 250 employees (potential SMEs[10]) are said to dominate the European chemicals industry, accounting for 96% of the 27,000 companies in the industry. In this respect, there is evidence from the Italian chemical industry that SMEs are concentrated in the fine and speciality chemicals sectors where they are able to focus on high value, low volume, tailor made products (Federchimica, 2008).

Table 3.1 presents a breakdown of the chemicals industry regarding the types of companies in the industry, according to classifications which are based on the number of employees.

Table 3.1: Size Class Distribution and Associated Percentage of Total Employment

	Percentage of Chemical Companies[1] (Whole Manufacturing Sector)[2]	**Percentage of Total Employment[1] (Whole Manufacturing Sector)[2]**
SME		
Micro (1-9)	63% (81%)	4% (14%)
Small (10-49)	23% (15%)	10% (20%)
Medium (50-249)	10% (4%)	23% (25%)
Large (250+)	4% (1%)	63% (41%)

Sources:
1. Cefic (2010) – figures calculated from data published by Eurostat and refer to NACE (v.2) Code C20 (Cefic, *pers. comm.).*
2. PLANET (2010) – figures calculated from data published by Eurostat and UK DTI estimations.

According to the data presented in Table 3.1, it is evident that SMEs which have less than 250 employees account for the majority of the companies in the chemicals sector. However, it is the large companies which dominate in terms of employment, with 4% out of the total number of companies accounting for 63% of employment in the

[10] As defined by Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises (COM, 2003c).

sector. Of these large companies 2.1% have 250-499 employees, 1.1% has 500-999 employees and only 0.7% has 1000 or more employees. In addition, large companies account for 70% of total sales while SME companies, although representing the majority of operators in the sector, only account for 30% of sales.

It is also noted that the company profile for the chemical industry differs greatly from that of the manufacturing sector as a whole. Micro industries make up 81% of manufacturing companies but only 63% of chemical companies. Micro industries are also responsible for 14% of employment in the manufacturing sector as a whole but account for only 4% of chemical sector employment.

Tables 3.2 sets out the numbers and percentages of companies, corresponding to the percentages displayed in Table 3.1, but subdivided into NACE (v.2) codes C20.1 and C20.2.

Table 3.2: Companies Manufacturing Substances, by Sector and Size of Company[1]

NACE (v.2) Code (Sector Description)[2]	Number of Employees (%)				
	Micro	**Small**	**Medium**	**Large**	**All**
C20.1 (Manufacture of Basic Chemicals, Fertilisers and Nitrogen Compounds, Plastics and Synthetic Rubber in Primary Forms)	5,486 (63%)	1,881[3] (22%)	983 (11%)	376 (4%)	**8,350 (100%)**
C20.2 (Manufacture of Pesticides and other Agrochemical Products)	396 (61%)	150 (23%)	87 (13%)	20 (3%)	**633 (100%)**

Notes:
1. SMEs identified based on number of employees only.
3. It is assumed that the figures for NACE (v.2) code C20.2 best represent companies in that manufacture polymers. Data on companies that convert polymers or produce polymer products is set out in Section 3.2.
3. Eurostat notes that this figure is estimated.
Source: Eurostat (SBS) data for 2009.

Furthermore, it is expected that the majority of SMEs are in fact active in the downstream section of the supply chain or are article producers rather than being producers of chemicals (Chemsec, 2012). It is estimated that only 0.3% of all European SMEs are chemical producers (Chemsec, 2012). According to Cefic (2006) (assumed to be based on 2004 data), 25% of SMEs (6,317) in the chemicals industry can be considered producers of substances, with the remaining 75% considered formulators; however, questions have been raised regarding how this figure was established.

Import of Chemicals

The Eurostat figures for the import of chemicals (other than polymers and rubber) into the EU27 in 2011 are set out in Table 3.3. (A breakdown of the corresponding figures for polymers and rubber are provided in Table 3.8 and Table 3.11, respectively.)

Table 3.3: Imports of Organic and Inorganic Chemicals into the EU 27 (2011)		
	Quantity (Million tonnes)	**Value (€ Billion)**
Organic Chemicals	5	13.5
Inorganic Chemicals	1	4
All Chemicals (excluding polymers and rubbers)	6	17.5

3.1.2 Germany

As was previously mentioned, Germany is the largest chemicals producing Member State in the EU, with an estimated market share of 28.8%. According to the VCI (Verband der Chemischen Industrie e.V., German Chemical Association), a large proportion of the German chemicals industry is made up of SMEs akin to the structure of the European industry. It is estimated that there are 2,000 companies which *"manufacture chemical products in Germany"* (VCI, 2011). Of these 2,000 companies it is estimated that 90% are smaller companies with less than *500* staff (no data from the 2011 document clarifies the number of companies with less than 250 employees).

Table 3.4 is reproduced from the earlier RPA report on REACH (RPA, 2006) and breaks down older data on the number of SMEs in the German chemicals industry further, providing a greater focus on those actually involved in the manufacture of chemical substances rather than in formulation, distribution or other activities. As can be seen from this table, the number is significantly smaller at 312 than might be assumed on the basis of the 2011 report by the VCI (90% of 2,000 could be taken to suggest 1,800 SMEs involved in chemicals manufacture).

Table 3.4: Substance Manufacture by SMEs in Germany				
Sector and NACE (v 1.1) Code	**Number of SMEs[1]**	**Percentage of SMEs**	**No. of SME Companies Manufacturing Substances[2]**	**Percentage of SME Companies Manufacturing Substances**
Basic chemicals	223	26	181	81
Pesticides	15	2	14	93
Paints	184	21	9	5
Consumer chemicals	193	22	19	10
Other chemicals	233	27	82	35
Man-made fibres	20	2	7	35
Total	868	100	312	-

Notes.
1. Based on number of employees only.
2. Estimated by experts from the relevant sector associations.
Source: RPA (2006)

Based on the above data, it appears that the German industry has a structure similar to the European industry as a whole. Furthermore, according to the VCI, a particular strength of the SMEs in the industry is in custom chemicals for specialised applications; they manufacture 24,000 different products in quantities less than 100 tonnes annually (VCI, 2011b).

3.1.3 France

The chemicals industry in France accounts for 15.5% of the total European market. According to the UIC (Union des Industries Chimiques/ Union of Chemical Industries), 3,350 companies are active in the French chemicals industry, with 94% of these having less than 250 employees and so potential SMEs (UIC, 2012). According to the Observatoire des Industries Chimiques (Observatory of the Chemical Industries, 2009), SMEs are over-represented in the industry.

The structure of the chemicals industry in France is reported to be divided as follows (Observatoire des Industries Chimiques, 2009):

- 63% of companies have less than 20 employees;
- 24% of companies have between 20 and 100 employees;
- 10% of companies have between 100 and 500 employees; and
- 3% of companies have over 500 employees.

No data was found regarding the number of SMEs actually involved in the manufacture of chemicals, as opposed to formulation, distribution, etc. in France. Nor was data found that more closely matched the EU definition of SMEs.

3.1.4 Italy

The Italian chemicals industry accounts for 10.2% of the European chemicals industry and employs 115,000 people in an estimated 3,000 companies (Federchimica, 2011). According to Federchimica (Federazione Nazionale dell'Industria Chimica/ National Federation of the Chemical Industry) (2008), the Italian chemicals industry can be divided into three groups:

- Italian SMEs (which account for 41% of the total value of production);
- Italian medium and large companies (22% of the total value of production); and
- Foreign owned companies (37% of the total value of production) (*importantly there is no clarification as to the size of such companies; as a result it is not possible to conclude that only 41% of companies are SMEs).*

Federchimica (2008) note that SMEs in the Italian chemicals industry are particularly active in fine and specialty chemicals where scale economies are not very relevant and the key to success often consists of offering customers tailor made products.

3.1.5 The UK

The UK chemicals industry accounts for 9.1% of the total European chemicals industry. It is estimated that turnover from the UK chemicals industry exceeds £57 billion and over 180,000 people are employed in 3,000 organisations across that Member State. According to the CIA (Chemical Industries Association), only 160 companies currently employ more than 250 people; therefore, similar to the European industry, the majority of the industry is made up of companies with less than 250 employees (i.e. potential SMEs) (CIA, 2012). Unfortunately, there is no data which clarifies specifically the number of SMEs actually involved in chemicals manufacture as opposed to other activities.

3.1.6 Spain

The chemicals industry in Spain accounts for 6.8% of the European chemicals industry. Table 3.5 provides data on the size of the companies within the Spanish industry based on the number of employees and the percentage of the market each size classification accounts for. These data are reproduced from Feique, the Federation of Employers of the Spanish Chemicals Industry (Federación Empresarial de la Industria Química Española), and cover all companies involved in the chemicals industry and not just chemicals manufacturers.

Table 3.5: Size of Companies in the Spanish Chemicals and Pharmaceuticals Industries

Number of Employees	Number of Companies	Percentage of Total
Less than 10	1,809	54.6
10-19	521	15.7
20-49	514	15.5
50-99	210	6.3
100-199	116	3.5
200-499	102	3.1
500-999	30	0.9
1,000 or more	9	0.3
Total	3,311	100

Source: reproduced from Feique (2011)

Although it is not possible from the data presented in Table 3.5 to establish the precise percentage of SMEs in the industry, it can be deduced that SMEs are likely to dominate, with 95.6% of companies having less than 200 employees. Consequently, as for other counties, SMEs can be assumed to constitute the majority of companies in the chemicals industry in Spain; again though, it is not known what percentage are actually manufacturers of chemicals rather than downstream users (including polymer manufacturers).

3.2 The Production and Trade in Polymers

3.2.1 Sources of Production Data

Data from the Eurostat database has been used to develop information on the EU market for polymers, based on production grouped under PRODCOM codes. For the purpose of this analysis, the PRODCOM codes set out in Table 3.6 are assumed to encompass the trade in polymers of concern to this study. However, it should be noted that Codes 20165970, 20165940 and 20165960 include natural polymers and chemically modified natural polymers, as well as the synthetic polymers of interest to this study.

PRODCOM data have only been used to inform the analysis of polymer production. The Eurostat database also contains data on employment and trade and these are grouped under NACE codes (NACE (v.2) codes). With regard to polymers, the NACE codes used were C22.1 (plastics in primary forms) and C22.2 (synthetic rubber in primary forms).

Table 3.6: PRODCOM Codes Considered

Code	Description
20161035	Linear polyethylene having a specific gravity < 0.94, in primary forms
20161039	Polyethylene having a specific gravity < 0.94, in primary forms (excluding linear)
20161050	Polyethylene having a specific gravity of >= 0.94, in primary forms
20161070	Ethylene-vinyl acetate copolymers, in primary forms
20161090	Polymers of ethylene, in primary forms (excluding polyethylene, ethylene-vinyl acetate copolymers)
20162035	Expansible polystyrene, in primary forms
20162039	Polystyrene, in primary forms (excluding expansible polystyrene)
20162050	Styrene-acrylonitrile (SAN) copolymers, in primary forms
20162070	Acrylonitrile-butadiene-styrene (ABS) copolymers, in primary forms
20162090	Polymers of styrene, in primary forms (excluding polystyrene, styrene-acrylonitrile (SAN) copolymers, acrylonitrile-butadiene-styrene (ABS) copolymers)
20163010	Polyvinyl chloride, not mixed with any other substances, in primary forms
20163023	Non-plasticised polyvinyl chloride mixed with any other substance, in primary forms
20163025	Plasticised polyvinyl chloride mixed with any other substance, in primary forms
20163040	Vinyl chloride-vinyl acetate copolymers and other vinyl chloride copolymers, in primary forms
20163060	Fluoropolymers
20163090	Polymers of halogenated olefins, in primary forms, n.e.c.
20164013	Polyacetals, in primary forms
20164015	Polyethylene glycols and other polyether alcohols, in primary forms
20164020	Polyethers, in primary forms (excluding polyacetals, polyether alcohols)
20164030	Epoxide resins, in primary forms
20164040	Polycarbonates, in primary forms
20164050	Alkyd resins, in primary forms
20164062	Polyethylene terephthalate having a viscosity number of >= 78 ml/g
20164064	Other polyethylene terephthalate
20164070	Unsaturated liquid polyesters, in primary forms (excluding polyacetals, polyethers, epoxide resins, polycarbonates, alkyd resins, polyethylene terephthalate)
20164080	Unsaturated polyesters, in primary forms (excluding liquid polyesters, polyacetals,

Table 3.6: PRODCOM Codes Considered	
Code	**Description**
	polyethers, epoxide resins, polycarbonates, alkyd resins, polyethylene terephthalate)
20164090	Polyesters, in primary forms (excluding polyacetals, polyethers, epoxide resins, polycarbonates, alkyd resins, polyethylene terephthalate, other unsaturated polyesters)
20165130	Polypropylene, in primary forms
20165150	Polymers of propylene or of other olefins, in primary forms (excluding polypropylene)
20165230	Polymers of vinyl acetate, in aqueous dispersion, in primary forms
20165250	Polymers of vinyl acetate, in primary forms (excluding in aqueous dispersion)
20165270	Polymers of vinyl esters or other vinyl polymers, in primary forms (excluding vinyl acetate)
20165350	Polymethyl methacrylate, in primary forms
20165390	Acrylic polymers, in primary forms (excluding polymethyl methacrylate)
20165450	Polyamide -6, -11, -12, -6.6, -6.9, -6.10 or -6.12, in primary forms
20165490	Polyamides, in primary forms (excluding polyamide -6, -11, -12, -6.6, -6.9, -6.10 or -6.12)
20165550	Urea resins and thiourea resins, in primary forms
20165570	Melamine resins, in primary forms
20165630	Amino resins, in primary forms (excluding urea and thiourea resins, melamine resins)
20165650	Phenolic resins, in primary forms
20165670	Polyurethanes, in primary forms
20165700	Silicones, in primary forms
20165920	Petroleum resins, coumarone-indene resins, polyterpenes, polysulphides, polysulphones, etc, n.e.c., in primary forms
20165940	Cellulose and its chemical derivatives, n.e.c., in primary forms
20165960	Natural and modified polymers, in primary forms (including alginic acid, hardened proteins, chemical derivatives of natural rubber)
20165970	Ion-exchangers based on synthetic or natural polymers
20171050	Synthetic latex rubber
20171090	Synthetic rubber (excluding latex)

3.2.2 Plastics Production in the EU

The term ‘plastics’ is used to describe plastic polymers with additives to enable processing and/or to give the properties needed for a desired application (OECD, 2004). The data on ‘plastics’ set out here should therefore be considered as representing polymer substances only, as well as polymer substances in mixtures and final articles. Plastics constitute a large material group with a global annual production that has doubled in 15 years, reaching 245 million tonnes in 2008 (PlasticsEurope, 2009) and 265 million tonnes in 2010 (PlasticsEurope, 2011). Overall EU27 plastics production figures for 2010, published by Eurostat, are set out in Table 3.7 (Eurostat, 2012).

Table 3.7: EU27 Plastics Production Figures for 2010 (Eurostat, 2012)			
Polymer Types Grouped by their PRODCOM Code	**Value (billion Euro)**	**Production (thousand tonnes)**	**Sales (thousand tonnes)**
201610: Ethylene based polymers	13.1	14.6	13.4
201620: Styrene based polymers	5.7	5.7	5.2
201630: Vinyl chloride and other halogenated polymers based polymers	7.5	8.6	8.6
201640: Polyesters	12.9	10.4	9.0
201651: Polypropylenes	10.8	12.0	10.7
201652: Vinyl based polymers (not vinyl chloride)	2.2	1.8	1.6
201653: Acrylics	4.7	3.2	3.0
201654: Polyamides	5.2	2.8	2.5
201655: Urea and melamine resins	1.8	4.9	4.4
201656: Polyurethanes plus phenolic and amino resins	6.3	5.2	4.5
201659: Cellulose, natural and other polymers (not rubber or silicones)	3.3	1.2	1.2
Total	***73.5***	***70.4***	***64.1***

The EU produced 57 million tonnes in 2010, 21.5% of global production and worth €104 billion (€203 billion for plastics converters) (PlasticsEurope, 2011). Synthetic fibres account for an additional 40 million tonnes/year (2009) (Engelhardt, 2010). In 2010 the plastics industry employed approximately 200,000 people, plus over 1.2 million in plastics converting and about 1.6 million for the whole plastics industry and plastics machine manufacturing (PlasticsEurope, 2011). Furthermore, the EU is a net exporter of plastics and plastic products, producing a trade surplus of €15.7 billion in 2010.

The split of plastics production across Europe in 2010 is displayed in Figure 3.2 (PlasticsEurope, 2011).

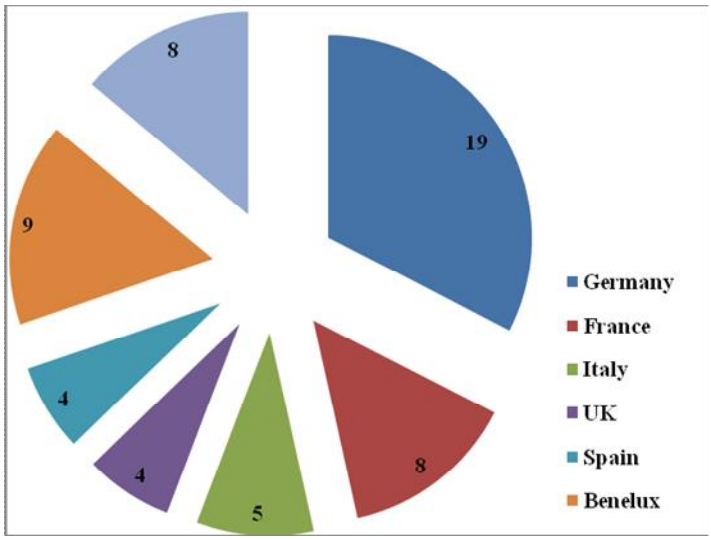


Figure 3.2: Plastics Production across Europe in 2010 (million tonnes) (PlasticsEurope, 2011)

Global and European plastic demand is dominated by the following polymer types:

- polypropylene (PP);
- low- and linear low-density polyethylene (PE (LD/LLD));
- polyvinyl chloride (PVC);
- high-density polyethylene PE (HD);
- polystyrene and expandable polystyrene (PS/EPS);
- polyethylene terephthalate, (PET excluding PET fibre); and
- plastic polyurethane (PUR) (only thermosetting polymer in this list).

The global (PlasticsEurope MRG, 2008) and European (PlasticsEurope, 2011) demand for plastics, based on different polymer types, is shown in Figure 3.3.

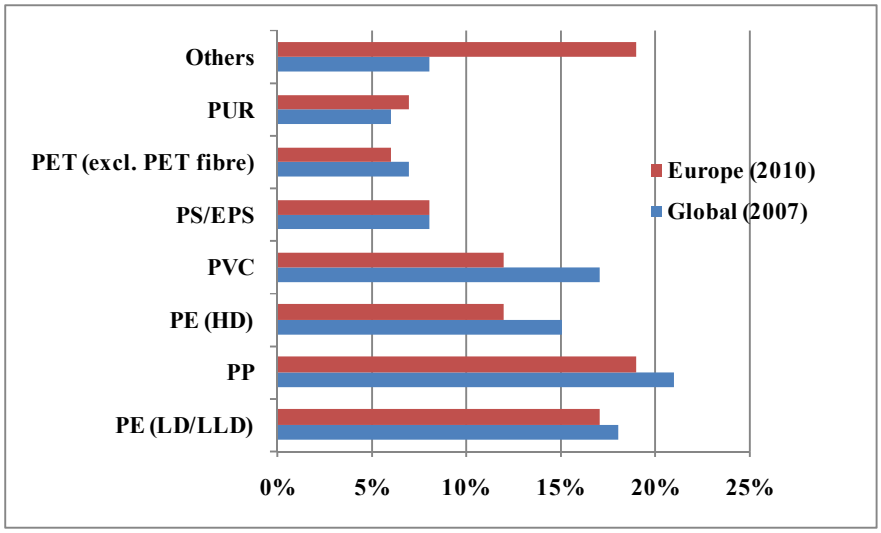


Figure 3.3: Global (PlasticsEurope MRG, 2008) and European Demand (PlasticsEurope, 2011)

In Europe, the use of plastics is dominated by packaging (39.0%), followed by building and construction (20.6%), automotive (7.5%), electrical and electronic (5.6%), and other sectors (27.3%) such as medical and leisure (PlasticsEurope, 2011).

Figure 3.4 sets out the number of companies, employees and turnover from plastics raw material production and plastics converting in 2010 (PEMRG, 2012). From this Figure, it is clear that the production of plastics raw materials is a significantly smaller industry than that of plastics converting. However, the production of plastics raw materials is responsible for a greater share of turnover than would be expected by the number of companies and employees.

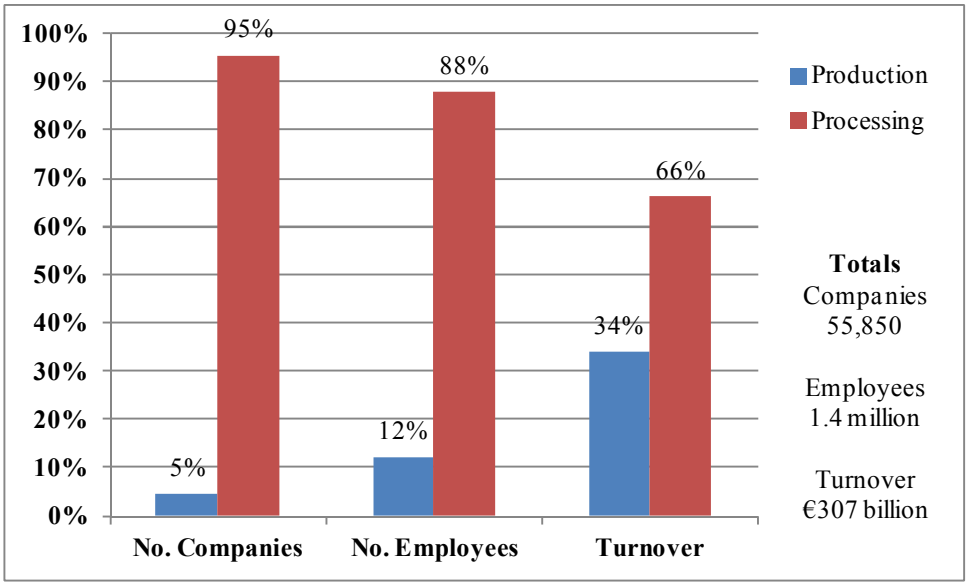


Figure 3.4: European Plastics Industry in 2010 (PEMRG, 2012)

The market in thermoplastics may also be divided into three classifications, 'Standard Plastics', 'Engineering Thermoplastics', and 'High Performance Polymers', as described by Figures 3.5 and 3.6, reproduced from data presented by the PlasticsEurope Market Research Group (PEMRG, 2012).

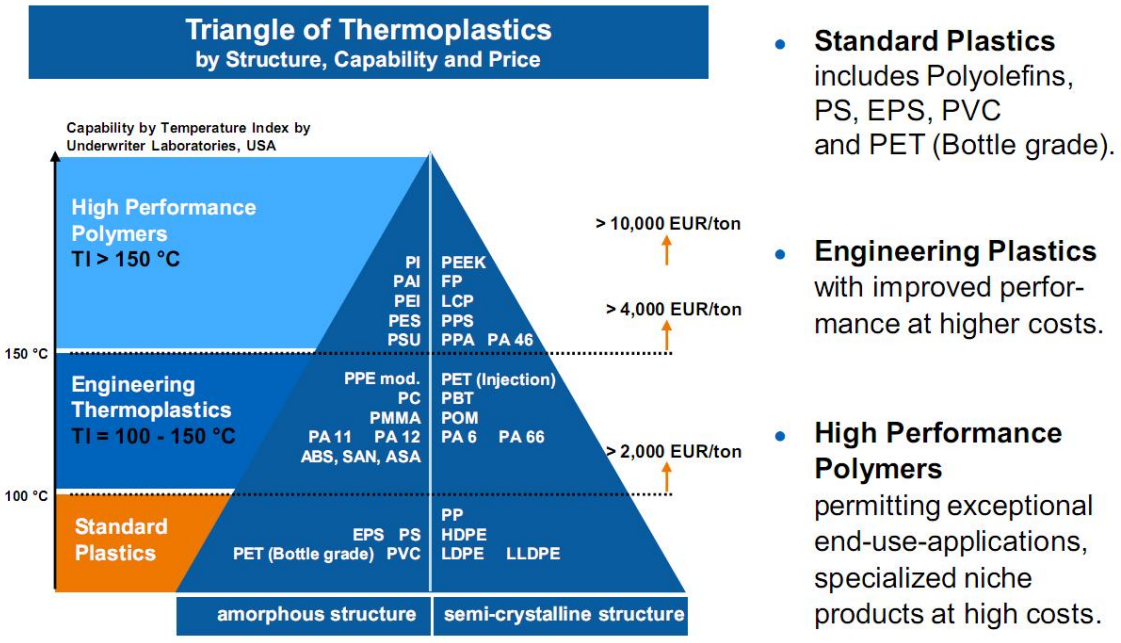
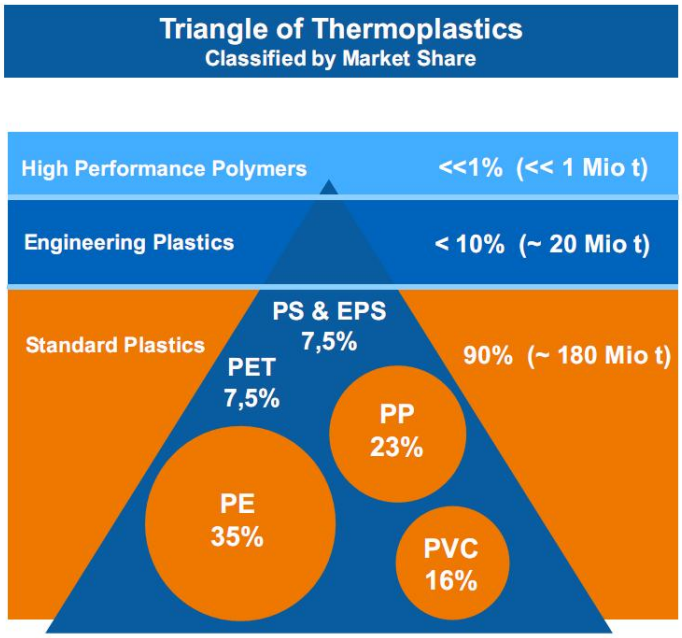


Figure 3.5: Thermoplastics Classification (Reproduced from PEMRG, 2012)



- **Standard Plastics** are the basics materials.
- **Polyolefins** are the largest product group
  Polyethylene: 35%
  Polypropylene: 23%
- **Engineering Plastics** are a small but valuable part of the market.
- **High Performance Polymers** are specialized for very demanding applications.

Figure 3.6: Thermoplastics Market Share (Reproduced from PEMRG, 2012)

Plastics Imports

The Eurostat figures for the import of polymers into the EU27 in 2011 are set out in Table 3.8.

Table 3.8: Polymer Imports into the EU 27 (2011)		
Polymer by Eurostat CM Code and Description	**Quantity (1,000 tonnes)**	**Value (€ Million)**
390110 polyethylene with a specific gravity of < 0,94, in primary forms	No data	No data
390120 polyethylene with a specific gravity of >= 0,94, in primary forms	3	3
390190 polymers of ethylene, in primary forms (excl. polyethylene and ethylene-vinyl acetate copolymers)	28	62
390210 polypropylene, in primary forms	39	46
390230 propylene copolymers, in primary forms	9	28
390290 polymers of propylene or of other olefins, in primary forms (excl. polypropylene, polyisobutylene and propylene copolymers)	34	91
390311 expansible polystyrene, in primary forms	5	7
390319 polystyrene, in primary forms (excl. expansible)	2	4
390330 acrylonitrile-butadiene-styrene copolymers 'abs', in primary forms	No data	No data
390390 polymers of styrene, in primary forms (excl. polystyrene, styrene-acrylonitrile copolymers "san" and acrylonitrile-butadiene-styrene "abs")	7	19
390410 poly'vinyl chloride', in primary forms, not mixed with any other substances	No data	No data
390422 plasticised poly'vinyl chloride', in primary forms, mixed with other substances	No data	No data
390490 polymers of vinyl chloride or other halogenated olefins, in primary forms (excl. poly'vinyl chloride', copolymers of vinyl chloride,	No data	No data

Table 3.8: Polymer Imports into the EU 27 (2011)		
Polymer by Eurostat CM Code and Description	**Quantity (1,000 tonnes)**	**Value (€ Million)**
polymers of vinyl chloride and fluoro-polymers)		
390599 polymers of vinyl esters and other vinyl polymers, in primary forms (excl. those of vinyl chloride or other halogenated olefins, poly"vinyl acetate", vinyl acetate copolymers and poly"vinyl alcohol", whether or not containing unhydrolised acetate groups)	2	15
390610 poly'methyl methacrylate', in primary forms	No data	No data
390690 acrylic polymers, in primary forms (excl. poly"methyl methacrylate")	20	103
390720 polyethers, in primary forms (excl. polyacetals and goods of 3002 10)	9	61
390730 epoxide resins, in primary forms	0	0
390740 polycarbonates, in primary forms	No data	No data
390750 alkyd resins, in primary forms	No data	No data
390760 poly"ethylene terephthalate", in primary forms	1	2
390791 unsaturated polyallyl esters and other polyesters, in primary forms (excl. polycarbonates, alkyd resins, poly"ethylene terephthalate" and poly"lactic acid")	0	0
390799 saturated polyesters in primary forms (excl. polycarbonates, alkyd resins, poly"ethylene terephthalate" and poly"lactic acid")	51	132
390810 polyamides-6, -11, -12, -6,6, -6,9, -6,10 or -6,12, in primary forms	No data	No data
390890 polyamides, in primary forms (excl. polyamides-6, -11, -12, -6,6, -6,9, -6,10 and -6,12)	4	21
390910 urea resins and thiourea resins, in primary forms	No data	No data
390940 phenolic resins, in primary forms	0	1
390950 polyurethanes, in primary forms	8	21
391000 silicones in primary forms	1	23
391190 polysulphides, polysulphones and other polymers and prepolymers produced by chemical synthesis, n.e.s., in primary forms	22	133
391231 carboxymethylcellulose and its salts, in primary forms	No data	No data
391239 cellulose ethers, in primary forms (excl. carboxymethylcellulose and its salts)	4	40
391290 cellulose and chemical derivatives thereof, n.e.s., in primary forms (excl. cellulose acetates, cellulose nitrates and cellulose ethers)	0	8
All primary polymers	***250***	***820***
Polymer products	***90***	***580***
All polymers and polymer products	***340***	***1,400***

Number of SMEs

The data for NACE (v.2) code C20.1 (Manufacture of Basic Chemicals, Fertilisers and Nitrogen Compounds, **Plastics and Synthetic Rubber in Primary Forms**) is provided in Section 3.2 (see especially Table 3.5)

The proportion of companies of different sizes that may be grouped within NACE (v.2) code C22.2 (Manufacture of plastic products) is set out in Table 3.9.

Table 3.9: Companies Manufacturing Plastic Products, by Sector and Size of Company[1]					
NACE (v.2) Code (Sector Description)	**Number of Employees (%)**				
	Micro	**Small**	**Medium**	**Large**	**All**
C22.2 (Manufacture of Plastic Products)	36,141 (64%)	14,412 (26%)	4,946 (9%)	722 (1%)	**51,275 (100%)**
Source: Eurostat (SBS) data for 2009. Note 1. SMEs identified based on number of employees only.					

Data from the plastics industry in Germany is presented in Table 3.10 (reproduced from GTAI (2010)). According to these data, there are 330 companies involved in plastics manufacturing in Germany (including compound and masterbatch manufacturers), employing a total of 79,000 people. Like the industry at the European level, plastics manufacturing is only a small section of the total plastics industry.

Table 3.10: Structure of the Plastics Industry in Germany 2009			
	Companies (Number)	**Employees (thousands)**	**Turnover (€ billion)**
Plastics processing	6,050[1]	310	48
Plastics manufacturing	330[1]	79	34
Total	7,190	437	88
Source: GTAI (2010). Notes: 1. Includes compound and masterbatch manufacturers and all officially registered companies.			

3.2.3 Numbers of Plastic Polymers

There are estimated to be at least 60,000 and potentially more than 86,000 different polymer materials according to material databases available to companies developing processes and products[11]. The recent REACH for Polymers study estimated the number of polymers on the EU market to be 30,000. However, no source or other justification was given for this figure (iSmithers, 2011).

According to the Matweb database (see footnote), the majority of polymers (i.e. 84%) are represented by thermoplastic polymers that can be employed for mass production processes such as injection moulding and extrusion to produce commodity products. Out of this large number of polymers, a smaller but highly relevant selection of materials used for products can be highlighted. For example, the European-based material database CAMPUS provides information on 4,300 thermoplastic polymers with a complete characterisation produced by 20 suppliers (mainly European material manufacturers, as well as U.S. material producers). Another materials database provided to plastic product designers (Autodesk Moldflow Insight in the 2012 release) contains over 8,600 thermoplastic materials from 435 suppliers and 185 thermoset materials from 44 suppliers.

[11] Data from searches of Matweb and IDES online databases, available from (http://www.matweb.com/) and (http://www.ides.com/) respectively.

Due to the highly global nature of the chemical industry business, this selection of polymers represents a valuable starting point for the definition of the most widespread and currently available polymers on the market in the EU.

In 2003, RPA considered the Trans-Atlantic Business Dialogue (TABD, 2002) recommendations regarding polymers estimations that 90,000 to 120,000 polymers were placed on the market in the EU at that time (three to four times the number of non-polymeric substances) (RPA, 2003). It is important to note that the definition of a 'polymer' used to derive these figures was not stated. Therefore, it is not clear whether the figures quoted relate to polymer substances (as defined by REACH), polymer products including additives, or some other definition. Indeed, the issue of substance identity is one which has proved particularly difficult for the polymer industry to reach agreement on with different companies applying their own criteria (and which in some cases are considered by those companies to be confidential business information (Plastics Platform, *pers. comm.*)).

However, the fact that these estimates exceed the total number of non-polymeric substances is not in itself a reason for disbelieving the estimates, as monomers are often capable of being used in a wide range of different ways and in conjunction with different co-monomers, etc. to produce a great many polymers. This highlights the need for a clear and agreed system for substance identification. Furthermore, we understand that polymers may be placed on the market for further polymerisation/reaction and that such additional polymerisation may involve the same monomers as those used to produce the original polymer (Plastics Platform, *pers. comm.*).

The TABD expressed concerns over the high cost of registration and evaluation, impacts on innovation, trade and competitiveness and issues associated with the practical implementation of REACH. More specifically, there was concern that manufacturers and importers of speciality polymers would be particularly affected. These speciality polymers are polymers that are often used in small quantities as part of a wide range of formulated products, making it difficult for the producer to identify the full range of downstream applications. They are also continually modified as part of innovation and to maintain competition by providing better performing products. The majority of these speciality polymers are produced in quantities of less than 10 tonnes per year per manufacturer/importer and have an expected 'market life' of between five to seven years.

In contrast to the TABD estimates, the VCI worked with German manufacturers of polymers to generate estimates on the likely number manufactured or imported in the EU based on CAS numbers. Through an examination of CAS numbers for different polymer descriptions, a lower estimate of 70,000 CAS number descriptions was derived as being a best estimate of the number relevant to production or import in quantities greater than 1 tonne per year. Behind each of these CAS numbers, however, it was understood that there may be five to ten different polymers, either being placed on the market and/or used as an intermediate. This suggests that there could be as many as 350,000 to 700,000 individual polymers (as a maximum) which

would have qualified as phase-in substances[12]. However, it was not clear whether all of these would be expected to meet the molecular weight criteria or the classification and labelling criteria. It was expected that most polymers that would require registration would be produced in quantities of less than 100 tonnes per year.

The lack of a universally agreed definition of a polymer may have contributed to this wide variation in estimates. Given that the issue of substance identification still exists, it has been decided for the purposes of this study that there was insufficient evidence to deviate from the 2003 assumption that there are likely to be 70,000 different polymer substances (including rubbers and silicones) that could be subject to registration.

In order to further justify this assumption, the European division of the International Patent Office's applications database for polymers (Section C- Chemistry; metallurgy) has been searched:

C08 corresponds to: Organic Macromolecular Compounds; Their Preparation or Chemical Working-up; Compositions Based Thereon[13].

To refine the search, the following classes were not considered, as they might refer to processes or mixtures:

- C08C "Treatment or Chemical or Chemical Modification of Rubbers",
- C08J "Working-up; General Processes of Compounding; After-Treatment Not Covered by Subclasses C08B, C08C, C08F, C08G or C08H",
- C08K "Use of Inorganic or Non-Macromolecular Organic Substances as Compounding Ingredients",
  C08L "Compositions of Macromolecular Compounds";

The following classes were considered:

- C08B: Polysaccharides; Derivatives Thereof (polysaccharides containing less than six saccharide radicals attached to each other by glycosidic linkages C07H; fermentation or enzyme-using processes C12P 19/00; sugar industry C13; production of cellulose D21);
- C08F: Macromolecular Compounds Obtained By Reactions Only Involving Carbon-to-Carbon Unsaturated Bonds (production of liquid hydrocarbon mixtures from lower carbon number hydrocarbons, e.g. by oligomerisation, C10G 50/00 ; fermentation or enzyme-using processes to synthesise a desired chemical compound or composition or to separate optical isomers from a racemic mixture C12P ; graft polymerisation of monomers containing carbon-to-carbon unsaturated bonds on to fibres, threads, yarns, fabrics or fibrous goods made from such materials D06M 14/00);

12 Note that, the above figures do not include those polymers which would result from a chemical reaction occurring upon end-use of other polymers.

13 http://www.wipo.int/ipcpub/#refresh=page&notion=scheme&version=20120101&symbol=C08

- C08G: Macromolecular Compounds Obtained Otherwise Than By Reactions Only Involving Carbon-to-Carbon Unsaturated Bonds (fermentation or enzyme-using processes to synthesise a desired chemical compound or composition or to separate optical isomers from a racemic mixture C12P);
- C08H: Derivatives Of Natural Macromolecular Compounds (polysaccharides C08B ; natural rubber C08C ; natural resins or their derivatives C09F ; working up pitch, asphalt or bitumen C10C 3/00).

The results are as follows:

- C08B: 5,213 patent applications (56,342 worldwide);
- C08F: 39,151 patent applications (over 100,000 worldwide);
- C08G: 43,419 patent applications (over 100,000 worldwide);
- C08H: 611 patent applications (6,045 worldwide);
- Total: 88,394 patent applications in Europe (and over 260,000 worldwide).

Some care is needed in drawing on the above figures though as:

> *...Studies have shown that around 80% of resident patent applications filed are for new inventions (first filings having no priority claims)…*
>
> *...Not all inventions are patented. Companies may choose alternative methods of intellectual property protection, such as trade secrecy or marketing techniques. The choice may vary according to the technology in question…*[14]

3.2.4 Rubber

Rubber production in 2010 for the EU27 and Turkey totalled 6.8 million tonnes, separated into tyre production (4.5 million tonnes) and the production of general rubber goods (GRG) (2.3 million tonnes) (ETRMA, 2011a). Of this, 4.2 million tonnes represents synthetic rather than natural based rubber with a value of €5.6 billion (Eurostat, 2012). 65% of GRG go into automotive applications (e.g. to make windscreen wipers, engine mountings, window seals, and fan belts), with the remaining production divided between many other uses (e.g. within pharmaceutical, mining, construction, and engineering industries) (ETRMA, 2011b). The EU27 countries primarily responsible for GRG production in 2010 were, in descending order, Germany (48%), France (23%), Italy (18%) and Spain (11%).

Rubber products are made from the rubber polymer plus additives, as described for other polymer products. Production of rubber products is undertaken by approximately 4,200 companies across the EU27 and Turkey (the majority of which are SMEs), with a combined turnover of €46 billion (€28 billion from tyre production and €18 billion from GRG) (ETRMA, 2011a). €7.9 billion is generated by exports (€4.0 billion from tyres and €3.9 billion from GRG), and €8.6 billion worth of rubber is imported (€5.0 billion from tyres and €3.6 billion from GRG). The companies

14 http://www.wipo.int/freepublications/en/patents/931/wipo_pub_931.pdf

provide direct employment for 360,000 people overall. In 2010, research and development by these companies amounted to 3.5% of annual turnover and 5% of annual turnover for tyre and GRG development, respectively. The distribution of GRG production across Europe is displayed in Figure 3.7.

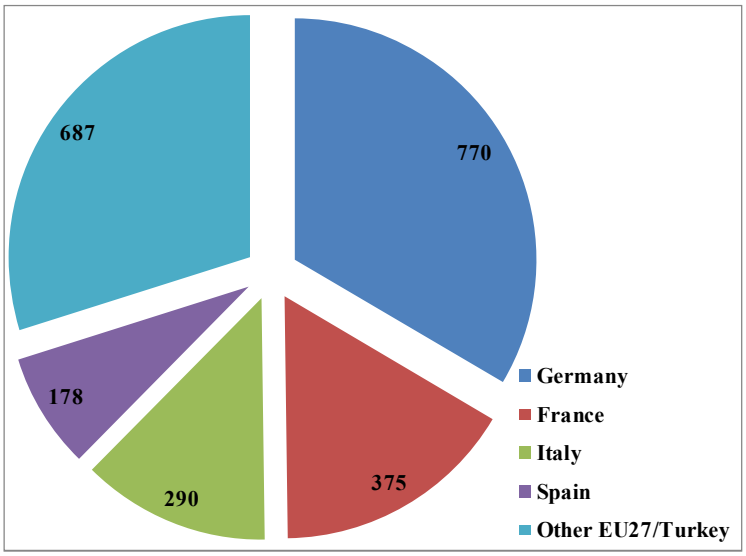


Figure 3.7: GRG Production across Europe in 2010 (million tonnes) (ETRMA, 2011a)

The total world consumption of rubber was 24.3 million tonnes in 2010 (13.9 million tonnes for tyres and 10.4 million tonnes for GRG), of which 13.6 million tonnes (56%) represented synthetic rubber (6.4 million tonnes for tyres and 7.2 million tonnes for GRG). After China (4.4 million tonnes), the EU27 was the largest consumer of synthetic rubber, responsible for 17% of global consumption (2.4 million tonnes).

The 2003 estimate that 70,000 different polymer substances would be subject to registration carried forward for this study includes elastomers (rubbers).

Rubber Imports

The Eurostat figures for the import of rubbers into the EU27 in 2011 are set out in Table 3.11.

Table 3.11: Rubber Imports into the EU 27 (2011)		
Polymer by Eurostat CM Code and Description	**Quantity (1,000 Tonnes)**	**Value (€ Million)**
400211 styrene-butadiene rubber latex 'sbr'; carboxylated styrene-butadiene rubber latex 'xsbr'	9	16
400219 styrene-butadiene rubber "sbr"; carboxylated styrene-butadiene rubber "xsbr", in primary forms or in plates, sheets or strip (excl. latex)	263	623
400220 butadiene rubber 'br', in primary forms or in plates, sheets	268	688

Table 3.11: Rubber Imports into the EU 27 (2011)		
Polymer by Eurostat CM Code and Description	**Quantity (1,000 Tonnes)**	**Value (€ Million)**
or strip		
400231 isobutylene isoprene rubber 'iir', in primary forms or in plates, sheets or strip	22	62
400239 halo-isobutene-isoprene rubber 'ciir' or 'biir', in primary forms or in plates, sheets or strip	60	152
400241 chloroprene latex 'chlorobutadiene rubber, cr'	1	4
400249 chloroprene 'chlorobutadiene rubber, cr', in primary forms or in plates, sheets or strip (excl. latex)	24	81
400251 latex of acrylonitrile-butadiene rubber 'nbr'	0	3
400259 acrylonitrile-butadiene rubber 'nbr', in primary forms or in plates, sheets or strip (excl. latex)	28	111
400260 isoprene rubber 'ir', in primary forms or in plates, sheets or strip	126	385
400270 ethylene-propylene diene rubber 'epdm', non-conjugated, in primary forms or in plates, sheets or strip	118	259
400291 synthetic rubber and factice derived from oils, in primary forms or in plates, sheets or strip (excl. styrene-butadiene rubber 'sbr', carboxylated styrene-butadiene rubber 'xsbr', butadiene rubber 'br', isobutylene isoprene rubber 'iir', halo-isobutene-isoprene rubber 'ciir' or 'biir', chloroprene rubber 'cr', acrylonitrile-butadiene rubber 'nbr', isoprene rubber 'ir' and non-conjugated ethylene-propylene diene rubber 'epdm')	1	4
400299 synthetic rubber and factice derived from oils, in primary forms or in plates, sheets or strip (excl. latex, styrene-butadiene rubber "sbr", carboxylated styrene-butadiene rubber "xsbr", butadiene rubber "br", isobutylene isoprene rubber "iir", halo-isobutene-isoprene rubber "ciir" or "biir", chloroprene rubber "cr", acrylonitrile-butadiene rubber "nbr", isoprene rubber "ir" and non-conjugated ethylene-propylene diene rubber "epdm")	64	217
All Primary Synthetic Rubber	***1,000***	***2,600***
All Primary Non-synthetic (Natural) Rubber	***1,3100***	***4,600***
All Primary Rubber and Rubber Products (inc. tyres)	***2,500***	***7,600***

Number of SMEs

According to data from Eurostat, the number of companies involved in the production of synthetic rubber in primary forms in Europe is relatively small; 100 enterprises are involved, employing 6,700 people. When the Eurostat database was interrogated for the proportion of companies of different sizes for NACE code C22.1 (Manufacture of rubber or rubber products) the figures shown in Table 3.12 were obtained.

Table 3.12: Companies Manufacturing Rubbers, by Sector and Size of Company[1]					
NACE (v.2) Code (Sector Description)	**Number of Employees (%)**				
	Micro	**Small**	**Medium**	**Large**	**All**
C22.1 (Manufacture of Rubber Products)	No data	1,710	No data	230[2]	**>1,940**
Source: Eurostat (SBS) data for 2009. Notes: 1. SMEs identified based on number of employees only. 2. Eurostat notes that this figure is estimated.					

3.2.5 Silicones

In 2010, 1.2 million tonnes of silicones were produced in the EU27. Silicone production generates employment for 10,000 people across Europe, with sales of approximately €3 billion (€2.5 billion per year (CES, 2011) and €3.3 billion in 2010 (Eurostat, 2012). Throughout the value chain, silicones are responsible for generating €9 billion per year. Silicone products include oligomers and polymers that are used in a wide range of applications including:

- personal care products;
- laundry products;
- textile finishing;
- lubricants;
- defoaming agents;
- rubbers (elastomers);
- sealants;
- medical and surgical applications;
- electrical insulation;
- seals;
- cable coatings; and
- textiles.

Some of the products listed above are polymers placed on the market (e.g. cable coatings) but others will be shorter chain oligomers (e.g. some laundry products and defoaming agents), while still other products are made up of monomer, oligomer and/or short chain polymer preparations that will react to form the final silicone polymer after use by an actor down the supply chain (e.g. sealants).

According to the European Silicones Centre (CES), the European silicone industry is based on six silicone producers which are capital intensive firms with significant levels of employment in research, production, marketing and sales. The six silicone producers employ an estimated 7,500 people, and therefore are not SMEs. SMEs are active in the downstream section of the silicone supply chain particularly in the form of formulators, distributors, end-use sales companies and finally indirect companies (CES, 2008).

The 2003 estimate that 70,000 different polymer substances would be subject to registration carried forward for this study includes silicones.

3.3 Assumptions for the Impact Assessment

The assumptions based on this section that have been carried forward to the assessment of options are set out in Section 7 of this report, and are not repeated here for brevity.

4. THE RISKS POSED BY POLYMERS AND OTHER SUBSTANCES

4.1 Information from Industry

Article 138(2b) of REACH requires the Commission to consider the *risks posed by polymers in comparison with other substances*, and to publish its findings. One of the requirements of this study is to conduct such an assessment for the Commission.

When the Commission announced the start of its work to fulfil Article 138(2b), the Polymer Service Group informed the Commission and the study team that it would be conducting a separate, parallel review on behalf of the polymer industry. The Polymer Service Group (PSG) was formed by an association of the Polymer Working Group of the European Chemical Industry Council (Cefic), the Resins Technical Platform, and PlasticsEurope. The stated aim of the study was to demonstrate that "*there is no reason to consider a general obligation to register polymers, since the REACH and CLP*[15] *regulations adequately address the hazard identification and consequent risk management associated with polymers"*.

The PSG study considered a total of over 4,500 data entries for polymers submitted by PSG member companies, which were further grouped under 585 discrete polymer names (PSG, *pers. comm*. 10 July 2012). The information provided on these polymers identified 372 monomers and other reactants, but the PSG noted that it was not certain that this included all monomers/reactants used to produce these polymers.

The PSG study was completed in July 2012, but the PSG has not provided RPA with any of the detailed data or findings coming out of the study.

4.2 Classification and Labelling Inventory

On 14 February 2012, ECHA published the Classification and Labelling Inventory (CLI) containing information from over three million notifications covering over 116,000 substances, including polymers (ECHA, 2012b). The version of the CLI used for the purposes of the analysis presented here was dated 31 May 2012 (ECHA, 2012a). The CLI provides details of classification and labelling as specified under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).

The CLI was searched to identify substances with different hazard classifications or combinations of classifications. There are, however, concerns regarding the robustness of the information from the CLI for statistical analysis, as explained below:

[15] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).

1. The CLI includes all classification and labelling (C&L) notifications for each substance and, on searching the CLI, it is clear that there are multiple entries for the same substance which may differ markedly. For example, entries differ even for the simplest substances such as hydrogen, with most notifiers' classifying hydrogen as a Flammable Gas (cat. 1) plus a classification relevant to the state in which it is supplied. However, one notifier has also classified hydrogen as a mutagen cat. 1B and a carcinogen cat. 1A (likely to be due to the presence of a classified impurity); another notifier classified hydrogen as an oxidising gas cat. 1 and a respiratory sensitiser cat. 1, but not as a flammable gas. In cases such as hydrogen, it may be simple to exclude unlikely classifications from statistical analysis, but this is clearly not practical for all substances in the absence of detailed expert knowledge on the properties of each of the substances in question. In the 31 May 2012 update of the CLI, there is an agreed classification and labelling for a high proportion of substances. Furthermore, it is to be expected that over time the situation will improve further as more notifiers and REACH registrants make every effort to come to an agreed entry to be included into the CLI, as required under Article 41 of CLP.

2. No reasons are provided for the classification decisions notified. Therefore, it is not possible to determine whether there may be justifiable reasons for the variations in classifications notified for the same substance (e.g. due to variations in impurities, etc.) or whether these variations simply represent errors or misunderstandings on the part of some notifiers. However, this should eventually be discussed between notifiers seeking to fulfil their obligations under Article 41 of CLP, once the platform to facilitate contacts between notifiers that ECHA intends to launch will be available.

3. When a search is made on the CLI based on classification, a substance will be identified if any of its notifiers classified that substance under the classification(s) included in the search string. Hence, hydrogen was still being included in the results of a search for carcinogens cat. 1A undertaken on 10 July 2012 (see point 1, above – as noted, this particular classification is likely to be due to the presence of a classified impurity).

4. The CLI has around 12,000 entries for which no classification has been provided, while for an additional 10,000 entries at least one notifier claimed "not classified" but others have included a classification in the notification for the same substance (COM, *pers. comm.)*. However, non-classified substances manufactured or imported in quantities of less than one tonne per year per registrant, or otherwise not registered (e.g. polymers), will still not be included in the CLI.

5. There are unexplained anomalies in the substance entries. For example, the entry for 'beryllium oxide' (EC number 215-133-1/ CAS number 1304-56-9) has two different entries with differing sets of classifications ticked as 'joint entries' (joint entries indicate those entered by lead registrants as part of joint registrations under REACH). Furthermore, only 2 notifiers are recorded for each of these 'joint entries' out of a total of 30 notifiers. These issues relating to beryllium oxide remained in the 31 May 2012 version of the CLI (ECHA 2012a), however a

harmonised classification was included at that time. The facility is available to only search harmonised classifications in the CLI but until there is a harmonised classification for all substances, such a search will return figures for a subset of the substances in the CLI only.

6. It is not clear whether the hazard information for polymers refers to the polymer substance or the polymer product (e.g. with plasticisers and fillers etc. that are outside of the scope of this study). It has been assumed that these hazards are associated with the polymer substance, however the Plastics Platform have indicated that some companies may have notified hazards for polymer products (PSG, *pers. comm.*).

7. There is no parameter by which polymer substances may be identified from other substances included in the CLI. Searches may be conducted for substances with names which include "poly" but this cannot be considered to be comprehensive.

Despite the issues set out above, the CLI is the only source currently available that can provide an overview of all CLP classifications for all substances. Furthermore, given the refusal of the polymer industry to provide data from its study into polymer hazards, the importance of the CLI as a unique source of such data is increased. The CLI has therefore been used for this study to provide initial estimates of the maximum percentage of substances, including polymer substances, which may be expected to have classifications, where such estimates are needed for the impact assessment.

4.3 Hazards from Polymers

4.3.1 Introduction

It is understood that polymers are, in general, not particularly reactive and their large size limits transport across biological membranes (Anastas *et al*, 2000); polymers are, therefore, often not considered hazardous in themselves. However, within a polymer substance there are non-polymeric substances of relevance to this study which may affect the hazard properties of that polymer substance, e.g. residual monomers, oligomers, low molecular weight fragments, by-products from condensation polymerisation, catalyst remnants, stabilisers and degradation products (Crompton, 2007). As noted in Section 2, the proportion of some of these components within the overall polymer substance (e.g. residual monomers) is likely to be carefully controlled to produce the properties desired of the polymer product to be produced, but other components may be less carefully controlled, such as by-products of the polymerisation process, or those generated by environmental stresses, e.g. and degradation products.

Since the non-polymeric substances within a polymer are usually of low molecular weight and are not tightly bound to the polymeric macro-molecules, they and/or their degradation products can migrate from a polymer substance or plastic product (Crompton, 2007; OECD, 2004) to air, water or other contact media (e.g. food). Polymer products may have additional hazards associated with them due to the

presence of non-polymeric compounds that are not considered to form part of the polymer substance itself, e.g. plasticisers, but these substances fall outside the scope of this study (see Section 3.1.4).

In 2006, the European Chemicals Bureau (ECB) provided RPA with details of substances notified under the Dangerous Substances Directive 67/548/EEC (DSD) with specific DSD classifications (from 2,924 substances) (RPA, 2006). One subset of the data provided by the ECB detailed the number and percentage of substances with classification and labelling proposals (i.e. likely classification as dangerous under DSD). The ECB data are expected to include substances of relevance to this study, and are given in Table 4.1.

Table 4.1: Substance Classification Notified under DSD

Industrial Activity[1]	Total Substances		Substances with a C&L Proposal	
	Number	% All Notified	Number	% of Substances from Industrial Activity
Polymers Industry	295	12.0	184	62.4
Stabilisers	103	3.8	77	74.8
Lubricants and Additives	91	3.3	64	70.3
Adhesives, Binding Agents	51	1.9	30	58.8
Flame Retardants and Fire Preventing Agents	26	1.0	9	34.6

Source: RPA, 2006

Assuming that the 566 substances covered in this assessment include a significant number of polymers, Table 4.1 provides evidence for the assumption that a significant percentage may also be hazardous in some manner. Unfortunately, these data do not allow for the identification of the number/percentage of such substances which are polymer substances, monomers, oligomers, additives that are to be considered as part of the polymer substance, or substances outside of the scope of this study.

4.3.2 Polymers

It was hoped that this study would be able to prepare a profile of polymers and the hazards associated with them by identifying a representative sample of all polymers and interrogating the Classification and Labelling Inventory (CLI) (ECHA, 2012) to identify the hazard classifications associated with these polymers.

Due to the complexity of polymer composition, it has not proved possible for the study team to identify a representative sample of all polymer substances. Furthermore, industry has not been able to provide the study team with such a sample, nor has ECHA the capability to provide the study team with the identity of polymers in the CLI. In the absence of a representative sample, a search was made of the CLI for all substances with names which include the phrase "polym". This search yielded a list of 1,151 substances. Searching the phrase "polymer", returned 1,108 substances, as summarised in Table 4.2.

Table 4.2: Hazard Classification of CLI Entries with Names that Include the Phrase "Polymer"		
Hazard Classification	**Number of Substances**	**Percentage of Substances**
Human Health Hazards		
CMR 1A or 1B	17	1.5%
Acute Tox 1 or 2	15	1.5%
Resp. or Skin Sensitiser 1	428	39%
STOT RE 1 or 2	68	6%
Any Human Health Hazard	1,014	92%
Environmental Hazards		
Aquatic Acute 1	60	6%
Aquatic Chronic 1 or 2	222	20%
Any Environmental Hazard	422	38%
All Substances		
All "Polymer" Substances in CLI	*1,101*	*100%*
Notes: *The search was refined by screening for entries that were clearly not polymers.*		

The research has been further refined by not considering the results that were clearly not polymers. The search for "polymer" AND CMR 1A or 1B classification resulted in 23 entries, but the six substances listed below were not considered as polymers (they are UVCB substances[16]):

- Low boiling point naphtha – unspecified [A complex combination of hydrocarbons obtained from the distillation of polymerized steam-cracked petroleum distillate. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C5 through C12.] Distillates (petroleum), polymd. steam-cracked petroleum distillates, C5-12 fraction (CAS number: 68477-50-9);

- Cracked gasoil [A complex combination of hydrocarbons produced by distilling cracked steam cracked distillate and/or its fractionation products. It consists of hydrocarbons having carbon numbers predominantly in the range of C10 to low molecular weight polymers.] Distillates (petroleum), cracked steam-cracked petroleum distillates (CAS Number: 68477-38-3);

- Light Oil Redistillate, high boiling [A complex combination of hydrocarbons obtained from the evaporation of solvent under vacuum from polymerized hydrocarbon resin. It consists predominantly of aromatic hydrocarbons having carbon numbers predominantly in the range of C8 through C9 and boiling in the range of approximately 120°C to 215°C (248°F to 419°F).] Aromatic hydrocarbons, C8-9, hydrocarbon resin polymn. by-product (CAS Number: 91995-20-9);

[16] It must be noted that these UVCB (Unknown or Variable composition, Complex reaction products or Biological materials) substances might contain low molecular weight polymers, believed to be of high concern (OECD, 2009).

- Petroleum gas [A complex combination of hydrocarbons obtained from the fractionation stabilization of catalytic polymerized naphtha. It consists of aliphatic hydrocarbons having carbon numbers in the range of C2 through C6, predominantly C2 through C4.] Gases (petroleum), catalytic polymd. naphtha stabilizer overhead, C2-4-rich (CAS Number: 68477-76-9);

- Petroleum gas [A complex combination of hydrocarbons from the fractionation stabilization products from polymerization of naphtha. It consists predominantly of hydrocarbons having carbon numbers in the range of C1 through C4.] Tail gas (petroleum), catalytic polymn. naphtha fractionation stabilizer (CAS Number: 68307-99-3);

- Low boiling point naphtha – unspecified [A complex combination of hydrocarbons obtained by distillation of the polymerized C8 through C12 fraction from steam-cracked petroleum distillates. It consists predominantly of aromatic hydrocarbons having carbon numbers predominantly in the range of C8 through C12.] Distillates (petroleum), steam-cracked, C8-12 fraction, polymd., distn. lights (CAS Number: 95009-23-7).

When searching for "polymer" and STOT RE 1 or 2, seventy one results were found, but three were not considered (two of the previous UVCB substances plus Graphite with CAS Number: 7782-42-5).

All the searches for the other relevant endpoints were adjusted following the same approach.

From Table 4.2 it is clear that only about 1% (1,108) of the 109,411 substances that can be consulted, at this point in time[17], in the CLI have the phrase "polymer" in their chemical name. The reason for this small percentage is unclear, although the following potential explanations have been identified:

1) a relatively small percentage of polymer substances are hazardous to human health or the environment;
2) many polymer substances have been grouped under single entries in the CLI;
3) many polymer substances do not have "polymer" in the chemical name under which they are recorded in the CLI[18]; and/or
4) manufacturers/importers of polymers may consider them mixtures and therefore not know that they need to be notified;
5) a combination of explanations 1 to 4. This final explanation would appear likely, but there is no data to quantify the relative importance of each.

PSG members have indicated to RPA that they know of notifications that are and are not dependent upon the presence of hazardous additives that are not part of the polymer substance as defined under REACH (PSG, *pers. comm.)*.

[17] 22nd November 2012.

[18] Searching the Japanese PolyInfo database for "poly", around 19,000 entries out of 35,000 have the phrase "poly" in the name, leaving around 46% of the polymer names without the phrase "poly".

Furthermore, it is important to note that PSG members have also indicated that ***hazards from a significant number of polymer substances may result from the presence of unreacted monomer***, particularly where these polymer substances have been isolated but are intended for further polymerisation or other chemical reaction.

In summary, the evidence provided here indicates that over 1,000 polymer substances, or groups of polymer substances, may have properties which are hazardous to human health and/or the environment. It must also be noted that the number of polymers/polymer groups not included in the CLI remains far too uncertain for the 1,000 figure to be used as the basis for further calculation. The percentages of polymers with identified hazard classifications are however considered to be representative of the distribution of polymer hazards across all hazardous polymers. Furthermore, after much discussion within the polymer industry, the PSG was not able quantify or reduce these uncertainties (PSG, *Pers. Comm.)*.

A previous RPA study for the Commission assumed that a large proportion of the 70,000 CAS number-based groups were expected to relate to products produced by specialty manufacturers for niche markets. Many of these were already classified and labelled for properties such as corrosivity, flammability and sensitisation. This is because of the nature of their end-uses which require that they are able to react with other substances/polymers. Any component that is not finally reacted may have a property of concern. As a result, a high proportion of the polymers (and nearly 100% of oligomers) were expected to contain an unreacted substance at greater than classification threshold for mixtures set out in CLP.

It is understood from the PSG (*Pers. Comm.)* that manufacturers may be considering polymers as mixtures and, as mixtures do not need to be notified, they are not included in the CLI. Moreover, it is possible that some of the identified entries are actually family/groups covering many different polymers.

Industry consultation in 2003 found that large proportions of the polymers being produced by some of the specialist manufacturers were already being classified, with the percentage varying from 50% to 100% for some companies and intended downstream uses (*pers. comm.* (2003), as quoted in RPA (2003)). These substances were therefore assumed to have some data already available for registration, with resultant cost savings for such registrants. However, fewer data were expected to be available to companies further downstream within the chain of polymer manufacture. It is also noted that it is not clear whether the hazards from the 'polymers' that were being classified by industry in 2003 were due to the polymer substances, polymer products (i.e. including additives outside of the scope of this study), or both.

Overall, based on the above, RPA (2003) concluded that between 30% and 50% of all polymers would have properties which would require classification. This assumption is further justified by the study conducted by an OECD Task Force in 2009[19].

[19] OECD (2009): *Data analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern*, **ENV/JM/MONO(2009)1**.

The OECD Task Force was composed of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology and the study was published in the context of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC). The main objective was to identify any correlation between polymer characteristics and potential for health or ecotoxicological concern. Data were analysed for a sample of 205 polymers selected by different countries (Australia, Canada, Japan, Korea and US) and classified as PLCs (Polymers of Low Concern) and non-PLCs following the US EPA criteria. The two main conclusions were that:

- *amongst the polymers fulfilling the PLC criteria, 87.8% showed low health concern and/or low ecotoxicological concern*;
- *the lower the number-average molecular weight (Mn), the higher the potential for health or ecotoxicological concern*.

Table 4.3 shows the relevant general data of the sample used in the study by the Task Force.

Table 4.3: General Data on the Sample Used in OECD (2009)

	Number	**Percentage**
Polymers in the sample	205	-
Polymers classified as PLC	139	67.8%
Polymers classified as non-PLC	66	32.2%
Polymers with unreacted monomers	147	71.7%
Polymers with no residual monomers	41	20%
Polymers with uncertain presence of unreacted monomers	17	8.3%

While most of the polymers contained one or more unreacted monomer species, the identity, concentration and toxicity of these were unknown. No further analysis was therefore possible on the role played by unreacted monomers in the toxicity of polymers. This is important as industry sources have indicated that many industrial polymers are likely to contain one or more unreacted monomers.

With respect to potential health hazards, 63 of the 205 polymers had no available data. Those that did have data were characterised as either "low health concern" or "potential health concern".

"Low health concern" is defined as:

- *None or minor observed effects;*
- *Low acute oral, inhalation or dermal toxicity (i.e. LD_{50} > 1,000 mg/kg);*
- *Mild/slight irritation to eye or skin.*

"Potential health concern" is defined as:

- *Moderate or high acute oral, inhalation or dermal toxicity (i.e. $LD_{50} \leq$ 1,000 mg/kg);*
- *Greater than mild eye or skin irritation;*
- *Positive skin sensitisation (including "limited evidence");*

- *Any positive mutagenicity or genotoxicity test (in vivo or in vitro);*
- *NOEL or NOAEL ≤ 750 mg/kg/day;*
- *Any other positive test result.*

The breakdown of polymers considered by the OECD Task Force between these two groups is shown in Table 4.4.

Table 4.4: "Health Concern" Data for the Polymers Studied in OECD (2009)			
	No data	**Low**	**Potential**
PLC	26 (18.7%)	96 (69.1%)	17 (12.2%)
No-PLC	37 (56.1%)	13 (19.7%)	16 (24.2%)
Total	63 (30.7%)	109 (53%)	33 (16.1%)
Removing from the sample the polymers that did not have any data:			
Polymers with toxicological data		76%	23%

It is important to note that the OECD includes as a hazard of low concern "mild irritation to eye or skin", as well as low acute toxicity: polymers meeting these characteristics would be classified as:

- Eye Irritant 2/2A/2B; or
- Skin Irritant 2 or Skin Mild Irritant 3; or
- Acute Toxic 3/4/5[20].

In terms of ecotoxicological data, 105 of the 205 polymers had no available information. For the total set and the remaining 100 polymers with information, the percentages showing different levels of concern are presented in Table 4.5. The rating scale adopted in OECD (2009) is:

- No data;
- "Low ecotoxicological concern" (EC_{50} or LC_{50} > 100 mg/L);
- "Moderate ecotoxicological concern" (EC_{50} or LC_{50} = 1- 100 mg/L correspondent to Aquatic Acute 2/3 or Aquatic Chronic 2/3 classification); and
- "High ecotoxicological concern" (EC_{50} or LC_{50} < 1 mg/L correspondent to Aquatic Acute 1 or Aquatic Chronic 1 classification).

Table 4.5: "Ecotoxicological Concern" Data for the Polymers Studied in OECD (2009)				
	No data	**Low**	**Moderate**	**High**
PLC	81 (58.3%)	45 (32.4%)	13 (9.3%)	0
Non-PLC	24 (36.4%)	13 (19.7%)	23 (34.8%)	6 (9.1%)
Total	105 (51.2%)	58 (28.3%)	36 (17.6%)	6 (2.9%)
Removing from the sample the polymers that did not have any data:				
Polymers with ecotoxicological data		71 (50%)	59 (41.5%)	12 (8.5%)

As can be seen from Table 4.5, **50% of the polymers for which data were available were associated with either moderate or high ecotoxicological concern**.

[20] http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev02/English/03e_part3.pdf

Importantly, superimposing by polymer class data on the numbers of polymers found to pose potential health and moderate or high ecotoxicological concern, it can be seen that while there is clearly some overlap, there are also some significant differences (see the two graphs given below which are replicas of those provided in the OECD (2009) report). For example, only low health concerns are associated with polyesters, but a significant number of these same polymers posed moderate to high ecotoxicological concerns. No data on health concerns was available for epoxy resins, however, moderate ecotoxicological concerns were identified. Similarly, polyamides, polyimides and polyvinyl showed potential human health concerns, but low ecotoxicological concerns where data were available.

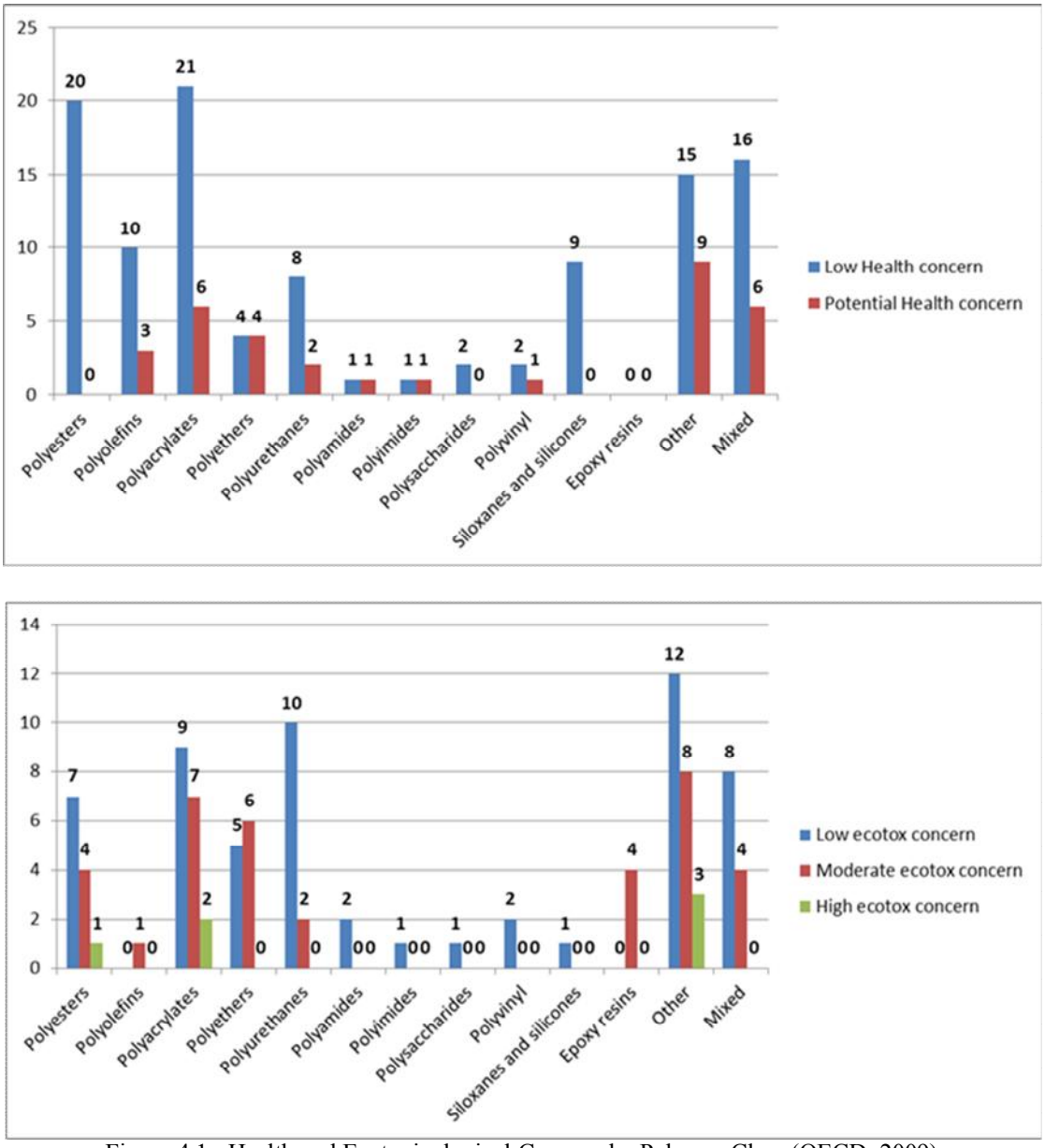


Figure 4.1: Health and Ecotoxicological Concern by Polymer Class (OECD, 2009)

Taken together, these findings suggest that it is not unreasonable to assume that around 50% of polymers would be expected to have either a health or environmental hazard classification.

4.3.3 Monomers

Hazards

As stated in Section 4.4.2, PSG members have indicated that, for a significant number of polymer substances, hazards may result from the presence of unreacted monomer, particularly where these polymer substances have been isolated but are intended for further polymerisation or other chemical reaction (PSG, *pers. comm.)*.

The CLI was therefore searched for the hazards associated with each of the monomers listed in Table 2.3. The number and percentage of these monomers with classifications for human health or environmental endpoints are summarised in Table 4.6, with analogous figures for all substances, given at the bottom of the table.

Table 4.6: Hazard Classification of Identified Monomers Notified in the CLI

Hazard Classification	Number of Substances	Percentage of Substances
Human Health Hazards		
CMR 1A or 1B	10	19%
Acute Tox 1	2	4%
Resp. or Skin Sensitiser 1	19	35%
STOT RE 1 or 2	6	11%
Any HH Hazard	47	85%
Environmental Hazards		
Aquatic Acute 1	7	13%
Aquatic Chronic 1 or 2	14	25%
Any Env. Hazard	16	29%
All Substances		
Monomer Sample Size	55	*100%*
Other Parameters		
Harmonised CLI Entry[21]	*38*	*69%*
Registered under REACH	*52*	*95%*

As already recalled in previous sections, the REACH Regulation defines a monomer as "*a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process*" (Art.3(5)). Common features of monomer molecules used in addition polymerisation are the presence of double bonds and the presence of side groups, and for monomer molecules used in condensation polymerisation the common features are the presence of functional groups and usually two or more reactive sites. As already reported in section 2.2.3, at least 20,000

[21] In accordance with Title V of the CLP Regulation.

substances are used as monomers. On this basis and considering that the hazard characteristics of the sample of 52 monomers cannot be regarded as representative of the whole set of monomers, it is assumed that the hazard characteristics of the population of monomers follows the same distribution as the population of chemical substances used or not used in polymerisation processes.

Registration

When the monomers listed in Table 3.2 were compared to the list of registered substances provided by ECHA, it was found that 95% had been registered by 19 July 2012 (ECHA, 2012c). The publicly available information from the registration dossiers for these monomers has been assessed to determine the extent to which they address the hazards and risks associated with the resultant polymers. From this assessment, it is clear that the hazard data, hazard assessment, and risk assessment provided for each focused exclusively on the use of the monomer to produce a polymer, with no consideration of downstream uses of that polymer. The only exceptions to this were where the substance had uses other than as a monomer, but again these assessments did not address the risks associated with the use of polymers.

The registration dossiers for acrylamide (CAS No. 76-06-1 & EC No. 201-173-7) were typical monomer registrations in general and are described in more detail here. The uses of the substance were summarised in the registration dossiers in terms the Use Descriptor system set out in Section R12 of ECHA (undated), where:

- *The sector of use category (SU) describes in which sector of the economy the substance is used. This includes mixing or re-packing of substances at formulator's level as well as industrial, professional and consumer end-uses.*

- *The chemical product category (PC) describes in which types of chemical products (= substances as such or in mixtures) the substance is finally contained when it is supplied to end-uses (by industrial, professional or consumer users).*

- *The process category (PROC) describes the application techniques or process types defined from the occupational perspective*

- *The environmental release category (ERC) describes the broad conditions of use from the environmental perspective.*

- *The article category (AC) describes the type of article into which the substance has eventually been processed. This also includes mixtures in their dried or cured form (e.g. dried printing ink in newspapers; dried coatings on various surfaces).*

The publicly available information from the registration dossiers does not describe a substance's uses beyond the summary provided by these use descriptors and details of the AC are not included.

The primary use descriptors included in the registration dossiers to describe the uses of acrylamide covered by the risk assessment were:

- PROC 0: Other: monomer for polymerisation;
- ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates);
- PC 19: Intermediate; and
- SU 0: Other: C20.5 - manufacturing: manufacture of other chemical.

However, some registrants also included the following Process Categories:

- PROC 1: Use in closed process, no likelihood of exposure;
- PROC 2: Use in closed, continuous process with occasional controlled exposure;
- PROC 3: Use in closed batch process (synthesis or formulation);
- PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises;
- PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities;
- PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing); and
- PROC 15: Use as laboratory reagent.

In every case, the use descriptors describe the use of the monomer in the production of the polymer only. Indeed, in answer to the registration question "Subsequent service life relevant for that use?" each monomer registrant answered "No". There was also no indication in any of the dossiers in the "Guidance on Safe Use" that this included any consideration of the subsequent polymer. Indeed, no indication could be found of the risks associated with the use of the polymer being considered at all in the monomer registrations reviewed.

4.3.4 Oligomers

As stated earlier, oligomers are not defined under REACH but are often referred to in discussions on polymer risk management, e.g. OECD (2009), and so oligomers are briefly considered here, for completeness. Oligomers may be described as very short chains of a few monomer units only (see IUPAC definition set out in Section 2.1.2). These short chain constituents of polymers may migrate from the polymer substance and contribute to the hazards associated with that polymer substance.

When manufactured, most polymers will be a mixture of chains of differing molecular weight and may include some oligomers. These substances are of a sufficiently small size so as to be able to cross biological membranes and potentially exert toxic effects. The potential hazard posed by oligomers has led to the requirement for a standard information package for polymers containing fractions of oligomers notified under Directive 67/548/EEC (Annex VII A with some additional information). As oligomers consist of only a few reacted monomers, they may have certain of the functional groups of the monomer used to manufacture the polymer (mostly

condensation polymers). These functional groups may be responsible for any (eco)toxicity that is expressed by the oligomer.

4.3.5 Emissions from Polymers

Release of chemicals associated with polymers may occur in all phases of the life cycle, including polymer production, use and end-of-life. The environmental fate of the polymer and of the substances released during the life cycle, including degradation products, will result in the potential for exposure of humans and the environment, without the imposition of risk management measures to control emissions.

Data on emissions to air and water from the production of monomers, polymers and plastic products are often available to industry to enable it to undertake life cycle analyses of its products (PlasticsEurope, *pers. comm.*). However, these data were not made available for this study. The EU risk assessment reports available for some of the monomers include some emissions data from polymer production. These data show varying emissions between different production sites and different polymers (European Commission (JRC), e.g. 2002a; 2002b; 2004; 2010), but do not allow for general industry wide estimates to be generated for the purposes of risk and impact assessment.

In general terms, the size and type of emissions from plastic products are controlled by many factors. The content of non-polymeric substances controls what can be released, while other factors control the potential of release into a surrounding medium, i.e. the migration potential. Consideration of the migration potential may be important in determining the extent to which the risks posed by polymer substances are being controlled via the registration of their monomers. However, monomer registration will not consider the risks posed by the emission of other substances such as oligomers or degradation products.

Migration is generally favoured if:

- the polymer matrix is permeable;
- the size of gaps between polymer molecules is larger than the size of migrant;
- the migrating substance is small, has a similar solubility parameter as the polymer and is volatile;
- the temperature is high; and
- the surrounding medium is water for water soluble migrants, fat containing for hydrophobic migrant and acidic for metals (Brydson, 1999; Sheftel, 2000).

4.3.6 Hazards from Polymers, Monomers and All Substances

The percentages of polymers (Table 4.2) and monomers (Table 4.6) and all substances in the CLI with different hazard classifications are set out in Table 4.7. However, it should be noted that Table 4.7 shows a comparison with **all** substances in the CLI, including polymers and monomers, as it was not possible to separate data for polymers and monomers before calculation.

Table 4.7: Hazard Profile of Substances in the CLI

	Percentage of Substances of Type Specified from All Substances Listed in CLI		
Hazard Classification	**Polymers in CLI**	**Monomers in CLI**	**All Substances in CLI**
Human Health Hazards			
CMR 1A or 1B	1.5%	19%	1%
CMR 1A, 1B, 2 or Lact.	10.4%	39%	3.3%
Acute Tox 1 or 2 (any route)	1.4%	4%	3.5%
Resp. or Skin Sensitiser 1	38.9%	35%	13.7%
STOT RE 1 or 2	6.2%	11%	4.1%
Any HH Hazard	92.1%	85%	90.1%
Environmental Hazards			
Aquatic Acute 1	5.4%	13%	13.8%
Aquatic Chronic 1 or 2	20.2%	25%	15.2%
Any Env. Hazard	38.3%	29%	31.7%

From Table 4.7 it can be seen that the polymers found in the CLI are classified in higher percentages in comparison to the whole set of substances for the relevant end-points considered. This is probably due to the fact that the polymers that have been classified are those for which toxicological and ecotoxicological data were already available and for which concern was already identified. The sample of monomers for which a search of the hazard characteristics has been conducted in the CLI is too small a sample to draw any conclusions.

4.4 Assumptions for the Impact Assessment

The assumptions based on this section that have been carried forward to the assessment of options are set out in Section 7 of this report, and are not repeated here for brevity.

5. APPROACHES TO THE RISK ASSESSMENT OF POLYMERS

5.1 Overview of Approaches to Polymer Risk Assessment

In this chapter, the regulatory criteria for requiring risk assessment on polymers within the chemical notification/ registration systems of the EU, Australia, Canada, Japan and the USA and the extent of associated data requirements are briefly summarised (see Table 5.1 and Table 5.2). Consideration has also been given to OECD activities intended to assist in defining the critical factors determining polymer risks, as well as alternative approaches to assessing risk being developed by academia. A more detailed discussion of the findings of the review of regulatory approaches to polymers is presented in Annex 1.

Importantly, our review demonstrated that there is a general consensus across the jurisdictions considered here that it is either:

1. unnecessary to require registration of many types of polymer; or
2. if registration or notification is judged appropriate, in many instances the test information burdens imposed on polymers may be reduced compared with those required for other types of substance.

For Europe the introduction of REACH led to a change in requirements for polymer registration with, under REACH, polymers being – with some exceptions – generally exempt from registration (see also Annex 1). Rather, the focus shifted to registration of the monomers used in manufacturing the polymers. Previously, under DSD, while notification of polymers was a requirement, the registration requirements were nonetheless simplified compared with most other substances and allowed for registration on the basis of either a 'polymer substance'[22] or 'polymer family'[23] basis. Similarly, while the regulatory requirements of several other jurisdictions include a default position of potentially requiring notification or registration of some polymers, they all include extensive exemption criteria and generally accept the concept of registration on a group (family) basis and/or no or markedly reduced information requirements if the polymer is judged to meet specific criteria defined as indicating that it is of low concern.

Currently, while many of the major endpoint criteria that can be used to estimate the potential hazard or risk posed by a particular polymer have been recognised globally, largely due to the OECD collaborative exercise, the detailed criteria that are currently applied by different regulatory bodies to define polymers of low risk differ significantly across jurisdictions (see overview in Table 5.1). Nonetheless, the key criteria that may be regarded as being of particular value to determine the level of risk posed by a polymer (or type of polymer, e.g. where families of polymers are

[22] i.e. a narrow group of (co) polymers of similar composition or molecular weight.

[23] Where a 'family' describes a group of polymer substances for which one parameter is fixed but another varies within a stated range. Notification of the entire family was possible by submitting representative data on substances from either extremes of the defining parameter range.

considered) have been defined - and their value assessed – by the OECD (see Table 5.2). These may be summarised as follows:

- number-average molecular weight;
- presence of particular reactive functional groups;
- polymer stability;
- polymer solubility (in water and other solvents);
- chemical class (referred to here as polymer type);
- residual monomer content; and
- human health hazard classification.

Final agreement on a pan-OECD basis for defining low concern polymers remains elusive, however, with several issues remaining regarding precise definitions.

From Table 5.1, it can be appreciated that, in the case of polymers that fail to qualify under the various exclusion criteria (i.e. for which registration or notification is required in a particular jurisdiction), there is considerable divergence as to the nature and extent of the datasets that are required to be submitted in support of their regulation/notification.

5.2 Assumptions for the Impact Assessment

The assumptions based on this section that have been carried forward to the assessment of options are set out in Section 7 of this report, and are not repeated here for brevity.

Table 5.1: Basis for Exception from Registration or Qualification for Reduced Registration Requirements						
Jurisdiction	**Europe**		**Australia**	**Canada**	**Japan**	**USA**
Key legislation	**DSD**	**REACH**	**Industrial Chemicals (Notification and Assessment) Act**	**Environmental Protection Act**	**Chemical Substances Control Law**	**Toxic Substances Control Act**
Polymer may not require registration if	-	Monomer registration: Either <2% w/w of monomer in polymer & the amount of monomer in the polymer is <1 t/a; or it is a recycled polymer; or it is a naturally-occurring polymer	-	-	Considered of low concern based on: number average MWt ≥1000; & no change in Wt under acid/alkali conditions; & no potentially toxic metals; & insoluble in water/organic solvents); or if produced/imported at ≤10 t/a & has low % of low MWT species	Meets definition of a polymer (based on % of polymerised units); & is a type of polymer not excluded from exception (e.g. cationic polymers excluded or not designed to degrade/decompose, or contains >2% of low MWt reactant/ monomers); & falls within particular MWt range; & meets established % composition limits
Polymer may qualify for reduced registration requirements	By grouping within a 'polymer substance' (of specific MWt or composition); or grouping within a'polymer family' (of defined MWt or composition); or meets RTP criteria based on high MWt and low % of low MWt constitutents; and has low solubility &	-	By grouping within a polymer family; or if of low concern based on: high average MWt or other characteristics; & low charge density; & not hazardous; & not readily dissociated; & stable); or falls within an	If meets criteria for: on-site intermediate or export only; or reduced requirement polymer - based on: MWt &/or low % of low MWt constitutents; or is a polyester made from specific reactants	-	Depending on which of 3 categories polymer falls within: Category 1 - MWt <1000 - data required on polymer but may not need to consider its monomers/ oligomers; Category 2 - MWt >1000 & >% low MWT composition – may need to included data on oligomers as

Table 5.1: Basis for Exception from Registration or Qualification for Reduced Registration Requirements						
Jurisdiction	**Europe**		**Australia**	**Canada**	**Japan**	**USA**
Key legislation	**DSD**	**REACH**	**Industrial Chemicals (Notification and Assessment) Act**	**Environmental Protection Act**	**Chemical Substances Control Law**	**Toxic Substances Control Act**
	extractability		established class of low hazard polymer (LRCP)			well as polymer itself; Category 3 - MWt > 1000 & minimal low MWT constitutes – may need to also included data on monomers as well as polymer

Table 5.2: Overview of Potential Minimum Datasets Required for Polymers Judged to Require some Registration or Notification							
Jurisdiction	**Europe**		**Australia**	**Canada**	**Japan**	**USA**	**Inclusion in OECD study on defining polymers of low concern**
Key legislation	**DSD**	**REACH**	**Industrial Chemicals (Notification and Assessment) Act**	**Environmental Protection Act**	**Chemical Substances Control Law**	**Toxic Substances Control Act**	
Identification	Name; synonyms; CAS number; molecular formula	Registration of polymer not required	Name; Synonyms; CAS number; Molecular formula (and same for monomers)	Name; Synonyms; CAS number; Molecular formula	Name & other identifying information	Name, synonyms Structural information	Data collected
% purity	Required		Required				
Nature of impurities	Required, including on any byproducts		Required for both hazardous & non-hazardous impurities and byproducts	Required, including indication of % present by weight		Required (including for byproducts), including indication of % present by weight	
Polymer Class							13 classes established: 1. Polyesters, 2. Polyolefins 3. Polyacrylates 4. Polyethers

Table 5.2: Overview of Potential Minimum Datasets Required for Polymers Judged to Require some Registration or Notification							
Jurisdiction	**Europe**		**Australia**	**Canada**	**Japan**	**USA**	**Inclusion in OECD study on defining polymers of low concern**
Key legislation	**DSD**	**REACH**	**Industrial Chemicals (Notification and Assessment) Act**	**Environmental Protection Act**	**Chemical Substances Control Law**	**Toxic Substances Control Act**	
							5. Polyurethanes 6. Polyamides 7. Polyimides 8. Polysaccharides 9. Polyvinyl 10. Siloxanes and silicones 11. Other 12. Mixed 13. Epoxy resins
Charge density			Required				
Particle size distribution			Required for solid polymers				
Reactive function groups (RFGs)	Data required on endgroups & frequency of functional groups		Full characterisation requried				3 categories established: 0 = not determined, 1 = no RFGs; 2 = contains any RFG
Functional group equivalent weight (FGEW)	Data required on frequency of functional groups						Yes
Number-average MWt %	Required		Required; Also weight-average MWt	Requried	Required; also MWt distribution	Required (as lowest value intended to be manufactured/ imported)	Yes
% low MWt oligomeric/ monomer contents	Require data on MWt distribution & composition		Require data on MWT distribution & composition			Require data on MWT distribution & composition (as maximum % wt of low MWts species)	Yes
Starting monomers	Require data on their identities &		Require data on their identities &	Require data on their identities &		Require data on their identities &	

Table 5.2: Overview of Potential Minimum Datasets Required for Polymers Judged to Require some Registration or Notification							
Jurisdiction	**Europe**		**Australia**	**Canada**	**Japan**	**USA**	**Inclusion in OECD study on defining polymers of low concern**
Key legislation	**DSD**	**REACH**	**Industrial Chemicals (Notification and Assessment) Act**	**Environmental Protection Act**	**Chemical Substances Control Law**	**Toxic Substances Control Act**	
	concentrations		concentrations	concentrations		concentrations	
Amounts of unreacted monomer in polymer	Require data on their identities & concentrations		Require data on their identities & concentrations			Require data on their identities & concentrations	Yes
Solubility			Require data on solubility (using defined test method TG 120)		Require data on solubility in water and organic solvents		Yes but only water considered (due to lack of data) – categorised as: < or > 1 x 10^6 mg/L
Extractability	Not for reduced package for polymers						Yes – only water considered (due to lack of data)
Physicochemical characterisation	Detailed profile required		Detailed profile required (including physical state under standard conditions & odour)		Detailed profile required		
Health toxicity	Not for reduced package for polymers					Available information	3 categories defined: 1. No data; 2. Low concern (no/minor effects; LD_{50} >1000 mg/kg; & mild/slight irritancy); 3. Potential concern (LD_{50} ≤1000 mg/kg; >mild irritancy; positive sensitization data; any positive genotoxici data, repeat dose NOAEL ≤750 mg/kg; other positive evidence)
Ecotoxicity	Not for reduced						4 categories defined:

Table 5.2: Overview of Potential Minimum Datasets Required for Polymers Judged to Require some Registration or Notification							
Jurisdiction	**Europe**		**Australia**	**Canada**	**Japan**	**USA**	**Inclusion in OECD study on defining polymers of low concern**
Key legislation	**DSD**	**REACH**	**Industrial Chemicals (Notification and Assessment) Act**	**Environmental Protection Act**	**Chemical Substances Control Law**	**Toxic Substances Control Act**	
	package for polymers						0. No data; 1. Low concern (EC/LC $_{50}$ >100 mg/L); 2. Moderate concern (EC/LC $_{50}$ 1-100 mg/L); 3. High concern (EC/LC $_{50}$ <1 mg/L)
Degredation/ Biodegradation	Not for reduced package for polymers		Requrie data on degredation, decomposition & depolymerisation products; also data on extent of loss of monomers and other constitutes from polymer		Require data on weight change under acid or alkali conditions		Data collected but not analysed
Total amount produced/ imported	If known		Estimate required for 1st 5 years	Estimate required		Estimate required for 1st year and maximum yearly amount during 1st 3years	
Proposed uses	Required		Required	Required		Required including indication of each use as % of total	
Concentration in products	If known			Required (if known)			
Waste disposal methods				Required (if known)		Optional	
Waste volumes	If known			Estimate required			
Worker exposure estimate	Required		Required, including consideration of number & types of	Required; also wider public health		Require information on nature of uses, levels of containment	

Table 5.2: Overview of Potential Minimum Datasets Required for Polymers Judged to Require some Registration or Notification							
Jurisdiction	**Europe**		**Australia**	**Canada**	**Japan**	**USA**	**Inclusion in OECD study on defining polymers of low concern**
Key legislation	**DSD**	**REACH**	**Industrial Chemicals (Notification and Assessment) Act**	**Environmental Protection Act**	**Chemical Substances Control Law**	**Toxic Substances Control Act**	
			workers at risk of exposure; also wider public health considerations	considerations		envisaged; Also wider public health considerations	
Environmental exposure estimate	Requried		Required, including consideration of manufacturing, transport, use and disposal scenarios	Required, including consideration of manufacturing, transport, use and disposal scenarios		Required, including consideration of manufacturing, transport, use and disposal scenarios, and release controls	

6. PREVIOUS REACH ASSESSMENTS ON POLYMERS

6.1 Proposals for Polymer Registration in 2003

Polymers were not identified in the White Paper as requiring registration under REACH (COM, 2001). However, provisions for the registration of polymers were included in Volume 1 of the Document published by the Commission to support its internet consultation run from 7 May to 10 July 2003 (COM, 2003a). These provisions for the registration of polymers were not included in the Commission Proposal of 2003 (COM, 2003b) but they were assessed for their potential impacts.

The 2003 proposals for the registration of polymers are summarised below:

- a non-registered monomer substance(s) or other non-registered substance(s) produced or imported into the EU would have to be registered if the polymer consists of 2% weight by weight (W/W) or more, making up 1 tonne or more per year, of such monomer substance(s) or other substance(s) (Point 15)[24]; and

- polymers produced or imported in quantities of greater than 1 tonne per year have to be registered if the polymer meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC, and which have:

    - a number-average molecular weight less than 10,000 Dalton, or

    - a content of greater than or equal to 2% of low molecular weight (i.e. less than 1,000 Dalton) species of monomer units including residual monomer(s) but excluding other components such as additives or impurities (Point 16).

These provisions would have applied to monomers used as isolated intermediates to ensure that they are registered although polymers that are used as isolated intermediates would have been exempted. The provisions would not have applied to polymers resulting from a chemical reaction occurring upon end-use of other polymers.

Under COM (2003a), the registration of polymers would have been less onerous than for other substances but more onerous than those proposed for isolated intermediates. The registration requirements considered for polymers, considered by RPA (2003) are set out in Table 6.1. Compared to the requirements for a non-polymer substance, the key differences relate to the fact that information on the toxicological and ecotoxicological properties of polymers were not required, thus, reducing the need for robust study summaries, information on animal testing and proposals for further testing.

[24] Point 15 provisions for the registration of monomers and other substances in polymers and including the exemption of monomers from the reduced registration provisions for isolated intermediates were included in COM (2003b) and within the text of REACH, as finally adopted.

Table 6.1: Registration Requirements for Polymers under COM (2003a)				
Information Required		**Threshold (Tonnes)**		
		1	**10**	**100**
1	Identity/details of Manufacturer/Importer	●	●	●
2	Identity/details of Substance	●	●	●
3	Manufacture and Use Information for the Substance	●	●	●
4	Proposed Classification & Labelling of Substance	●	●	●
5	Guidance on Safe use of Substance			
6 Summaries of Physicochemical Information				
(i)	Physicochemical information specified in Annex V	●	●	●
(ii)	Physicochemical information specified in Annex VI		●	●
(iii)	Physicochemical information specified in Annex VII			●
10	Registration Number	●	●	●
12	Chemical Safety Report (CSR)	●	●	●
Sources: RPA (2003), based on COM (2003a).				

Physicochemical information requirements for polymers under COM (2003a) are summarised in Table 6.2, where they are compared to the requirements under REACH Annex VII. From Table 6.2, it can be seen that the physicochemical endpoints for which information would have been required under COM (2003a) are greater than those adopted under REACH for substances manufactured/imported in quantities greater than 1 tonne but less than 10 tonnes per year.

Table 6.2: Information Requirements (Phase-in Substances Not Meeting Annex III Criteria)	
From COM (2003a)	**Required under REACH (Annex VII)**
1 Tonne and Over	
-	Physical state of substance (at 20 °C and 101.3 kPa)
Melting/ freezing point	Melting/ freezing point
Boiling point	Boiling point
Relative density	Relative density
Vapour pressure	Vapour pressure
Surface tension	Surface tension
Water extractivity (only for polymers and in place of water solubility)	Water solubility
Partition coefficient n-octanol/water	Partition coefficient (at least n-octanol/ water ratio)
Flash-point	Flash-point
Flammability	Flammability
Explosive properties	Explosive properties
Self-ignition temperature	Self-ignition temperature
Oxidising properties	Oxidising properties
Granulometry	Granulometry
10 Tonnes and Over	
Light-stability (if polymer is not specifically light-stabilised)	-
Long-term extractivity - leachate study	-
100 Tonnes and Over	
Stability in organic solvents and identity of relevant degradation products	-
Dissociation constant	-
Viscosity	-
Reactivity towards container material	-

6.2 Previous Assessment of Polymer Registration Proposals

6.2.1 Assumptions for Information Requirements and Sharing

In the impact assessment of COM (2003a), it was assumed that, for polymers, information would only need to be provided on physicochemical properties, as appropriate to the tonnage manufactured/imported up to the requirements proposed for substances produced in quantities less than 1,000 t/y (RPA, 2003). Similarly, the provisions with regard to the potential for information sharing within consortia for the purposes of registering a polymer were assumed to be consistent with those for other substances.

6.2.2 Non-Registered Monomers and Other Substances

Many of the monomers that provide the basis for the manufacture of polymers were recognised to effectively represent bulk substances placed widely on the market and, thus, would require registration in their own right (irrespective of their use as monomers). Many companies (both large and SMEs) were assumed to act as formulators buying in the monomers, oligomers and the other substances used in the manufacture of a polymer. Given the above, RPA (2003) stated that industry did not believe that a significant number of monomers or other substances would have to be registered under Point 15 of COM (2003a).

6.2.3 Estimates Used

Upper and lower bound estimates were developed as to the number of registrations that were expected to result, based on the data provided by the TABD, VCI and individual companies discussed in Section 3.3.2:

- **Lower bound**: 35,000 (50% of 70,000) polymers to be considered for registration assuming that the CAS number groupings can be maintained for registration purposes; and

- **Upper bound**: 200,000 (50% of 400,000) polymers to be considered for registration assuming that CAS number groupings cannot be maintained and that around three registrations per group would be required to reflect those polymers having dangerous properties.

Note that the upper bound assumption was developed to reflect the arguments made by companies regarding the need to register individual polymers for technical reasons. In particular, it was argued that small changes in polymer substance composition can lead to significant changes in the physicochemical properties of the polymers and, hence, in their hazard potential (small changes in additive content/mix can also result in significant changes but these are outside of the scope of this study). Arguments over the need to guard commercial confidentiality, particularly for SMEs, were also taken into account in this upper bound estimate.

RPA (2003) allocated the total numbers of registrations across the four tonnage bands. It was assumed that 20% of the total number of registrations was for

polymers manufactured or imported above 100 tonnes per year, evenly split between this tonnage band and that for substances above 1,000 tonnes per year. The remainder of the registrations were assumed to be for substances less than 100 tonnes per year, based on industry information; within these lower tonnages the number of registrations were evenly split between those greater than 1 tonne per year and those greater than 10 tonnes per year, as set out in Table 6.3.

Table 6.3: Estimates of Polymer Registrations from RPA (2003)

Quantity	Total Polymers Potentially Undergoing Registration		Percentage of Total
	Lower Bound	Upper Bound	
>1,000 t/y	1,750	10,000	5%
>100 t/y	5,250	30,000	15%
>10 t/y	14,000	80,000	40%
>1 t/y	14,000	80,000	40%
Total	***35,000***	***200,000***	***100%***

6.3 Previous Costings

RPA (2003) identified a number of separate activities or 'cost items,' that would be needed for the registration of substances, as set out in Table 6.4, with those of relevance to the registration of polymers highlighted in blue.

Table 6.4: Deriving the Cost Items in Manufacturers and Importers Dossiers

Cost Item	Description
Physicochem hazard assessment	Activities include data collection, data analysis (e.g. explosivity and flammability) and classification and labelling. For >1,000t/y, 1 professionals working for 4 - 5 hours. Note that REACH did not adopt the COM (2003a) additional requirements for higher tonnage substances
Human health hazard assessment	Activities include data collection, human data evaluation, non-human data evaluation, quantitative analysis (DNEL derivation), physicochemical analysis and classification and labelling. For >1t/y, 1 professional working for 4 - 5 hours and for >100t/y, 1 professional working for 4.5 days
Environmental hazard assessment	Activities include data collection, data evaluation, classification and labelling and qualitative analysis (PNEC Derivation). For >1t/y, 1 professional working for 4 hours and for >100t/y, 1 professional working for 3 days (or 2 for 1.5 days)
Polymer analytics	Activities include data collection and evaluation, physicochemical analysis, classification and labelling. For all tonnages, 1 professional working for 5 days plus €5,000 for additional analytics of polymers that do not end up being registered
PBT assessment no emissions	Activities include data collection and comparison to PBT/vPvB. For >1t/y, 1 professional working for 45 minutes and for >100t/y, 1 professional working for 2 hours
PBT assessment with emissions	Activities include data collection, comparison to PBT/vPvB and emissions characterisation. For >1t/y, 1 professional working for 3 hours and for >100t/y, 1 professional working for 7 hours
Exposure assessment	Activities include data entry, modelling of emissions scenarios across different user characteristics, evaluation of modelling results and sensitivity testing

Table 6.4: Deriving the Cost Items in Manufacturers and Importers Dossiers	
Cost Item	**Description**
Robust study summary	For >100t/y and >1,000t/y, 1 professional working for 4 and 8 hours respectively
Risk characterisation	Activities include evaluation of risks to human health and environment, consideration of implications of physicochemical properties and determination of adequate controls. For >1t/y, 1 professionals working for 6 hours and for >100t/y, 1 professionals working for 5 days
Chemical safety report	For >1t/y, 1 professional working for 4 hours and for >100t/y, 1 professionals working for 2 days
Summary of info on properties	For >1t/y, 1 professional working for 4 hours and for >100t/y, 1 professional working for 1 day
Preparation of test proposals	For all tonnages, 1 professionals working for 4 hours each
Administrative costs	Activities include organising and contracting testing as required, establishing and updating data management systems (e.g. downstream users), arranging internal and external meetings, contacting and managing other legal and scientific experts, circulation of CSR etc. For >1t/y, 1 professionals working for 5 days and for >100t/y, 1 professionals working for 10 days
Downstream user phase-in info	Activities include collecting and analysing data, meeting with users, confirming differences in data, communicating preliminary results, etc. For >1t/y and >10t/y, 2 professionals working for 2 to 4 days. For >100t/y and >1,000t/y, equivalent to 2 professionals working for 5 – 7½ days each, allowing for greater number of downstream uses
Downstream user intermediate and polymer information gathering	Activities as for phase-in substances, with reduced requirements assumed given expected reduction in likely number of downstream users. For >1t/y, 2 professionals working for 2 days and for >100t/y, 2 professionals working for 2½ – 3 days
Consortia administration	Activities per manufacturer include: data collection, arranging and holding internal and external meetings, contacting downstream users and obtaining feedback, dealing with legal and contractual issues, etc. For >1t/y, 1 professional working for 3 days per company and for >1,000t/y, 2 professionals working for 5 days per company
Note: Highlighted rows indicate cost items considered to be of full or partial relevance to the registration of polymers	

6.4 Costs of Registrations – Latest Data

The recent study to assess the impacts of REACH on competitiveness (COM, 2012) identified cost drivers and estimated the costs of registration for those substances falling into the first tranche. The average cost (mode) per registration was between €50,000 and €100,000. However, the cost distribution was very wide, varying by type of substance, size of SIEF and type of registrant, with manufacturers reporting higher figures (more than 10% reporting over €250,000) and importers reporting values between €10,000 and €25,000. The mean for the registration of one substance was around €150,000 and the median (believed to be the most appropriate central value estimate) around €70,000.

The main cost drivers stated by registrants were:

- ECHA fees (often representing 50% or more of the total costs especially for those substances which do not require complicated studies, data collection and

SIEF and consortia related costs);
- access to data-studies/Letters of Access (€5,000 to €10,000 for a simple substance);
- administration of SIEFs;
- in-house staff and consultant fees; and
- additional tests.

The estimated total costs from registration so far, as estimated by industry, are between €1.1 billion and €2.3 billion (i.e. 26,000 registration dossiers at €50,000 to €100,000 per dossier). Registration costs have amounted to <0.5% of annual turnover for 60% of registrants, with larger firms generally reporting higher average registration costs per substance (€87,000 versus €35,000 for microenterprises and €57,000 for small and medium enterprises). The registration costs for intermediates are typically less than €10,000.

When considering the registration information presented here it is important to note that 90% of registrations to date relate to substances produced at greater than 1,000 tonnes per annum of which 87% were submitted by large companies; in addition, 21% of registrations relate to intermediates (ECHA, 2011a). Table 6.5 provides a summary of the registration cost data gathered by CSES (2012) for COM (2012).

Table 6.5: Percentage Registrants Incurring Costs for Single Registrations

Registration Cost Range (€)	Importers	Manufacturers	All Registrants
0-10,000	8%	4%	5%
1001-25,000	20%	8%	11%
25,001-50,000	24%	20%	21%
50,001-100,000	26%	29%	28%
100,001-250,000	21%	23%	22%
250,001-500,000	2%	9%	8%
500,001-1,000,000	0%	3%	2%
>1,000,000	0%	4%	3%
All	100%	100%	100%

It should be noted that the figures shown in Table 6.5 include the cost of obtaining data. However, 54% of these data for endpoints requiring *in vivo* tests (generally the most expensive tests) came from tests carried out prior to the introduction of REACH, access to which was then sold to other registrants via letters of access (ECHA, 2011). The percentage of such data that came from old tests was considerably higher for some test endpoints, e.g. 85% for acute toxicity, 78% for skin irritation and 75% for eye irritation.

In addition, as noted above, the cost of a single intermediate registration was estimated to be less than €10,000 (COM, 2012). However, this figure included the costs of the registration of transported intermediates over 1,000 tonnes (as for 1 to 10 tonne substances). This latter consideration is likely to have significantly increased the average cost given that 72% of intermediate registrations at the time of the CSES study were for transported intermediates (ECHA, 2011a).

7. ASSUMPTIONS FOR OPTIONS ASSESSMENT

7.1 General Assumptions

The previous sections have set out information regarding the production, trade and registration costs of polymers. These data provide the basis for the assumptions adopted as the basis for assessing the costs of different options for the registration of polymers, including the extension of the current provision for the registration of monomers.

For clarity, the assumptions that act as the basis for the analysis presented in the later sections of this report are summarised below, starting with key assumptions on the numbers of polymers that may be affected as given in Table 7.1.

Table 7.1: Key Assumptions

Assumption	Estimate
Number of different polymers on the EU market	70,000
Number of isolated intermediates	15,000
Percentage of polymers meeting criteria for on-site or transported isolated intermediates	50%
Percentage of polymers meeting criteria for transported isolated intermediates	25%
Number of monomers	10,000
Number of monomers registered by 2015	2,000

The number of polymers on the EU market has been estimated on the basis of RPA (2003) and includes post reacted polymers (cf. 2.3.5), but not isolated intermediates and non-isolated intermediates (it is assumed that there would be very few polymers that would meet the criteria for the latter). For this analysis, we assumed that there are 70,000 polymers manufactured or imported on the EU market and 15,000 isolated intermediates (around 20% of the 70,000). This estimate includes synthetic rubbers (cf. 3.2.3) and silicones (cf. 3.2.4). Further justification for this estimate has been provided in Sections 3.2.2 and 3.2.3.

Industry indicated that a significant proportion of polymers would not meet the criteria for intermediates but no estimates were provided. It has therefore been assumed that polymers are split evenly between isolated intermediates and non-intermediates. Furthermore, it is assumed that there is an equal split between on-site and transported isolated intermediates (see also Section 2.3.5).

As indicated earlier, no estimates have been provided from the study undertaken by Cefic's Polymer Steering Group on the total number of substances used as monomers (or even a rough ball-park figure), or of polymers. We have therefore relied on the data presented in Section 2.2.3, to develop our assumptions. Based on these data, it has been assumed that around 10,000 monomers (basic and specialty monomers) are currently placed on the EU market, with around 2,000 manufactured or imported in quantities above 100 tonnes.

Table 7.2 presents the assumptions about the distribution of polymers and monomers that have been registered and will be registered across tonnage bands. This also

includes the number of dossiers that will be submitted in total and the number of these which would be joint rather than individual submissions.

Table 7.2: Assumptions for Screening Polymers for Registration Requirements					
Assumption	**Distribution across Tonnage Bands**				
	≥1000 tpa	**≥100 tpa/ ≤1,000 tpa**	**≥10tpa/ ≤100 tpa**	**≥1tpa/ ≤10 tpa**	***Total***
Polymers	5%	15%	40%	40%	*100%*
Monomers	5%	15%	40%	40%	*100%*
Numbers of Polymers	3,500	10,500	28,000	28,000	*70,000*
Numbers of Monomers	500	1,500	4,000	4,000	*10,000*
Numbers of Monomers still to be Registered by 2015	0	0	4,000	4,000	*8,000*
Numbers of Monomers Registered by 2015	500	1,500	0	0	*2,000*
Percentage of polymers manufactured or imported by microenterprises	2.5%	2.5%	10%	25%	-
Percentage of polymers manufactured or imported by small enterprises	7.5%	7.5%	20%	30%	-
Percentage of polymers manufactured or imported by medium enterprises	30%	40%	30%	30%	-
Percentage of polymers manufactured or imported by large enterprises	60%	50%	40%	15%	-
Number of dossiers submitted per polymer	4	2	1.5	1.3	-
Percentage of joint dossier submission	50%	50%	30%	20%	-

RPA (2003) allocated the total numbers of registrations across the four tonnage bands. It was assumed that 20% of the total number of registrations was for polymers manufactured or imported above 100 tonnes per year, split between this tonnage band and that for substances above 1,000 tonnes per year. The remainder of the registrations were assumed to be for substances less than 100 tonnes per year, based on industry information; within these lower tonnages the number of registrations were evenly split between those greater than 1 tonne per year and those greater than 10 tonnes per year (see also Section 6.2.3). With no hard data, an equal split between tonnage bands has been assumed.

Table 7.3 presents our working assumptions on the numbers of polymers that are likely to have different types of hazardous properties (based on the findings of the OECD, 2009 study) and that will have usage profiles that can be described as dispersive or diffuse (as defined in REACH, for example, in Annex III). These assumptions are used to both determining testing costs but also to differentiate the information requirements for Registration.

Table 7.3: Assumptions for Screening Polymers for Registration Requirements	
Screening assumption	**Estimate**
Polymers that should have a CLP classification as for mixtures	50%
Polymers of Low Concern	70%
Polymers with dispersive/diffuse uses	30%
Polymers with CMR/vPvB/PBT properties	2%
Polymers with physical-chemical data	100%
Monomers with classification[1]	85%

Note that the figure of 50% of polymers having a CLP classification is not only based on the OECD report (2009) (see Section 4.3.2) but also on consultation with polymer and monomer manufacturers specifically for the purposes of this study, as well as information provided to RPA for the Revised BIA produced in 2003 (again based on personal communications with companies from the polymer industry).

The assumption on the number of polymers that will meet the PLC criteria has been drawn on the basis of the OECD study. The assumption on the percentage of polymers with dispersive/diffuse uses is the same as for chemical substances and is based on the estimate of the Danish and Nordic Product Registers (20%) and the previous estimates of 40% by the Commission.

The assumption on polymers meeting the criteria to be classified as CMR/vPvB/PBT is based on Table 4.6 in Section 4. From an assessment of the number of likely PBTs undertaken for Part B of this report, there are expected to be only a very small proportion of substances that have PBT/vPvB properties. Most of the polymers are expected to be persistent but not bioaccumulative, since biological membranes are not permeable to substances of very large molecular size. However, bioaccumulation cannot be excluded, for example, for cationic polymers[25]. On this basis, the estimate is based on CMR data only. Regarding the assumption on the percentage of polymers with physico-chemical data, it is believed that most if not all that are placed on the market will have the full set of data for commercial and transport purposes. Regarding monomers with classification, it is assumed that the same percentage for substances found to have a classification in the CLI will apply to monomers.

Polymers with an existing classification where one or more new classifications might be identified

As discussed in Section 4.3.2, it is assumed that 50% of polymers should have a classification already. Of these, 25% would be found to have one or more additional classifications assuming a level of testing equivalent to Annex X. Other Annexes would be less effective at identifying these additional classifications as in the Table 7.4 below.

Table 7.4: Effectiveness of Data/Testing Requirements at Identifying New Classifications	
On-site isolated intermediates	0%
Annex VII	60%
Annex VIII	70%
Annex IX	90%
Annex X	100%

[25] Muir *et al* (1997): *Localization, depuration, bioaccumulation and impairment of ion regulation associated with cationic polymer exposure in rainbow trout (Oncorhynchus mykiss)*, **Xenobiotica**, Volume (27) 10. Available at Internet site: http://www.deepdyve.com/lp/informa-healthcare/localization-depuration-bioaccumulation-and-impairment-of-ion-gUyc7McS46

Polymers with no existing classification where a new classification would be found

Of the polymers with an existing classification, it is assumed that 70% qualify as Polymers of Low Concern (PLC) and 30% do not. Of those that do not qualify as PLC (30%), we assume that 85% would be found to have one or more classifications assuming a level of testing equivalent to Annex X. Other Annexes would be less effective at identifying these additional classifications, as in Table 7.4. It is further assumed that the hazard profiles of the resulting polymers from the different screening criteria discussed in Section 8.1.2 will follow the percentages presented in Table 4.5 (as such, 2% will be CMR Cat 1a/1b and 6% will be CMR Cat 1a/1b/2 or Lact.).

With respect to the information requirements set out in Table 7.5 (below), it has been assumed that information will be provided for registration sufficient to identify a polymer, and group that polymer with other similar polymers for registration purposes. It is not assumed that all registrants would provide all of the information set out in Table 7.5. Rather, registrants would provide only that information needed for the identification and grouping of their polymers. Industry has indicated that, where no analytical and substance ID information is available to registrants, the provision of information sufficient for these purposes would cost approximately €25,000 per substance (PSG, *pers. comm.*). However, as data will be available for some polymers, we have assumed an average cost of €10,000 across all polymers for obtaining information for substance identification/grouping; note that this in line with data previously communicated to RPA (RPA, 2003). Industry has also indicated that the process of determining and applying the criteria to permit substance identification/grouping would be expected to take approximately two years to complete for all polymers.

It is not assumed that the list of information provided in Table 7.5 (below) is comprehensive or definitive. It is assumed that some of the information listed in the table may not be used for these purposes by industry and that other information may be added to the list provided in Table 7.5, either prior to the introduction of any registration for polymers or during the process of SIEF formation. It is however assumed that this is indicative of that which would be used by registrants.

The information requirements in relation to Annexes VII to X that have been used for some or all of the options for the registration of polymers are set out in Table 7.6, together with the assumptions that accompany these. In the analysis of options, the data in Table 7.6 have been used to develop test costs, number (and hence cost) of animal test proposals (and, as such number and cost of dossier updates) and costs of summarising existing data.

It is believed that one of the main drivers of the "hazardousness" of polymers is the presence of unreacted monomers. On this basis, it is assumed that read across from hazard properties of the constituent monomers will be carried out. Monomers belonging to the same class (listed and described in Table 2.4) are believed to have similar behaviour. In the absence of any hard data on the extent to which this might be the case, we have assumed that this applies to 30% of polymers.

Table 7.5: Substance Identification General and Structural Information for Registration – Assumed Cost €10,000 in Total[1]									
Properties	**Annex[2] (Tonnage Threshold)**	**Relevant to Polymers[3]**	**Percentage of Polymers to which relevant (%)[4]**	**Readily Available Information[5]**	**Percentage of Polymers with data/information[6]**				**Notes**
					≥1000 tpa	**≥100 to ≤1,000 tpa**	**≥10tpa to ≤100 tpa**	**≥1tpa to ≤10 tpa**	
Identifiers									
Name or other identifier of each substance	VI (≥1tpa)	Y	100%	Y	95%	95%	95%	95%	-
Names in IUPAC nomenclature or other international chemical name(s)	VI (≥1tpa)	C	40%	N	5%	5%	5%	5%	IUPAC nomenclature is possible for homopolymers, but is more complex for copolymers and blends
Other names (usual name, trade name, abbreviation)	VI (≥1tpa)	Y	100%	Y	95%	95%	95%	95%	-
EINECs or ELINCs number	VI (≥1tpa)	N	0%	N	N/A	N/A	N/A	N/A	-
CAS name and CAS number	VI (≥1tpa)	C	40%	N	5%	5%	5%	5%	CAS numbering for polymers may be complicated for copolymers and blends
Other identity code	VI (≥1tpa)	Y	100%	Y	95%	95%	95%	95%	Particularly relevant as CAS number and IUPAC nomenclature often insufficient for unambiguous identification
Structural information									
Molecular and structural formula (including smiles notation)	VI (≥1tpa)	C	40%	N	5%	5%	5%	5%	This may be complex for copolymers and blends
Molecular weight or molecular weight range	VI (≥1tpa)	Y	100%	Y	95%	95%	95%	95%	-

Table 7.5: Substance Identification General and Structural Information for Registration – Assumed Cost €10,000 in Total[1]									
Properties	**Annex[2] (Tonnage Threshold)**	**Relevant to Polymers[3]**	**Percentage of Polymers to which relevant (%)[4]**	**Readily Available Information[5]**	**Percentage of Polymers with data/information[6]**				**Notes**
					≥1000 tpa	**≥100 to ≤1,000 tpa**	**≥10tpa to ≤100 tpa**	**≥1tpa to ≤10 tpa**	
Characterisation information									
Number average and weight average molecular weight	P (≥1tpa)	Y	100%	Y	95%	95%	95%	95%	-
GPC data and molecular weight distribution (MWD)	P (≥1tpa)	Y	100%	C	40%	40%	40%	40%	Not all polymer manufacturers measure MWD or poly-dispersity
Identity of monomer units	P (≥1tpa)	Y	100%	Y	95%	95%	95%	95%	-
Proportion of different monomer units	P (≥1tpa)	Y	100%	Y	95%	95%	95%	95%	-
Distribution of monomer units or groups of monomer units	P (≥1tpa)	C	40%	Y	95%	95%	95%	95%	Representation of this may be difficult
Chain length mean and distribution	P (≥1tpa)	C	40%	Y	95%	95%	95%	95%	Network and cross-linked polymers may be too complex for this parameter
Degree of crosslinking	P (≥1tpa)	C	40%	Y	95%	95%	95%	95%	This will be affected by the curing and post-cure regime in thermosets and elastomers
Functional group molar concentration	P (≥1tpa)	Y	100%	C	40%	40%	40%	40%	Not routinely measured by some polymer producers but it is for reactive resins and monomers used for example in thermosets.

Table 7.5: Substance Identification General and Structural Information for Registration – Assumed Cost €10,000 in Total[1]									
Properties	**Annex[2] (Tonnage Threshold)**	**Relevant to Polymers[3]**	**Percentage of Polymers to which relevant (%)[4]**	**Readily Available Information[5]**	**Percentage of Polymers with data/information[6]**				**Notes**
					≥1000 tpa	**≥100 to ≤1,000 tpa**	**≥10tpa to ≤100 tpa**	**≥1tpa to ≤10 tpa**	
Availability of monomeric functional groups for further chemical reaction or interaction with surrounding media	P (≥1tpa)	C	40%	Y	95%	95%	95%	95%	This will be affected by the degree of reaction and the need in some polymers for residual monomer to confer certain properties or performance. Some resins may also be supplied in so-called B-stage state of reaction for further processing
Polydispersity	P (≥1tpa)	Y	100%	C	40%	40%	40%	40%	Not all polymer manufacturers measure MWD or polydispersity
Composition information									
Degree of purity (w/w %)	VI (≥1tpa)	C	100%	N	40%	40%	40%	40%	Not all polymer manufacturers measure purity routinely
Nature of impurities, including by-products	VI (≥1tpa)	Y	100%	Y	95%	95%	95%	95%	-
Weight percentage of main impurities	VI (≥1tpa)	Y	100%	Y	95%	95%	95%	95%	-
Nature and order of magnitude of any additives	VI (≥1tpa)	Y	100%	N	5%	5%	5%	5%	-
Spectral data (UV, IR, Raman, NMR or MS)	VI (≥1tpa)	Y	100%	N	5%	5%	5%	5%	-
High pressure liquid chromatogram, gas chromatogram	VI (≥1tpa)	Y	100%	N	5%	5%	5%	5%	-

Table 7.5: Substance Identification General and Structural Information for Registration – Assumed Cost €10,000 in Total[1]									
Properties	**Annex[2] (Tonnage Threshold)**	**Relevant to Polymers[3]**	**Percentage of Polymers to which relevant (%)[4]**	**Readily Available Information[5]**	**Percentage of Polymers with data/information[6]**				**Notes**
					≥1000 tpa	**≥100 to ≤1,000 tpa**	**≥10tpa to ≤100 tpa**	**≥1tpa to ≤10 tpa**	
Description of analytical methods or appropriate bibliographical reference for the identification of the substance and those impurities and additives present	VI (≥1tpa)	Y	100%	Y	95%	95%	95%	95%	-
Identity of non-reacted monomers	P (≥1tpa)	Y	100%	Y	95%	95%	95%	95%	-
Weight percentage of non-reacted monomers	P (≥1tpa)	C	40%	Y	95%	95%	95%	95%	This will be dependent on the degree of reaction and for thermosets the cure regime

Notes.
1. PSG estimate €25,000 for Substance ID testing, on average.
2. Relevant REACH Annex number or "P" to indicate a polymer specific requirement.
3. Relevance of property to polymers: "Y" = Yes, "N" = No, and "C" = Certain polymers only, determined by expert judgement by the study team.
4. Where relevant to polymers ("Y" in previous column) it is assumed that this will apply to all substances (100%). Where an endpoint is relevant to certain polymers only ("C" in previous column) it has been assumed that this applies to 40% of polymers. Where an endpoint is considered not to be relevant ("N" in previous column) it has been assumed that it is not relevant for all polymers (i.e. 0% assumed). With no data provided by industry or other sources to inform the derivation of estimates, the assumptions adopted here are tentative in nature.
5. Availability of information to polymer registrants: "Y" = Yes, "N" = No, and "C" = Certain polymers only, determined by expert judgement by the study team.
6. Where information is readily available (i.e. "Y" in previous column) it is assumed that this will apply to 95% of substances. Where information is available to certain polymers only ("C" in previous column) it has been assumed that this applies to 40% of polymers. Where information is not likely to be available ("N" in previous column) it has been assumed information will not be available for 95% of polymers (i.e. information available for 5%). With no data provided by industry or other sources to inform the derivation of estimates, the assumptions adopted here are tentative in nature.

Table 7.6: Physicochemical and (Eco)Toxicological Information for Registration										
Properties	**Annex[1] (Tonnage Threshold)**	**Relevant to Polymers[2]**	**Percentage of Polymers to which relevant (%)[3]**	**Readily Available Information[4]**	**Percentage of Polymers with data/information[5]**				**Test Costs (€)[6]**	**Notes**
					≥1000 tpa	**≥100 tpa/ ≤1,000 tpa**	**≥10tpa/ ≤100 tpa**	**≥1tpa/ ≤10 tpa**		
Physicochemical Properties										
Cure regime	P (≥1tpa)	Y	100%	Y	95%	95%	95%	95%	-	This information should be given as it will affect a number of the properties reported. Assumed to be an administration cost
State of substance	VII (≥1tpa)	Y	100%	Y	95%	95%	95%	95%	1,000	-
Melting/freezing point	VII (≥1tpa)	C	40%	Y	95%	95%	95%	95%	877	Relevant to semi-crystalline polymers only
Glass transition temperature (Tg)	P (≥1tpa)	C	40%	N	5%	5%	5%	5%	877	Both semi-crystalline and amorphous polymers will have a Tg, however it is typically only measured for amorphous polymers. The Tg may be quoted as a range, as it is affected by processing conditions as well as measurement technique. Assumed same cost as other temperature/state transition tests

Table 7.6: Physicochemical and (Eco)Toxicological Information for Registration										
Properties	**Annex[1] (Tonnage Threshold)**	**Relevant to Polymers[2]**	**Percentage of Polymers to which relevant (%)[3]**	**Readily Available Information[4]**	**Percentage of Polymers with data/information[5]**				**Test Costs (€)[6]**	**Notes**
					≥1000 tpa	**≥100 tpa/ ≤1,000 tpa**	**≥10tpa/ ≤100 tpa**	**≥1tpa/ ≤10 tpa**		
Boiling point	VII (≥1tpa)	C	40%	Y	95%	95%	95%	95%	877	This will be relevant for low MW polymers and oligomers, and those polymers containing large amounts of residual monomer. For those high MW polymers without residual monomer or polymerisation by-products, this will not be valid
Decomposition temperature	P (≥1tpa)	Y	100%	N	5%	5%	5%	5%	877	Assumed same cost as other temperature/state transition tests
Relative density	VII (≥1tpa)	Y	100%	Y	95%	95%	95%	95%	770	-
Vapour pressure	VII (≥1tpa)	C	40%	N	5%	5%	5%	5%	2,278	This will be relevant for low MW polymers and oligomers, and those polymers containing large amounts of residual monomer. For those high MW polymers without residual monomer or polymerisation by-products, this will not be valid
Surface tension	VII (≥1tpa)	C	40%	N	5%	5%	5%	5%	1,120	This is only valid for those polymers that are in a liquid state, which may be limited to low MW polymers and oligomers

Table 7.6: Physicochemical and (Eco)Toxicological Information for Registration										
Properties	**Annex[1] (Tonnage Threshold)**	**Relevant to Polymers[2]**	**Percentage of Polymers to which relevant (%)[3]**	**Readily Available Information[4]**	**Percentage of Polymers with data/information[5]**				**Test Costs (€)[6]**	**Notes**
					≥1000 tpa	**≥100 tpa/ ≤1,000 tpa**	**≥10tpa/ ≤100 tpa**	**≥1tpa/ ≤10 tpa**		
Solubility (water, solvents, oils)	VII (≥1tpa)	Y	100%	C	95%	95%	95%	95%	4,303	Solubility in various media is widely measured for polymers but not for all polymers in all media. Cost based on data for non-polymeric substances
Stability (thermal, UV, environmental, oxidative and hydrolytic)	P (≥1tpa)	Y	100%	C	95%	95%	95%	95%	2,500	Stability is widely measured for polymers but not all breakdown routes are considered for all polymers
Partition coefficient	VII (≥1tpa)	Y	40%	N	5%	5%	5%	5%	3,482	Relevant to anionic and cationic polymers and polymers such as acid doped and ion polymers in contact with solubilising media
Water extractivity	P (≥1tpa)	Y	100%	C	95%	95%	95%	95%	-	Based on NONS requirements (see comment on long term extractivity)
Long term extractivity (leachate test)	P (≥1tpa)	Y	100%	N	5%	5%	5%	5%	3,721	This is not routinely measured on all polymers but only on those used in food and drink contact, in water applications and in pharmaceutical packaging and medical devices
Flash-point	VII (≥1tpa)	C	40%	N	5%	5%	5%	5%	922	This parameter will only be relevant to the lower MW polymers and oligomers and those with volatile residual monomer, reactants or reaction by-products.

Table 7.6: Physicochemical and (Eco)Toxicological Information for Registration										
Properties	**Annex[1] (Tonnage Threshold)**	**Relevant to Polymers[2]**	**Percentage of Polymers to which relevant (%)[3]**	**Readily Available Information[4]**	**Percentage of Polymers with data/information[5]**				**Test Costs (€)[6]**	**Notes**
					≥1000 tpa	**≥100 tpa/ ≤1,000 tpa**	**≥10tpa/ ≤100 tpa**	**≥1tpa/ ≤10 tpa**		
Flammability	VII (≥1tpa)	Y	100%	Y	95%	95%	95%	95%	660	-
Explosive properties	VII (≥1tpa)	C	40%	N	5%	5%	5%	5%	3,369	This parameter will only be relevant to the lower MW polymers and oligomers and those with volatile residual monomer or reaction by-products
Self-ignition temperature	VII (≥1tpa)	C	40%	Y	95%	95%	95%	95%	2,223	This parameter will only be relevant to the lower MW polymers and oligomers and those with volatile residual monomer or reaction by-products.
Oxidising properties	VII (≥1tpa)	C	40%	N	5%	5%	5%	5%	3,415	This parameter is not routinely measured for most polymers
Granulometry/morphology (solids only)	VII (≥1tpa)	Y	100%	N	5%	5%	5%	5%	2,287	While this is sometimes measured for polymers it is not common to do so
Stability in organic solvents and identity of relevant degradation products	IX (≥100tpa)	Y	100%	N	95%	95%	95%	95%	4,600	-
Dissociation constant	IX (≥10tpa)	C	40%	N	95%	95%	95%	95%	3,869	This parameter may only be relevant to speciality polymers
Viscosity	IX (≥100tpa)	C	40%	Y	95%	95%	95%	95%	1,491	This parameter will be relevant for lower MW polymers
Toxicological Properties										
Skin irritation or skin corrosion (*in vitro)*	VII (≥1tpa)	Y	100%	N	5%	5%	5%	5%	1,500	-

Table 7.6: Physicochemical and (Eco)Toxicological Information for Registration										
Properties	**Annex[1] (Tonnage Threshold)**	**Relevant to Polymers[2]**	**Percentage of Polymers to which relevant (%)[3]**	**Readily Available Information[4]**	**Percentage of Polymers with data/information[5]**				**Test Costs (€)[6]**	**Notes**
					≥1000 tpa	**≥100 tpa/ ≤1,000 tpa**	**≥10tpa/ ≤100 tpa**	**≥1tpa/ ≤10 tpa**		
Skin irritation or skin corrosion (*in vivo)*	VIII (≥10tpa)	Y	100%	N	5%	5%	5%	5%	1,600	-
Eye irritation (*in vitro)*	VII (≥1tpa)	Y	100%	N	5%	5%	5%	5%	1,350	-
Eye irritation (*in vivo)*	VIII (≥10tpa)	Y	100%	N	5%	5%	5%	5%	1,300	-
Skin sensitisation (*in vivo* Murine Local Lymph Node Assay (LLNA), unless exceptional)	VII (≥1tpa)	Y	100%	N	5%	5%	5%	5%	4,000	-
Mutagenicity (*in vitro* gene mutation in bacteria)	VII (≥1tpa)	Y	100%	N	5%	5%	5%	5%	3,200	-
Mutagenicity (*in vitro* cytogenicity study in mammalian cells or in vitro micronucleus study)	VIII (≥10tpa)	Y	100%	N	5%	5%	5%	5%	14,000	-
Mutagenicity (*in vitro* gene mutation study in mammalian cells, if other tests negative)	VIII (≥10tpa)	Y	100%	N	5%	5%	5%	5%	12,000	
Mutagenicity (*in vitro* somatic cell study if positive genotoxicity study)	X (≥1,000tpa)	Y	100%	N	5%	5%	5%	5%	3,465	-
Acute toxicity (oral)	VII (≥1tpa)	Y	100%	N	5%	5%	5%	5%	1,500	-
Acute toxicity (inhalation and dermal)	VIII (≥10tpa)	Y	100%	N	5%	5%	5%	5%	12,000 (dermal 2,200)	-
Repeated dose toxicity (*in vivo* short-term (28 days))	VIII (≥10tpa)	Y	100%	N	5%	5%	5%	5%	50,000	-

Table 7.6: Physicochemical and (Eco)Toxicological Information for Registration										
Properties	**Annex[1] (Tonnage Threshold)**	**Relevant to Polymers[2]**	**Percentage of Polymers to which relevant (%)[3]**	**Readily Available Information[4]**	**Percentage of Polymers with data/information[5]**				**Test Costs (€)[6]**	**Notes**
					≥1000 tpa	**≥100 tpa/ ≤1,000 tpa**	**≥10tpa/ ≤100 tpa**	**≥1tpa/ ≤10 tpa**		
Repeated dose toxicity (*in vivo* sub-chronic (90 days)	IX (≥100tpa)	Y	100%	N	5%	5%	5%	5%	120,000	BIA
Repeated dose toxicity (*in vivo* sub-chronic (≥ 12 months), if justified from other studies)	X (≥1,000tpa)	Y	100%	N	5%	5%	5%	5%	805,000	Testing company catalogue
Reproductive toxicity (*in vivo* screening (OECD 421 or 422))	VIII (≥10tpa)	Y	100%	N	5%	5%	5%	5%	110,000	
Reproductive toxicity (pre-natal developmental toxicity)	IX (≥100tpa)	Y	100%	N	5%	5%	5%	5%	111,000	Testing company catalogue
Reproductive toxicity (2 generation reproductive toxicity with exceptions)	IX (≥100tpa)	Y	100%	N	5%	5%	5%	5%	330,000	Testing company catalogue
Reproductive toxicity (developmental toxicity (OECD 414))	X	Y	100%	N	5%	5%	5%	5%	134,700	-
Toxicokinetics (assessment of available information)	VIII (≥10tpa)	Y	100%	N	5%	5%	5%	5%	1,300	Testing company catalogue
Carcinogenicity study	X (≥1,000tpa)	Y	100%	N	5%	5%	5%	5%	400,000	Cefic figure for full carc. assessment was over €2 million however this included many of the tests set out above. BIA estimate was €359,769 which has been rounded to the nearest 100,000
Ecotoxicological Properties										

Table 7.6: Physicochemical and (Eco)Toxicological Information for Registration										
Properties	**Annex[1] (Tonnage Threshold)**	**Relevant to Polymers[2]**	**Percentage of Polymers to which relevant (%)[3]**	**Readily Available Information[4]**	**Percentage of Polymers with data/information[5]**				**Test Costs (€)[6]**	**Notes**
					≥1000 tpa	**≥100 tpa/ ≤1,000 tpa**	**≥10tpa/ ≤100 tpa**	**≥1tpa/ ≤10 tpa**		
Aquatic toxicity (*in vivo* short-term invertebrate)	VII (≥1tpa)	Y	100%	N	5%	5%	5%	5%	4,500	BIA was 359,769
Aquatic toxicity (*in vivo* short-term fish)	VIII (≥10tpa)	Y	100%	N	N/A	5%	5%	5%	4,300	-
Aquatic toxicity (Activated sludge respiration inhibition testing)	VIII (≥10tpa)	Y	200%	N	N/A	5%	5%	5%	2,500	-
Aquatic toxicity (long-term invertebrate)	IX (≥100tpa)	Y	100%	N	N/A	N/A	5%	5%	14,000	BIA
Aquatic toxicity (*in vivo* long-term fish)	IX (≥100tpa)	Y	100%	N	5%	5%	5%	5%	20,000	Testing company catalogue
Aquatic toxicity (*in vivo* fish early-life stage (FELS) toxicity test)	IX (≥100tpa)	Y	100%	N	5%	5%	5%	5%	21,000	Testing company catalogue
Aquatic toxicity (*in vivo* fish short-term toxicity test on embryo and sac-fry stages)	IX (≥100tpa)	Y	100%	N	5%	5%	5%	5%		
Aquatic toxicity (*in vivo* fish juvenile growth test)	IX (≥100tpa)	Y	100%	N	5%	5%	5%	5%		
Degradation (ready biodegradation)	VII (≥1tpa)	Y	100%	N	5%	5%	5%	5%	4,500	-
Degradation (abiotic hydrolysis as function of pH)	VIII (≥10tpa)	Y	100%	N	N/A	5%	5%	5%	3,700	Testing company catalogue (Cefic/BIA €7,000)
Degradation (further abiotic testing if need identified by CSA)	VIII (≥10tpa)	Y	100%	N	5%	5%	5%	5%	3,300	Assume Cefic/BIA estimate above includes additional testing

Table 7.6: Physicochemical and (Eco)Toxicological Information for Registration										
Properties	**Annex[1] (Tonnage Threshold)**	**Relevant to Polymers[2]**	**Percentage of Polymers to which relevant (%)[3]**	**Readily Available Information[4]**	**Percentage of Polymers with data/information[5]**				**Test Costs (€)[6]**	**Notes**
					≥1000 tpa	**≥100 tpa/ ≤1,000 tpa**	**≥10tpa/ ≤100 tpa**	**≥1tpa/ ≤10 tpa**		
Degradation (biotic simulation – ultimate degradation in surface water)	IX (≥100tpa)	Y	100%	N	N/A	N/A	5%	5%	3,700	Testing company catalogue
Degradation (biotic soil simulation testing (for substances with a high potential for adsorption to soil)	IX (≥100tpa)	Y	100%	N	5%	5%	5%	5%	61,400	Testing company catalogue
Degradation (biotic sediment simulation testing (for substances with a high potential for adsorption to sediment)	IX (≥100tpa)	Y	100%	N	5%	5%	5%	5%	65,500	Testing company catalogue
Degradation (biotic identification of degradation products)	IX (≥100tpa)	Y	100%	N	5%	5%	5%	5%	28,900	Testing company catalogue
Degradation (further biotic testing if need identified by CSA)	IX (≥100tpa)	Y	100%	N	5%	5%	5%	5%	13,000	Testing company catalogue
Fate and behaviour in the environment (adsorption/desorption screening)	VIII (≥10tpa)	Y	100%	N	N/A	5%	5%	5%	3,200	-
Fate and behaviour in the environment (bioaccumulation in aquatic species, preferably fish)	IX (≥100tpa)	Y	100%	N	N/A	N/A	5%	5%	71,741	Testing company catalogue

Table 7.6: Physicochemical and (Eco)Toxicological Information for Registration										
Properties	**Annex[1] (Tonnage Threshold)**	**Relevant to Polymers[2]**	**Percentage of Polymers to which relevant (%)[3]**	**Readily Available Information[4]**	**Percentage of Polymers with data/information[5]**				**Test Costs (€)[6]**	**Notes**
					≥1000 tpa	**≥100 tpa/ ≤1,000 tpa**	**≥10tpa/ ≤100 tpa**	**≥1tpa/ ≤10 tpa**		
Fate and behaviour in the environment (further adsorption/desorption if warranted from screening under Annex VIII)	IX (≥100tpa)	Y	100%	N	5%	5%	5%	5%	5,700	Testing company catalogue
Fate and behaviour in the environment (further environmental fate and behaviour of substance or degradation products if need identified by CSA)	X (≥1,000tpa)	Y	100%	N	N/A	N/A	N/A	5%	3,190	-
Effects on terrestrial organisms (short-term toxicity on invertebrates)	IX (≥100tpa)	Y	100%	N	N/A	N/A	5%	5%	16,300	-
Effects on terrestrial organisms (effects on soil micro-organisms)	IX (≥100tpa)	Y	100%	N	5%	5%	5%	5%	11,765	-
Effects on terrestrial organisms (short-term toxicity on plants)	IX (≥100tpa)	Y	100%	N	5%	5%	5%	5%	22,440	Cefic (BIA figure €76,000)
Effects on terrestrial organisms (long-term toxicity on invertebrates)	X (≥1,000tpa)	Y	100%	N	N/A	N/A	N/A	5%	38,257	-
Effects on terrestrial organisms (long-term toxicity on plants)					5%	5%	5%	5%	22,440	-
Long-term toxicity to sediment organisms (long-term toxicity on sediment organisms)	X (≥1,000tpa)	Y	100%	N	N/A	N/A	N/A	5%	37,648	-

Table 7.6: Physicochemical and (Eco)Toxicological Information for Registration										
Properties	**Annex[1] (Tonnage Threshold)**	**Relevant to Polymers[2]**	**Percentage of Polymers to which relevant (%)[3]**	**Readily Available Information[4]**	**Percentage of Polymers with data/information[5]**				**Test Costs (€)[6]**	**Notes**
					≥1000 tpa	**≥100 tpa/ ≤1,000 tpa**	**≥10tpa/ ≤100 tpa**	**≥1tpa/ ≤10 tpa**		
Long-term or reproductive toxicity to birds	X (≥1,000tpa)	Y	100%	N	N/A	N/A	N/A	5%	96,167	-
Other										
Description of analytical methods supplied on request	IX (≥100tpa)	Y	100%	N	N/A	N/A	5%	5%	-	Administration cost only

Notes.
1. Relevant REACH Annex number or "P" to indicate a polymer specific requirement.
2. Relevance of property to polymers: "Y" = Yes, "N" = No, and "C" = Certain polymers only, determined by expert judgement by the study team.
3. Where relevant to polymers ("Y" in previous column) it is assumed that this will apply to all substances (100%). Where an endpoint is relevant to certain polymers only ("C" in previous column) it has been assumed that this applies to 40% of polymers. Where an endpoint is considered not to be relevant ("N" in previous column) it has been assumed that it is not relevant for all polymers (i.e. 0% assumed). With no data provided by industry or other sources to inform the derivation of estimates, the assumptions adopted here are tentative in nature
4. Availability of information to polymer registrants: "Y" = Yes, "N" = No, and "C" = Certain polymers only, determined by expert judgement by the study team.
5. Where information is readily available (i.e. "Y" in previous column) it is assumed that this will apply to 95% of substances. Where information is available to certain polymers only ("C" in previous column) it has been assumed that this applies to 40% of polymers. Where information is not likely to be available ("N" in previous column) it has been assumed information will not be available for 95% of polymers (i.e. information available for 5%). With no data provided by industry or other sources to inform the derivation of estimates, the assumptions adopted here are tentative in nature6. A combined figure derived from data provided by Cefic, the Commission Business Impact Assessment (BIA) and catalogue costs from a private testing organisation, unless otherwise stated.

7.2 Cost Assumptions for Impact Assessment

Based on the cost elements in Table 6.4 and drawing on costs used for Part B of this report on substances manufactured or imported in quantities of 1 to 10 tonnes and presented in Section 7.3.4 of Part B, cost estimates have been generated for each of the items listed in Table 6.4. These are provided in Table 7.7.

Table 7.7: Costs per Phase-in Polymer Registration

Cost Item	Tonnage Threshold (Tonnes)			
	1	10	100	1,000
Registration Costs for a Phase-in Polymer				
Polymer Analytics	€ 10,000	€ 10,000	€ 10,000	€ 10,000
Read across	€ 500	€ 500	€ 500	€ 500
Data summary per endpoint	€ 250	€ 250	€ 250	€ 250
PBT Assessment	200	€ 200	€ 200	€ 200
Proposal for animal testing	€ 500	€ 500	€ 500	€ 500
Revised SDS	€ 500	€ 500	€ 500	€ 500
Dossier Update (applies to all polymers requiring animal tests)	€ 1,000	€ 1,000	€ 1,000	€ 1,000
Chemical Safety Assessment	€ 2,500	€ 4,000	€ 6,000	€ 10,000
CSA for polymers with dispersive/diffuse uses	€ 3,600	€ 4,450	€ 12,700	€ 25,000
Administration costs	€ 5,000	€ 5,000	€ 10,000	€ 10,000
Administration costs for polymers with dispersive/diffuse uses	€ 7,000	€ 7,000	€ 15,000	€ 16,000
Total Consortium Members' Costs for a Phase-in Polymer[1]				
Polymer Analytics	€ 10,000	€ 10,000	€ 10,000	€ 10,000
Data summary per endpoint	€ 250	€ 250	€ 250	€ 250
Read across	€ 500	€ 500	€ 500	€ 500
PBT Assessment	€ 200	€ 200	€ 200	€ 200
Proposal for animal testing	€ 500	€ 500	€ 500	€ 500
Revised SDS	€ 500	€ 500	€ 500	€ 500
Dossier Update (applies to all polymers requiring animal tests)	€ 1,000	€ 1,000	€ 1,000	€ 1,000
Chemical Safety Assessment	€ 2,500	€ 4,000	€ 6,000	€ 10,000
CSA for polymers with dispersive/diffuse uses	€ 3,600	€ 4,450	€ 12,700	€ 25,000
Consortia Administration	€ 24,000	€ 24,000	€ 39,000	€ 60,000
Consortia Administration costs for dispersive/diffuse uses	€ 26,000	€ 26,000	€ 44,000	€ 66,000
Costs for Registration of a Polymer as per on- site Isolated Intermediate				
Polymer Analytics	€ 10,000	€ 10,000	€ 10,000	€ 10,000
Administration costs	€ 5,000	€ 5,000	€ 5,000	€ 5,000
Data summary per endpoint	€ 250	€ 250	€ 250	€ 250
Costs of Extending Monomer Registration to include Use of a Polymer (taken to be equivalent to CSA Costs for Polymers)				
Costs of Extended Monomer Registration (per polymer with non-diffuse/dispersive uses)	€ 2,500	€ 4,000	€ 6,000	€ 10,000
Costs of Extended Monomer Registration (per polymer with diffuse/dispersive uses)	€ 3,600	€ 4,450	€ 12,700	€ 25,000

1. It is assumed that these costs would be shared across 3 or more companies. Consortia of less than 3 companies are not considered to be cost-effective

Table 7.8 below shows the fees and charges (€) payable to ECHA by size of companies (Regulation No 340/2008) for Registration of chemical substances; it is assumed that they would apply to polymers as well.

Table 7.8: Fees and Charges (€) Payable to ECHA by Size of Companies (Regulation No 340/2008) for polymers				
	LE[1] (Individual submission – joint submission)	**ME[1] (Individual submission – joint submission)**	**SE[1] (Individual submission – joint submission)**	**MiE[1] (Individual submission – joint submission)**
Registration of intermediates	€ 1,600 – € 1,200	€ 1,120 – € 840	€ 640 – € 480	€ 160 – € 120
Registration of polymers manufactured or imported in quantities of 1 to 10 tonnes	€ 1,600 – € 1,200	€ 1,120 – € 840	€ 640 – € 480	€ 160 – € 120
Registration of polymers manufactured or imported in quantities of 10 to 100 t	€ 4,300 - € 3,225	€ 3,010 - € 2,258	€ 1,720 - € 1,290	€ 430 - € 323
Registration of polymers manufactured or imported in quantities of 100 to 1,000 t	€ 11,500 - € 8,625	€ 8,050 - € 6,038	€ 4,600 - € 3,450	€ 1,150 - € 863
Registration of polymers manufactured or imported in quantities of >1,000 t	€ 31,000 - € 23,250	€ 21,700 - € 23,250	€ 12,400 – € 9,300	€ 3,100 - € 2,325
Update of the tonnage range:				
From 1-10 tonnes range to 10-100 tonnes range	€ 2,700 – € 2,025	€ 1,890 – € 1,418	€ 1,080 – € 810	€ 270 – € 203
From 1-10 tonnes range to 100-1,000 tonnes range	€ 9,900 – € 7,425	€ 6,930 – € 5,198	€ 3,960 – € 2,970	€ 990 – € 743
From 1-10 tonnes range to over 1,000 tonnes range	€ 29,400 – € 22,050	€ 20,580 – € 15,435	€ 11,760 – € 8,820	€ 2,940 – € 2,205
From 10-100 tonnes range to 100-1,000 tonnes range	€ 7,200 - € 5,400	€ 5,040 - € 3,780	€ 2,880 - € 2,160	€ 720 - € 540
From 10-100 tonnes range to over 1,000 tonnes range	€ 26,700 - € 20,025	€ 18,690 - € 14,018	€ 10,680 - € 8,010	€ 2,670 - € 2,003
From 100-1,000 tonnes range to over 1,000 tonnes range	€ 19,500 - € 14,625	€ 13,650 - € 10,238	€ 7,800 - € 5,850	€ 1,950 - € 1,463
Other updates:				
Change in identity of the registrant	€ 1,500	€ 1,050	€ 600	€ 150
Change in the access granted to information in the submission (per item)	€ 1,500 – € 1,125	€ 1,050 – € 788	€ 600 – € 450	€ 150 – € 113
Request of confidentiality:				
Degree of purity and/or identity of impurities or additives	€ 4,500 – € 3,375	€ 3,150 – € 2,363	€ 1,800 – € 1,350	€ 450 – € 338
Relevant tonnage band	€ 1,500 – € 1,125	€ 1,050 – € 788	€ 600 – € 450	€ 150 – € 113
A study summary or a robust study summary	€ 4,500 – € 3,375	€ 3,150 – € 2,363	€ 1,800 – € 1,350	€ 450 – € 338
Information in the safety data sheet	€ 3,000 – € 2,250	€ 2,100 – € 1,575	€ 1,200 – € 900	€ 300 – € 225
Trade name of the substance	€ 1,500 – € 1,125	€ 1,050 – € 788	€ 600 – € 450	€ 150 – € 113
Note 1: LE: Large Enterprises; ME: Medium Enterprises; SE: Small Enterprises; MiE: Micro Enterprises				

8. REGISTRATION OPTIONS FOR POLYMERS

8.1 Overview

The broad aim of the study is to undertake an assessment of alternative options to the current situation (the baseline or 'do nothing' option) regarding the registration of polymers under REACH. Here, there are two broad approaches to the development of information requirements for registration in relation to polymers:

- **Separate Registration for Polymers:** Polymers undergo registration in their own right.

- **Extension of Monomer Registration to Include Polymers**: Currently, the information provided by monomer registrants (uses of monomers, any CSA/CSR and guidance on safe use) is limited to the use of the monomer. Requirements could be altered such that monomer registration would need to include the use of the 'monomer substance' as defined by Article 6(3), within each polymer substance manufactured from that monomer, throughout the lifecycle of those polymer substances.

For both approaches, options have been developed on the basis of different combinations of:

- **screening methods for dividing polymers into groups:** three **Screening Options** have been developed to divide polymers into groups on the basis of likely level of concern. Each screening option offers the potential to target registration requirements at a subset of polymers; and

- **scale of information required:** variations in the amount and level of detail of the data/information that must be supplied for those polymers requiring registration. These have been termed '**Information Options**'.

In this way, the different combinations of Information Options and Screening Options allow the development of a series of "Registration Options" that differ in terms of:

- the polymer groups that are required to register; and
- the information required of those polymer groups.

The basis for the options is described in the remainder of this section.

8.2 Screening Options

8.2.1 Overview of Screening and Screening Criteria

As noted in Section 8.1, three Screening Options have been derived to allow the screening identification of groups of polymers likely to be of greater/lesser concern. All three of these Screening Options make use of one or more of the three screening criteria set out in Table 8.1 and all three result in the identification of (at least one) group of substances likely to represent a higher level of concern from a human health/environmental risk perspective than the others.

Table 8.1: Polymer Screening Criteria	
Screening Criterion 1: CLP Classification for Mixtures	Monomer classified for any human health or environment endpoint under CLP and residual monomer concentration (w/w) above the generic cut-off values for mixture classification set out in Table 1.1 of CLP (see Figure 7.1) based on CLP mixture classification.
Screening Criterion 2: 'Polymers of Low Concern' (Based on REACH Consultation of 2003 (COM, 2003a) and Supported by PLC Approaches)	A number-average molecular weight less than 10,000 Dalton, or A content of ≥2% of less than 1,000 Dalton residual monomers and oligomers but excluding other components such as additives or impurities (figure from COM, 2003a, as the OECD figure of 5% is still likely include a large proportion of non-PLCs), or A content of ≥0.5% of less than 500 Dalton residual monomers and oligomers but excluding other components such as additives or impurities (as the OECD figure of 2% is still likely include a large proportion of non-PLCs)
Screening Criterion 3: Downstream use of substance	Based simply on whether or not the polymer has a dispersive/diffuse use[26]

Based on the Screening Criteria set out in Table 8.1, the Screening Options can be summarised as follows:

- **Screening Option 1 - one-dimensional targeting/screening** on the basis of whether the polymer has/has no dispersive/diffuse use;
- **Screening Option 2 - multi-dimensional targeting/screening** on the basis of all permutations of all three of the above Screening Criteria;

[26] "*Wide-dispersive use refers to many small point sources or diffuse release by for instance the public at large or sources like traffic… wide-dispersive use can relate to both indoor and outdoor use. Wide-dispersive uses are characterised by use(s) of a substance on its own, in a preparation or in article at many places (sites) that may result in not insignificant releases and exposure to a considerable part of the population (workers, consumers general public) and/or environment. This means that uses taking place at many places, which however do not result in significant releases of a substance, may be considered only a "widespread" but not as "wide-dispersive"* (chapter R.16.2.1.6 of the Guidance on Information Requirements and Chemical Safety Assessment).

- **Screening Option 3 - linear targeting/screening** on the basis of the outcome of a stepwise single line of questioning (yes/no answers in respect of the three Screening Criteria above). There are two sub-options in this case with these differing only in the order in which questions are put.

These Screening Options and their associated mechanisms are described in more detail in the following sub-sections.

8.2.2 Screening Option 1: One-dimensional Targeting/Screening

Screening Option 1 is a simple screening approach that divides polymers into two Polymer Groups (X and Y) on the basis of whether or not the polymer has one or more dispersive/diffuse uses. As such, this screening approach uses Screening Criterion 3 alone.

8.2.3 Screening Option 2: Multi-dimensional Targeting/Screening

Screening Option 2 is based on all three of the Screening Criteria set out in Table 8.1 and divides polymers into groups on the basis of the eight possible permutations of outcomes for the three Screening Criteria. These possible permutations and associated groups are provided in Table 8.2.

As can be seen from Table 8.2, while there are eight possible permutations, for simplicity, two of these have been merged into a single Polymer Group (Group A - reflecting all polymer substances that have no CLP classification as a mixture and where the polymer substance qualifies as a Polymer of Low Concern - PLC). Both of these permutations are likely to have a similar (low) level of concern attached to them.

Table 8.2: Definition of Polymer Groups for Registration

Permutation	Polymer Group	Screening Criteria		
		1: CLP Classification for Mixtures?	2: Qualify as a PLC?	3: Wide Dispersive Use?
1	Group A	N	Y	N
2		N	Y	Y
3	Group B	Y	Y	N
4	Group C	Y	Y	Y
5	Group D	N	N	N
6	Group E	N	N	Y
7	Group F	Y	N	N
8	Group G	Y	N	Y

8.2.4 Screening Option 3: Linear Targeting/Screening

As with Screening Option 2 (described above), Screening Option 3 considers the three Screening Criteria set out in Table 8.1. In contrast to the multi-dimensional approach however, it employs a stepwise (linear) questioning approach to screen polymers into (a smaller number of) Polymer Groups.

Two Screening Sub-options (3a and 3b) have been developed, with these differing in terms of the order in which questions are put. Figures 8.1 and 8.2 illustrate the approaches using flowcharts. These also identify which of the Polymer Groups identified in Table 8.2 would be required to register (and which would not).

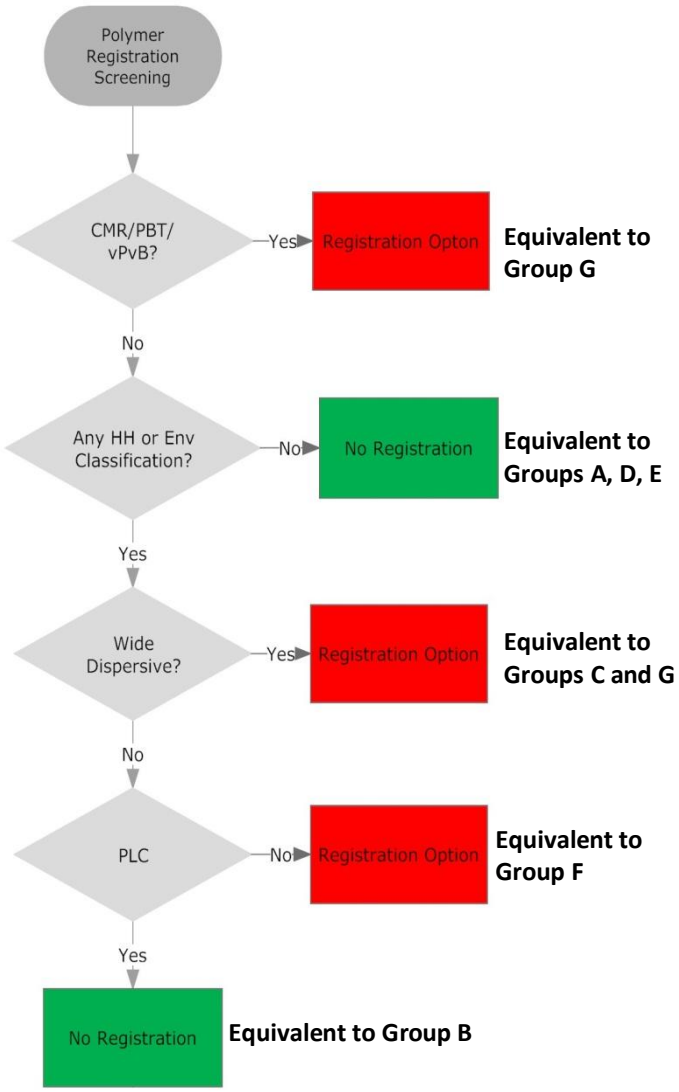


Figure 8.1: Linear (Stepwise) Screening under Screening Option 3a

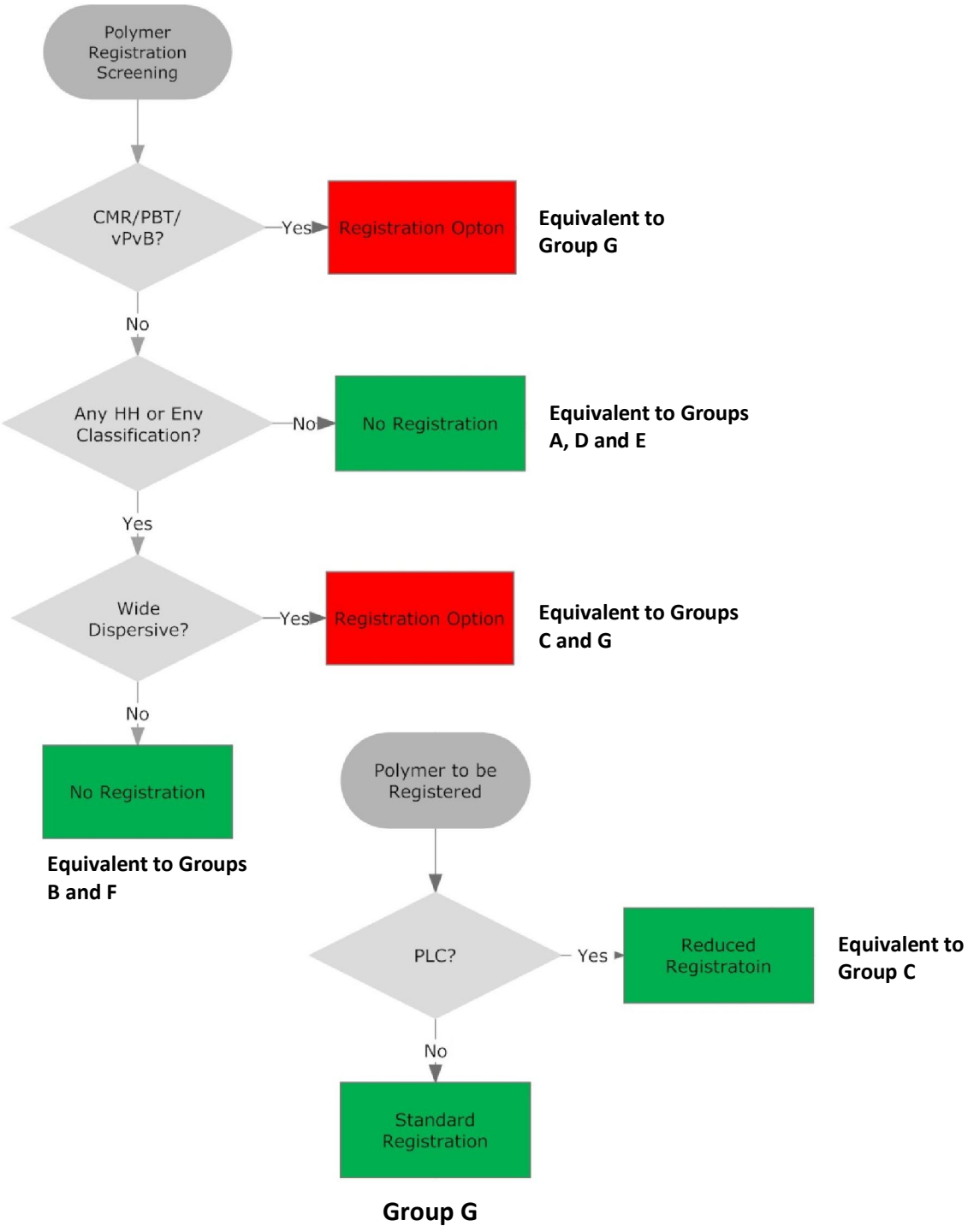


Figure 8.2: Linear (Stepwise) Screening under Screening Option 3b

8.3 Information Options

8.3.1 Overview

Section 8.2 has described three screening options, where each of these screening options divides polymers into two or more polymer groups. In turn, one or more of these polymer groups can be taken forward to registration, meaning that information on the properties and use of polymers in those groups would need to be registered (in some form or other) under REACH. When considering the level of information that would need to be supplied by registrants of polymers in each of these groups, and who would need to register this information, there are a number of options.

In terms of options for who would be required to register, as noted in Section 8.1, there are two broad approaches that can be considered:

I. Separate Registration for Polymers (i.e. as occurs with non-polymeric substances, the manufacturer/importer of a polymer would be required to register the polymer under REACH); and

II. Extension of Monomer Registration to Include Polymers (i.e. the use of a polymer would be registered by the manufacturer/importer of the constituent monomer(s)).

In terms of the level of information that would be required from registrants in each case, there are a number of possibilities.

Information Options for Separate Registration of Polymers

In the case of separate registration of polymers (I), however, the information required of registrants of polymers under REACH is not defined (as, at present, polymers do not have to be registered under REACH). As such, a number of different options for information requirements can be defined.

Drawing from the requirements and tonnage thresholds for non-polymers, several potential options for information requirements (Information Options) have been defined ranging from minimal requirements (submission of information such as substance identity and available data) through to more comprehensive requirements (such as full information requirements matching the registration requirements for non-polymers).

The Information Options in relation to both approaches (extended monomer registration and separate registration for polymers) are described in the subsections below.

Information Options for Extended Monomer Registration

In the case of the extension of monomer registration to include polymers (II), drawing on the information requirements that apply to registration of uses of phase in substances (non-polymeric substances) under REACH, the information that would be required of monomer registrants is effectively predefined. The option requires monomer registrants to register the use of the monomer in resultant polymers in the same way that registrants of phase in substances must consider downstream uses of those substances.

8.3.2 Information Options for Separate Registration of Polymers (I)

As described in Section 8.3.1, Information Options in relation to separate registration of polymers have been drawn from the registration requirements and tonnage thresholds for non-polymers under REACH. Four Information Options have been defined, ranging from minimal information requirements (registration of information such as substance identity and available data) through to more comprehensive information requirements (such as full registration matching the registration requirements for non-polymers). These Information Options are summarised in Tables 8.3 and 8.4.

As can be seen from these tables, in increasing order of robustness, the Information Options are as follows:

- **Information Option 1 - Minimal:** Requirements as for on-site isolated intermediates;

- **Information Option 2a and b - Partial:** Annex VII data as set out in Table 7.6 for all registrations and CSA (with or without exposure assessment) for registrations of polymers manufactured or imported in quantities >100t per year (<100 t would not need a CSA);

- **Information Option 3a and b - Partial Plus:** Full Annex VII information as set out in Table 7.6 for registering 1-10 t substances and information from Annex VIII for registering >10 t substances. CSA (with or without exposure assessment) either for registrations of polymers manufactured or imported in quantities >100 t per year or for all substances (depending on sub-option);

- **Information Option 4a and b - Full:** For registering substances, adoption of the information requirements and tonnage thresholds that currently apply for other substances. CSA for all substances and for substances manufactured or imported in quantities >100t or >10 t per year (depending on sub-option) CSA would include an exposure assessment.

The test data that would be required under the different Information Options were set out in Table 7.6.

As already noted, all of these Information Options are drawn from existing requirements in relation to non-polymer substances under REACH. However, not

all of these requirements will be relevant or indeed technically feasible for some or all polymers. Discussion on the relevance of the REACH requirements for non-polymers is provided in Section 8.5 and Table 7.6 (on test data) already provides an indication of the extent to which certain test/data endpoints may be applicable to certain polymers.

8.3.3 Information Options for Extension of Monomer Registrations (II)

Manufacturers and importers of monomers are currently required to register their monomers in the same way as for any other substance. However, under Article 6(2), monomers may not be registered as isolated intermediates, even when they meet the criteria for such intermediates as set out in Article 3(15).

At present, the information provided by monomer registrants (uses of monomers, any CSA/CSR, and guidance on safe use) is limited to the use of the monomer and does not include any aspect of the use of the resultant polymer. Furthermore, the monomer registrations reviewed as part of this study did not include any risk assessment of residual monomers in polymers (this might however be due to their low concentrations in the polymers considered).

In terms of the Information Options in relation to extension of monomer registration, this is limited to a single option. Monomer registrations would need to include the use of the 'monomer substance' (as defined by Article 6(3)) for the polymer substances manufactured from that monomer, throughout the lifecycle of those polymer substances, i.e. from the point in polymer manufacture when the substance first meets the definition of a polymer and ends after the formation of an article and/or when the substance enters the waste phase. Processes that modify the polymer structure and/or properties would need to be adequately addressed.

8.4 Combined (Registration) Options

8.4.1 Overview

Section 8.2 has described the three options for screening polymers into groups on the basis of likely properties of concern (the Screening Options). On the basis of these Screening Options, selected polymer groups can, in turn, be included or excluded from registering information under REACH.

In relation to the information required of the selected polymer groups identified by screening, Section 8.3 has described the options for requirements for information (Information Options) on registering polymers (whether as part of an extended monomer registration or as a separate polymer registration).

Table 8.3: Information Options - Summary of Information Requirements							
Information Requirements	**Tonnage Threshold for Information Requirements**						
	1 - Minimal	**2a - Partial**	**2b - Partial - CSA**	**3a - Partial Plus**	**3b - Partial Plus - CSA**	**4a - Full**	**4b - Full - CSA**
As for on-site isolated intermediates	All polymers	All polymers	All polymers	All polymers	All polymers	All polymers	All polymers
As for Annex VII		>1tpa	>1tpa	>1tpa	>1tpa	1-10tpa	1-10tpa
As for Annex VIII				>10tpa	>10tpa	10-100tpa	10-100tpa
As for Annex IX						100-1000tpa	100-1000tpa
As for Annex X						>1000tpa	>1000tpa
CSA			>100tpa		>100tpa		>10tpa

Table 8.4: Information Options - Description of Information Requirements		
Option	**Test Data Requirements**	**Chemical Safety Assessment**
1 - Minimal	Requirements as for on-site isolated intermediates for registering substances, i.e: • identity of the manufacturer; • identity of the polymer. • classification of the polymer; • any available existing information on physicochemical, human health or environmental properties of the polymer. Where a full study report is available, a study summary shall be submitted; • a brief general description of the use; and • details of risk management measures used or recommended	None
2a - Partial	Full Annex VII for registering >1t substances	None
2b - Partial - CSA	As 2a	CSA for all registering substances manufactured or imported in quantities >100tpa per year.
3a - Partial Plus	Full Annex VII for registering 1-10tpa substances and Annex VIII data for registering >10tpa substances	None
3b - Partial Plus - CSA+	As 3a	As 2b
4a - Full	Adoption of the information requirements and tonnage thresholds that currently apply for other substances	None
4b - Full - CSA	As 4a	CSA for all registering substances manufactured or imported in quantities >10tpa per year.

Clearly, the combination of both Screening and Information options allows the development of a series of 'Registration Options' in relation to:

- the polymer groups that are required to register; and
- the information required of those polymer groups.

Registration Options have been produced to reflect increasing robustness of registration requirements across groups and, where the screening approach permits it, greater differentiation of requirements such that higher information requirements are applied to those polymer groups likely to include polymers of greatest concern.

Registration Options differ slightly between those applied to extended monomer registration versus separate polymer registration but only as regards the level of information required (as there is only one Information Option for extended monomer registration). In both cases (extended monomer registration and separate polymer registration) Registration Options reflect a number of possibilities ranging from:

- '**Low':** representing no information for some polymer groups and minimal information for others; to
- **'High':** representing provision of (higher) information requirements in relation to all polymer groups.

8.4.2 Registration Options for Separate Registration of Polymers (Scenario I)

Registration options in relation to separate registration of polymers are more complex than those presented for extended monomer registration. This is because, whilst the screening approaches are identical, under the separate registration of polymers, there is a greater range of Information Options that could be applied. As such, where the Registration Options provided in Tables 8.5 and 8.6 (for extended monomers) need to reflect only whether or not information is required, those for separate registration of polymers also need to reflect the possibility that higher information requirements could be applied to those polymers likely to represent the greatest concern.

Across all of the screening options, then, Registration Options have been developed to reflect the following:

- **Registration Option - Low a -** no/minimal registration requirements applied to screening groups depending on the likely level of concern attached to each group;

- **Registration Option - Low b -** no/minimal/partial registration requirements applied to screening groups depending on the likely level of concern attached to each group;

- **Registration Option - Low-Medium -** no/minimal/partial registration requirements applied to screening groups depending on the likely level of concern attached to each group;
- **Registration Option - Medium -** no/minimal/partial/partial plus registration requirements applied to screening groups depending on the likely level of concern attached to each group;
- **Registration Option - Medium-High -** no/minimal/partial/partial plus/full registration requirements applied to screening groups depending on the likely level of concern attached to each group;
- **Registration Option - High -** as Medium-High but more groups with full requirements.

The specific requirements in terms of which polymer groups must supply what level of information are described in the sub-sections below.

Registration Options under Screening Option 1: One-dimensional Screening

As described in Section 8.2.2, Screening Option 1 involves a simple screening approach that divides polymers into two Polymer Groups X and Y, comprising polymers with and polymers without a dispersive/diffuse use respectively. The Information Options for differentiated registration requirements in relation to these groups are provided in Table 8.5. Here, the table provides a summary of the registration requirements that would apply to each Polymer Group under each of the Information Options (Low to High).

Registration Options for Screening Option 2: Multi-dimensional Targeting/Screening

As noted in Section 8.2.3, Screening Option 2 is based on use of all three of the Screening Criteria defined in Table 8.1, namely.

- **Screening Criteria 1 - CLP Classification for Mixtures:** Where a monomer is classified for any human health or environment endpoint under CLP and residual monomer concentration (w/w) above the generic cut-off values for mixture classification set out in Table 1.1 of CLP (see Figure 7.1) ;
- **Screening Criteria 2 - 'Polymers of Low Concern':** Based on REACH Consultation of 2003 (COM, 2003a) and Supported by PLC Approaches; and
- **Screening Criteria 3 - Downstream use of substance:** Based simply on whether or not the polymer has a dispersive/diffuse use.

This defines seven Polymer Groups (A to G) on the basis of the various permutations of these criteria. In this way, each polymer group reflects a different permutation/outcome of screening, each reflects slightly different characteristics in terms of potential hazard and exposure. In turn, applying different levels of registration requirements (i.e. different Information Options) to each of these Polymer Groups provides the basis for Registration Options targeted towards those polymer groups likely to be most concern.

Table 8.5: Level of Registration and Associated Requirements (Registration Options) for Each Polymer Group Identified by Screening Option 1												
Dossier and Information Requirements						**Information Option (tpa)**						
						1 - Minimal	**2a - Partial**	**2b - Partial - CSA**	**3a - Partial Plus**	**3b - Partial Plus - CSA**	**4a - Full**	**4b - Full - CSA**
On-site isolated intermediates						All	All	All	All	All	All	All
Annex VII							>1	>1	1-10	1-10	1-10	1-10
Annex VIII									>10	>10	10-100	10-100
Annex IX											100-1000	100-1000
Annex X											>1000	>1000
CSA								>100		>100		>10
Screening Option	**Registration Option**	**Polymer Group**	**Wide Dispersive Use?**	**CLP Classification for Mixtures?**	**Qualify as a PLC?**	**Information Option**						
						1 - Minimal	**2a - Partial - CSA**	**2b - Partial - CSA+**	**3a - Partial Plus - CSA**	**3b - Partial Plus - CSA+**	**4a - Full - CSA+**	**4b - Full - CSA++**
Screening Option 1: Screening Based on Diffuse/Dispersive Use Only	**Low a**	X	N	-	-	X						
		Y	Y	-	-	X						
	Low b	X	N	-	-	X						
		Y	Y	-	-			X				
	Low-Medium	X	N	-	-		X					
		Y	Y	-	-			X				
	Medium	X	N	-	-		X					
		Y	Y	-	-					X		
	Medium-High	X	N	-	-				X			
		Y	Y	-	-					X		
	High	X	N	-	-						X	
		Y	Y	-	-							X

Table 8.6: Level of Registration and Associated Requirements (Registration Options) for Each Polymer Group Identified by Screening Option 2													
Dossier and Information Requirements						**Information Option (tpa)**							
						1 - Minimal	**2a - Partial**	**2b - Partial - CSA**	**3a - Partial Plus**	**3b - Partial Plus - CSA**	**4a - Full**	**4b - Full - CSA**
On-site isolated intermediates						All	All	All	All	All	All	All
Annex VII							>1	>1	1-10	1-10	1-10	1-10
Annex VIII									>10	>10	10-100	10-100
Annex IX											100-1000	100-1000
Annex X											>1000	>1000
CSA								>100		>100		>10
Screening Option	**Registration Option**	**Polymer Group**	**Wide Dispersive Use?**	**CLP Classification for Mixtures?**	**Qualify as a PLC?**	**Information Option (tpa)**						
						1 - Minimal	**2a - Partial - CSA**	**2b - Partial - CSA+**	**3a - Partial Plus - CSA**	**3b - Partial Plus - CSA+**	**4a - Full - CSA+**	**4b - Full - CSA++**
Screening Option 2: Multidimensional Screening	**Low a**	A	-	N	Y							
		B	N	Y	Y							
		C	Y	Y	Y	X						
		D	N	N	N							
		E	Y	N	N							
		F	N	Y	N	X						
		G	Y	Y	N	X						
		Summary				C, F, G						
	Low b	A	-	N	Y							
		B	N	Y	Y							
		C	Y	Y	Y	X						
		D	N	N	N							
		E	Y	N	N							
		F	N	Y	N	X						
		G	Y	Y	N			X				
		Summary				C, F		G				
	Low-Medium	A	-	N	Y	X						
		B	N	Y	Y	X						

Table 8.6: Level of Registration and Associated Requirements (Registration Options) for Each Polymer Group Identified by Screening Option 2												
		C	Y	Y	Y	X						
		D	N	N	N	X						
		E	Y	N	N	X						
		F	N	Y	N	X						
		G	Y	Y	N			X				
		Summary				All except G		G				
	Medium	A	-	N	Y	X						
		B	N	Y	Y		X					
		C	Y	Y	Y			X				
		D	N	N	N		X					
		E	Y	N	N			X				
		F	N	Y	N		X					
		G	Y	Y	N					X		
		Summary				A	B, D, F	C, E		G		
	Medium-High	A	-	N	Y	X						
		B	N	Y	Y		X					
		C	Y	Y	Y			X				
		D	N	N	N		X					
		E	Y	N	N			X				
		F	N	Y	N				X			
		G	Y	Y	N							X
		Summary				A	B, D	C, E	F			G
	High	A	-	N	Y	X						
		B	N	Y	Y		X					
		C	Y	Y	Y					X		
		D	N	N	N		X					
		E	Y	N	N			X				
		F	N	Y	N						X	
		G	Y	Y	N							X
		Summary				A	B, D	E		C	F	G

Table 8.7: Level of Registration and Associated Requirements (Registration Options) for Each Polymer Group Identified by Screening Options 3a and 3b													
Dossier and Information Requirements						**Information Option (tpa)**							
						1 - Minimal	**2a - Partial**	**2b - Partial - CSA**	**3a - Partial Plus**	**3b - Partial Plus - CSA**	**4a - Full**	**4b - Full - CSA**
On-site isolated intermediates						All	All	All	All	All	All	All
Annex VII							>1	>1	1-10	1-10	1-10	1-10
Annex VIII									>10	>10	10-100	10-100
Annex IX											100-1000	100-1000
Annex X											>1000	>1000
CSA								>100		>100		>10
Screening Option	**Registration Option**	**Polymer Group**	**Wide Dispersive Use?**	**CLP Classification for Mixtures?**	**Qualify as a PLC?**	**Information Option (tpa)**						
						1 - Minimal	**2a - Partial - CSA**	**2b - Partial - CSA+**	**3a - Partial Plus - CSA**	**3b - Partial Plus - CSA+**	**4a - Full - CSA+**	**4b - Full - CSA++**
Screening Option 3a: Linear Screening as in Figure 7.2	**Low a**	C	Y	Y	Y	X						
		F	N	Y	N	X						
		G	Y	Y	N	X						
		Summary				C, F, G						
	Low b	C	Y	Y	Y	X						
		F	N	Y	N	X						
		G	Y	Y	N			X				
		Summary				C, F		G				
	Low-Medium	C	Y	Y	Y	X						
		F	N	Y	N	X						
		G	Y	Y	N			X				
		Summary				C, F		G				
	Medium	C	Y	Y	Y			X				
		F	N	Y	N		X					
		G	Y	Y	N					X		
		Summary					F	C		G		
	Medium-	C	Y	Y	Y			X				

	High	F	N	Y	N				X			
		G	Y	Y	N							X
		Summary						C	F			G
	High	C	Y	Y	Y					X		
		F	N	Y	N						X	
		G	Y	Y	N							X
		Summary								C	F	G
Screening Option 3b: Linear Screening as in Figure 7.3	**Low a**	C	Y	Y	Y	X						
		G	Y	Y	N	X						
		Summary				C,G						
	Low b	C	Y	Y	Y	X						
		G	Y	Y	N			X				
		Summary				C		G				
	Low-Medium	C	Y	Y	Y	X						
		G	Y	Y	N			X				
		Summary				C		G				
	Medium	C	Y	Y	Y			X				
		G	Y	Y	N					X		
		Summary						C		G		
	Medium-High	C	Y	Y	Y			X				
		G	Y	Y	N							X
		Summary						C				G
	High	C	Y	Y	Y					X		
		G	Y	Y	N							X
		Summary								C		G

For example, of the seven groups, Polymer Group A represents those substances likely to be of least concern and, hence, where the Information Option can be the most relaxed. Conversely, Polymer Group G represents substances likely to be of most concern and, hence, where the Information Option should be most stringent. The Registration Options for differentiated registration requirements in relation to these groups are provided in Table 8.6. The table provides a summary of the registration requirements that would apply to each Polymer Group under each of the Information Options (Low to High).

It should be noted that under all Screening Options using the screening criteria, where any information on a polymer at any stage of the process (prior to registration or during registration) identifies CMR, PBT or vPvB properties, that polymer is automatically promoted to/included in the highest Registration Option polymer group regardless of its attributes in relation to the other criteria in Table 8.3. As such, all CMR, PBT or vPvB polymers are always in Group G.

Registration Options for Screening Option 3: Linear Targeting/Screening

As described in Section 8.2.4, as is the case with Screening Option 2, Screening Option 3 considers the same three Screening Criteria but employs a stepwise (linear) questioning approach to screen polymers into (a smaller number of) Polymer Groups. Two Screening Sub-options (3a and 3b) have been developed, with these differing in terms of the order in which the questions are posed. The Registration Options for differentiated registration requirements in relation to the Polymer Groups identified using the two Screening Sub-options are set out in Table 8.7. Here, the table provides a summary of the registration requirements that would apply to each Polymer Group under each of the Information Options (Low to High).

8.4.3 Registration Options for Extension of Monomer Registrations (Scenario II)

Low to High registration options in relation to extended monomer registration relate simply to whether or not information on polymers needs to be provided by the manufacturer/importer of the constituent monomer(s). As described earlier in Section 8.2, there are three screening options and, hence, there are three sets of Registration Options (one for each Screening Option). These are summarised in Tables 8.8 and 8.9.

As can be seen from Table 8.8, owing to the fact that Screening Option 1 only differentiates between two different polymer groups, there are only two Registration Options.

Table 8.8: Polymers Included in Monomer Registration - Screening Option 1: One Dimensional Screening (Diffuse/Dispersive Uses)

	Polymers Included in Monomer Registrations	
	Polymers with No Dispersive/Diffuse Use	**Polymers with a Dispersive/Use**
Low Option		X
High Option	X	X

In contrast, as screening options based on all three screening criteria differentiate between a larger number of polymer groups. As the linear screening approaches (Options 3a and 3b) identify a subset of the polymer groups identified by the multidimensional screening option (Option 2), there is overlap between these options.

Table 8.9: Polymers Included in Monomer Registration – Screening Options 2 and 3								
		Polymers Included in Monomer Registration						
Polymer Group (From Screening Option 2)		A	B	C	D	E	F	G
Wide Dispersive Use?		-	N	Y	N	Y	N	Y
CLP Classification for Mixtures?		N	Y	Y	N	N	Y	Y
Qualify as a PLC?		Y	Y	Y	N	N	N	N
Screening Option 2: Multidimensional Screening	**Low***	-	-	X	-	-		X
	Low-Medium**	-	-	X	-	-	X	X
	Medium-High	-	-	X	-	X	X	X
	High	-	-	X	X	X	X	X
Screening Option 3a: Linear Screening as in Figure 1.2	**Low*****	-	-		-	-		X
	Medium*	-	-	X	-	-		X
	High**	-	-	X	-	-	X	X
Screening Option 3b: Linear Screening as in Figure 1.3	**Low*****	-	-		-	-	-	X
	High*	-	-	X	-	-	-	X

8.5 REACH Registration Requirements - Relevance for Polymers

8.5.1 Introduction

Thus far this section has outlined registration requirements for polymers with reference to the information and CSA requirements under REACH for other substances. This section describes these requirements in a little more detail and indicates the extent to which these are assumed to be relevant and/or technically feasible for the registration of polymers, should this be deemed necessary.

8.5.2 Registration of Intermediates

Summary of Requirements

There are three forms of intermediate defined under Article 3 of REACH:

> *intermediate: means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis):*
>
> *(a)* ***non-isolated intermediate****: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one*

vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;

(b) ***on-site isolated intermediate****: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;*

(c) ***transported isolated intermediate****: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;*

NOTE - site: means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared;

Non-isolated intermediates are exempt from the provisions of REACH (Article 2(1)c).

Article 2 states that both forms of isolated intermediate are exempted from the normal information requirements for registration with the exception of the provisions of Article 8 which allows for the appointment of an Only Representative and Article 9 which provides an exemption from registration for PPORD. Under Article 2, isolated intermediates are also exempted from the provisions for authorisation as set out under Title VII. Furthermore, there are only limited provisions for the evaluation of the registration dossiers for on-site but not transported isolated intermediates (Article 49).

The reduced registration requirements for both types of isolated intermediate are dependent on registrants being able to justify that the substance is only manufactured/imported/transported and used under strictly controlled conditions throughout its whole lifecycle as an intermediate. The general information requirements for the registration of **on-site and transported isolated intermediates** are limited to the information set out in Annex VI, namely (Article 17 and Article 18):

- Identity of the manufacturer.
- Identity of the intermediate.
- Classification of the intermediate.
- Any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted.
- A brief general description of the use.
- Details of risk management measures used or recommended.

For on-site isolated intermediates, the information listed above only needs to be provided, "*to the extent that the manufacturer is able to submit it without any additional testing*" (Article 17). However, no such limitation applies to transported isolated intermediates (Article 18). Furthermore, for transported isolated intermediates manufactured and/or imported in quantities greater than 1,000 tonnes

per year per registrant, the information requirements are extended to cover those required for the registration of substances in the 1 to 10 tonne per year range, as set out in Annex VII (also discussed in detail in Section 5.6 of this report).

Polymer Registration

Information Option 1 (Minimal) is based on the registration requirements described for on-site isolated intermediates. However, it is not assumed that a registrant will need to prove strictly controlled conditions for their polymer to qualify for Information Option 1. This is because the requirement for strictly controlled conditions is in effect a screening option and it is suggested that this screening option be replaced in the case of polymers by those detailed earlier in this section.

Evaluation Overview

Title VI of REACH describes three types of evaluation under REACH:

- Dossier Evaluation (Chapter 1: Article 40 to Article 43), including:
  - evaluation of testing proposals (Article 40); and
  - compliance checks on registration dossiers (Article 41).

- Substance Evaluation (Chapter 2: Article 44 to Article 48).

- Evaluation of On-site Isolated Intermediates (Chapter 3: Article 49).

Furthermore, Chapter 4 of Title (VI) sets out the common provisions for the functioning of evaluations, the adoption of evaluation decisions and their publication (Article 50 to Article 54).

It is assumed that any polymer registration would be subject to the same evaluation provisions under REACH as other substance registrations.

Dossier Evaluation

Dossier evaluation includes the examination by ECHA of all **testing proposals** submitted in support of registrations. In this respect, ECHA should give priority to the evaluation of proposals relating to substances that have, or may have, PBT, vPvB, sensitising and/or carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances manufactured/imported in quantities above 100 tonnes per year per registrant, with uses resulting in widespread and diffuse exposure and which fulfil the criteria for the range of hazard endpoints set out in Article 40.

Any testing proposals that involve the use of vertebrate animals must be published on the ECHA Internet site for consultation. Following any consultation, ECHA is required to make a decision on whether to accept, reject or modify the proposals submitted to it.

Recital 63 makes it clear that the evaluation of testing proposals should ensure that the generation of information is tailored to real information needs, and Recital 64 further clarifies that a key element of such evaluation is the prevention of unnecessary animal testing.

Compliance Checks

ECHA is required to check at least 5% of registration dossiers for compliance with all of the requirements of REACH and may require the registrant to provide additional information within a reasonable timeframe set by ECHA. ECHA should give priority to the evaluation of dossiers for joint registration with classification or hazard study data submitted separately from that of the lead registrant, substances claimed to meet the criteria of Annex III or substances included in the Community Rolling Action Plan for substance evaluation (CoRAP).

Substance Evaluation

ECHA, in co-operation with MS, is required to prioritise substances that are considered to constitute a risk to human health or the environment. Substances are to be evaluated as part of Community Rolling Action Plans (CoRAPs) covering a period of three years. The CoRAP is adopted by ECHA which is required to publish this on its Internet site and identifying the MS that will be responsible for each evaluation.

ECHA is then responsible for co-ordinating substance evaluation supported by the Member State Competent Authorities (CAs). CAs undertaking substance evaluation can require the registrant to provide information in addition to that provided in its registration dossier, to assist the CA in its evaluation. Following evaluation, CAs are required to inform ECHA on whether and how the results of the evaluation should be used, information that ECHA must then pass on to the registrant, the Commission and other CAs.

Evaluation of Intermediates

The partial exemption for on-site isolated intermediates from the evaluation provisions set out in Article 49 would not apply under Information Option 1.

8.5.3 Information Requirements

The information requirements for the substances registered in quantities of 10 tonnes or more are set out in Annexes VIII to X to REACH, where the level of information required increases depending upon the quantity manufactured or imported. These requirements are in addition to those set out in Annex VI. Information requirements increase with tonnage in the following manner.

- 1 tonne or more (Annexes VI & VII);
- 1 tonne or more (Polymer specific physicochemical information);
- 10 tonnes or more (Annexes VI, VII & VIII);
- 100 tonnes or more (Annexes VI, VII, VIII & IX); and

- 1,000 tonnes or more (Annexes VI, VII, VIII, IX & X).

The information requirements for the registration of substances from Annexes VII to XI are summarised in Table 7.5, along with other information that potentially could be relevant to the registration of certain types of polymer, and have not been reproduced here for brevity. These polymer specific requirements have been identified, based on review of previous polymer registration regimes in place or proposed for the EU and information provided by industry (see Section 5.6). It is assumed that only those properties relevant to the type of polymer being registered would be required for registration.

ECHA Guidance

The ECHA guidance (ECHA, undated) directs registrants to a wide range of published collections of physicochemical data, peer reviewed and non-peer reviewed sources. The point is made that any given data source may not include all of the physicochemical data required to fulfil the Annex VII data requirements and more than one source may need to be accessed. Caution is also advised when non-peer reviewed data are cited as the reliability of such data is not certain. However, the identified sources of information do not currently provide data of relevance to polymers. The ECHA guidance would therefore need to be updated to include polymers, should comparable collections of data exist for them.

Where data are not available for the substance to be registered, ECHA (undated) also provides references to a range of freely- or commercially-available computer-based calculation models that can be used to predict the physicochemical properties of substances. These models utilise Quantitative Structure Property Relationships[27] (QSPRs) to make their predictions. The principle features are summarised for each of the model listed, including the physicochemical endpoints estimated and the model's reliability and limitations. Further information on the models available is provided by the ECETOC Technical Report No. 89 (ECETOC, 2003) and the explanatory material that accompanies each model. It is important to note that the models described are extensive but not exhaustive and the models may have been developed further and/or new models developed since the drafting of the guidance.

It is understood that current QSPR and QSAR models may be used with varying degrees of success for simple homo and copolymer structures but they are not capable of accurately predicting all properties and particularly those that are dependent on, and sensitive to, the morphology of semicrystalline polymers (PSG, *pers.comm.*[28]). This is particularly true of volatile transport properties that affect factors such as VOC diffusion and release rate. However, in the absence of other data they can provide some insights. Further work will therefore be needed to provide guidance on the applicability of available QSPRs to polymers. This work may identify the need for the development of further QSPR tools in the future.

[27] The more common expression Quantitative Structure Activity Relationship (QSAR) is generally used for models that predict biological/toxicological effects rather than the physicochemical properties of interest here.

[28] Corroborated by polymer experts at GnoSys.

Furthermore, were any of the Registration Options described here to be adopted there would need to be additional guidance from ECHA to guide registrants through their registration obligations, and regulatory authorities through their responsibilities. Other existing guidance would need to be amended or supplemented by polymer-specific guidance, e.g. guidance for downstream users.

8.5.4 CSA Overview

In general, a CSA must be carried out for substances registered in quantities of 10 tonnes or more, as set out in Article 14 and detailed in Annex I. Further details of the requirements for PBT/vPvB assessment are set out in Annex XIII. The preparation of the CSA is likely to be an iterative process, with the amount of work required to complete a CSA depending upon the number of iterations required. The information in the CSA must be documented in a Chemical Safety Report (CSR) and communicated in the supply chain via SDS. Further non-binding guidance on the preparation of a CSA and a CSR is provided in ECHA (undated). However, this guidance does not currently make specific reference to the risk assessment of polymers. ECHA guidance would therefore need to be reviewed and updated, as appropriate.

Hazard Assessment

The first stage of a hazard assessment (HA) is the gathering of information to meet the tonnage dependent information requirements discussed earlier. The available information is then evaluated for:

- **Relevance** for hazard identification or risk characterisation.
- **Reliability** for use in hazard and risk assessment. Use of the Klimishch scoring system is recommended.
- **Adequacy** for hazard and risk assessment (includes assessment of available test data, non-test data (includes (Q)SARs, read-across and grouping approaches) and human data (includes analytical, descriptive and correlational epidemiology plus case reports and controlled studies on human volunteers).

The HA process involves a weight of evidence approach that requires expert judgement. Again, ECHA would need to assess whether its current guidance adequately covers the assessment of polymers, and amend this guidance, as needed.

Persistence, Bioaccumulation and Toxicity

The identification and assessment of PBT/vPvB properties are required as part of a CSA and these properties need to be documented in both the Chemical Safety Report (CSR) and any SDS supplied with the substance.

The criteria for identifying substances as being Persistent, Bioaccumulative and Toxic (PBT) and/or as being very Persistent and very Bioaccumulative (vPvB) are set out in Annex XIII to REACH, and summarised in Table 8.10.

Table 8.10: Criteria for PBT or vPvB from Annex XIII			
	Persistence (degradation half life (days))	**Bioaccumulation**	**Toxicity**
PBT	• marine water > 60; • estuarine water > 40; • marine sediment > 180; • estuarine sediment > 120; or • soil > 120	Bioconcentration factor in aquatic species is higher than 2,000 L/kg	• long-term (NOEC) or EC10 for marine or freshwater organisms < 0,01 mg/l; • meets CLP criteria for: • Carc./ Mut. Cat. 1A; 1B; • Repr. Cat. 1A, 1B or 2; or • specific target organ toxicity after repeated exposure (STOT RE category 1 or 2)
vPvB	• marine, fresh or estuarine water > 60; • marine, fresh or estuarine water sediment > 180; or • soil > 180	Bioconcentration factor in aquatic species is higher than 5,000 L/kg	N/A

Screening for PBT/ vPvB

The information required under Annexes VII and VIII (plus other available information) should be used to screen a substance against the PBT/vPvB screening data set out in Section 3.1 of Annex XIII and summarised in Table 8.11.

Table 8.11: PBT/vPvB Screening Criteria from Annex XIII			
Property	**Screening Data**	**Assessment with Min. Data**	
		Annex VII	**Annex VIII**
P or vP	Ready biodegradation (test 9.2.1.1)[1]	Y	-
	Other screening tests (e.g. enhanced ready test, tests on inherent biodegradability)	N	Abiotic hydrolysis (9.2.2.1 only)
	Estimated by biodegradation (Q)SAR models in accordance with Section 1.3 of Annex XI[2]	?	?
	Other information provided that its suitability and reliability can be reasonably demonstrated	N	N
B or vB	Octanol-water partitioning coefficient experimentally determined	Y	-
	estimated by (Q)SAR models in accordance with Section 1.3 of Annex XI	?	?
	Other information provided that its suitability and reliability can be reasonably demonstrated	N	N
T	(a) Short-term aquatic toxicity (test 9.1.3)	N	Y
	(b) Other information provided that its suitability and reliability can be reasonably demonstrated	If CMR or STOT RE	If CMR or STOT RE
Notes. 1. ECHA (undated) states that valid QSARs may be used to predict acute toxicity. 2. ECHA (undated) recommends Biowin 2 (non-linear model prediction) and Biowin 3 (ultimate biodegradation time) or Biowin 6 (MITI non-linear model prediction)			

PBT/vPvB Assessment

If the criteria for **persistence** are met, then ECHA (undated) recommends that an assessment of likely exposure receptors before undertaking required testing for identified receptors only, as summarised in Table 8.12.

Table 8.12: Possible Additional Testing for Persistence		
Exposure Identified to Receptor	**Test**	**Comment**
Soil	Transformation in soil test (OECD 307)	-
Coastal water	Marine water and/or water/sediment test (OECD 308/309 aerobic only)	-
Estuarine water	Brackish water/sediment test (OECD 308/309 aerobic only)	Not needed if assessed for coastal water
Fresh water	Surface water and/or water/sediment test (OECD 308/309 aerobic only	Not needed if assessed for coastal or estuarine water
Potential for long rang transport	Oceanic water die-away test (OECD 309)	-

If a substance matches the screening criteria for **bioaccumulation** then ECHA (undated) indicates that bioconcentration factor (BCF) testing may be required and recommends the OECD 305 test. However, a weight-of-evidence assessment should be undertaken first to attempt to justify that a substance does not meet the criteria for bioaccumulation properties. Furthermore, to avoid unnecessary animal testing, testing should only be undertaken where it is clear that the substance also meets the criteria for the identification of persistent properties.

ECHA (undated) indicates that additional chronic toxicity testing should first be carried out on non-vertebrate species, unless there are indications that fish are the most sensitive group and that it is entirely the responsibility of the registrant to rank the sensitivities. However, chronic toxicity testing should not be undertaken where:

- the substance is classified or likely to be classified under CLP as Carcinogenic Cat. 1A or 1B;
- the substance is classified or likely to be classified under CLP as a Germ Cell Mutagen Cat. 1A or 1B;
- the substance is classified or likely to be classified under CLP as a being Toxic to Reproduction Cat. 1A, 1B or 2;
- any EC50 is not < 0.1 mg/l from acute aquatic toxicity data, however confirmation that not false negative is necessary and chronic testing may still be needed; or
- P or B assessments are negative.

Annex XIII states that no additional information needs to be generated for the assessment of PBT/vPvB properties if there is no indication of P or B properties following the result from the screening test or other information.

Exposure Assessment

An exposure assessment (EA) is required as part of a CSA where the HA identifies:

- PBT or vPvB properties; or
- classification as hazardous for any hazard endpoint under CLP set out in Article 14(4) and Annex I.

An EA is also required were a registrant chooses to rely upon the exposure based waiving of information requirements under Annex XI, and is required for each application of a substance (see ECHA (undated), Figure D.2-1). The EA should also consider all relevant stages in life-cycle of a substance within the EU, including:

- manufacture;
- formulation;
- industrial use
- professional use;
- consumer use;
- service life of articles;
- waste life stage (not a downstream use under REACH); and
- environmental receptors.

To determine or predict the level to which human beings or the environment are exposed to a substance, consideration also has to be given to the risk management measures (RMM) used to control exposures[29].

8.5.5 Risk Characterisation

The next step in the process is risk characterisation, which involves the assessment of hazard and exposure data from the earlier stages of the CSA and the determination of whether the risks posed by a substance are adequately controlled throughout its life-cycle. The level of risk is measured in terms of risk characterisation ratios (RCRs) that are determined for all relevant hazard endpoints, receptors, exposure routes and time scales.

[29] It should be noted that there it is not common for the polymer industry to assess exposure and there is little published experience of exposure assessment for polymers in general for all modes of exposure that would lead to oral, dermal or inhalation exposure or involve extractibles that may impact on human health and the environment. The exceptions are those polymers used in food, drink, water and pharmaceutical containment and dispensing where measurements of extractibles and contact migration are routinely carried out. More general exposure assessment methods linked to defined exposure scenarios may need to be developed or guidance provided by EU authorities, such as ECHA.

9. RESULTS OF THE OPTIONS APPRAISAL – PREDICTED COSTS

9.1 Introduction

9.1.1 Summary of Key Sector Statistics

Polymers sales represent twenty four per cent of the EU chemical industry sales, around 104 billion euros per year, as presented in Figure 9.1 (Cefic, 2011).

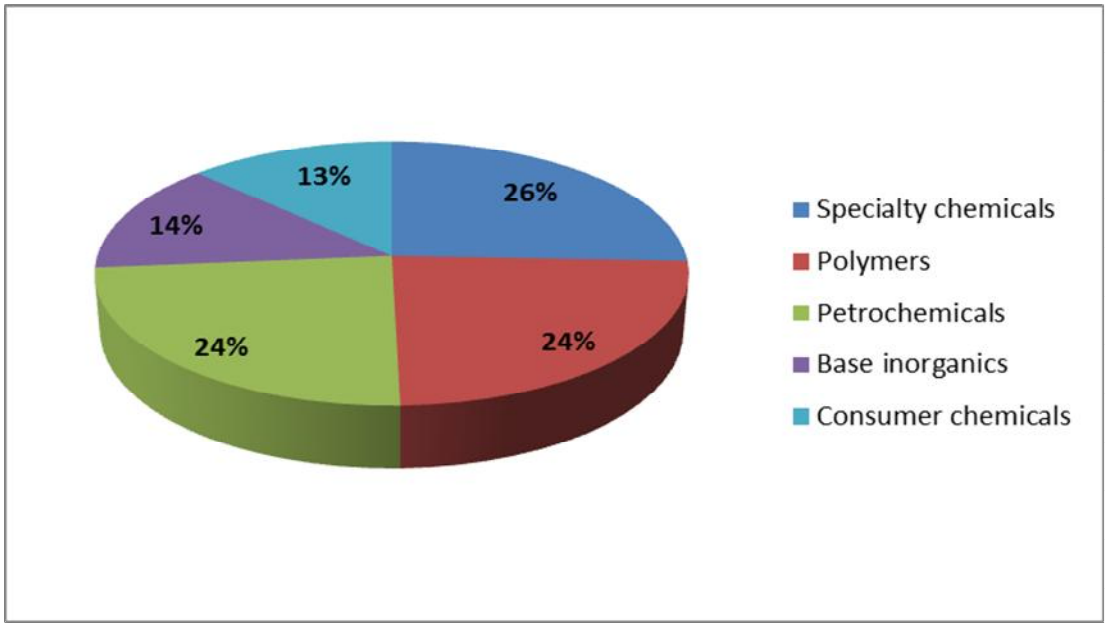


Figure 9.1: EU Chemical Industry Sales by Sector (Cefic, 2011)

According to PlasticsEurope (2010), polymers production is around 57 million tonnes per year[30]. Of the 55,850 companies in the polymers sector, ninety five per cent are considered to be formulators (involved in the processing of polymers) while five per cent are polymers manufacturers, with this equating to around 2,800 companies, employing between 170,000 – 200,000 workers (around 12% of the 1.4 million workers in the chemical industry). Data were compiled from Eurostat, Europlastic, Cefic and ETRMA; further discussions on the key data for the sector were provided in Section 3.1 but are summarised in Table 9.1 below. Table 9.2 provides data on SMEs within the sector.

As evident from the Table 9.1, the polymers sector is worth one quarter of the whole chemical sector in Europe. As for the other manufacturing sectors, small and medium enterprises are very important, in terms of number of companies and people employed (around thirty seven per cent).

30 Without considering rubber production and imports.

Table 9.1: Data on the polymers Industry in Europe	
	Estimate
Polymer sales 2010	€104 billion per year
Polymer production (volume)	57 million tpa
Polymer production (companies)	2,800
Polymer production (employees)	170,000 to 200,000
Standard plastics (production)	180 million tpa
Standard plastics (sales)	€37 billion per year
Engineering plastics (production)	20 million tpa
Engineering plastics (sales)	€60 billion per year
High performance plastics (production)	0.001 million tpa
High performance plastics (sales)	€7 billion per year
Polymer imports (volume)	250.000 tpa
Polymer imports (sales)	€820 million per year
Synthetic rubber production (volume)	4.2 million tpa
Synthetic rubber production (sales/turnover)	€5.6 billion per year
Synthetic rubber production (companies)	510
Synthetic rubber production (number employed)	44,000
Synthetic rubber imports (volume)	1 million tpa
Synthetic rubber imports (sales/turnover)	€2.6 billion per year

Table 9.2: Data on SMEs in the polymers Industry[31]	
	Estimate
SMEs (by number of companies)	96%
Micro enterprises (by number of companies)	63%
Small enterprises (by number of companies)	22%
Medium-sized enterprises (by number of companies)	11%
Large enterprises (by number of companies)	4%
SMEs (by total number of people employed)	37%
Micro enterprises (by total number of people employed)	4%
Small enterprises (by total number of people employed)	10%
Medium-sized enterprises (by total number of people employed)	23%
Large enterprises (by total number of people employed)	63%

A model has been developed for the purposes of this study to combine all the assumptions set out in Section 7, generating information on:

- the number of polymers to be registered under each option;
- the estimated costs to companies associated with the administration and fulfillment of registration requirements on a per substance basis, where these also reflect differences in the requirements assumed to apply under each of the options; this includes the costs to both polymer and monomer registrants;
- the estimated fees to registrants, taking into account the availability of data and the variations in fees payable by companies of different sizes;
- the potential impacts of the above on the other operations of registrants in terms of innovation and competitiveness.

[31] Based on figures for NACE (v.2) Code C20.1 (Manufacture of Basic Chemicals, Fertilisers and Nitrogen Compounds, Plastics and Synthetic Rubber in Primary Forms). SME status based on assessment of number of employees only. Percentages of enterprises by size in terms of employment is based on Cefic (2010).

The remainder of this section provides a discussion on the above, with this including a comparison across the options (while benefits are discussed in Section 10). More detailed tables have been placed in Annex 2 to this report.

9.1.2 The Options

The assessment has considered a large number of different options and permutations of these regarding registration and information requirements. To ease an understanding of the differences between the options, Table 9.3 summarises the definition of the polymer groups for Registration, while Table 9.4 and Table 9.5 identify the polymer groups triggered under each option, respectively for the extended monomer Registration scenario and the polymer Registration scenario.

Table 9.3: Definition of Polymer Groups for Registration

Permutation	Polymer Group	Screening Criteria		
		1: CLP Classification for Mixtures?	2: Qualify as a PLC?	3: Wide Dispersive Use?
1	Group A	N	Y	N
2		N	Y	Y
3	Group B	Y	Y	N
4	Group C	Y	Y	Y
5	Group D	N	N	N
6	Group E	N	N	Y
7	Group F	Y	N	N
8	Group G	Y	N	Y

Table 9.4: Polymers included in Monomer Registration – Screening Options 2 and 3

		Polymers Included in Monomer Registration							
Polymer Group (From Screening Option 2)		A	B	C	D	E	F	G	**Total**
Wide Dispersive Use?		-	N	Y	N	Y	N	Y	
CLP Classification for Mixtures?		N	Y	Y	N	N	Y	Y	
Qualify as a PLC?		Y	Y	Y	N	N	N	N	
Screening Option 1: one dimensional screening	**Low**	A	-	C	-	E	-	G	**A+C+E+G**
	High	A	B	C	D	E	F	G	**A+B+C+D+E+F+G**
Screening Option 2: Multidimensional Screening	**Low**	-	-	C	-	-	-	G	**C+G**
	Low-Medium	-	-	C	-	-	F	G	**C+F+G**
	Medium-High	-	-	C	-	E	F	G	**C+E+F+G**
	High	-	-	C	D	E	F	G	**C+D+E+F+G**
Screening Option 3a: Linear Screening as in Figure 1.2	**Low**	-	-	-	-	-	-	G	**G**
	Medium	-	-	C	-	-	-	G	**C+G**
	High	-	-	C	-	-	F	G	**C+F+G**
Screening Option 3b: Linear Screening as in Figure 1.3	**Low**	-	-		-	-	-	G	**G**
	High	-	-	C	-	-	-	G	**C+G**

Table 9.5: Summary of Level of Registration and Associated Requirements for Each Group Identified by each Screening Option								
Dossier and Information Requirements		**1 - Minimal**	**2a - Partial**	**2b - Partial - CSA**	**3a - Partial**	**3b - Partial Plus - CSA**	**4a - Full**	**4b - Full - CSA**
On-site isolated intermediates		All	All	All	All	All	All	All
Annex VII			>1	>1	1-10	1-10	1-10	1-10
Annex VIII					>10	>10	10-100	10-100
Annex IX							>100	>100
Annex X							>1000	>1000
CSA				>100		>100		>10
Screening Option	**Registration Option**	**1 - Minimal**	**2a - Partial**	**2b - Partial - CSA**	**3a - Partial**	**3b - Partial Plus - CSA**	**4a - Full**	**4b - Full - CSA**
Screening Option 1: Screening Based on Diffuse/Dispersive Use (DD) and Non-Diffuse/Dispersive Use (ND) Only	Low	All						
	Low b	ND		DD				
	Low-Medium		ND	DD				
	Medium		ND			DD		
	Medium-High				ND	DD		
	High						ND	DD
Screening Option 2: Multidimensional Screening	Low a	C, F, G						
	Low b	C, F		G				
	Low-Medium	All except G		G				
	Medium	A	B, D, F	C, E		G		
	Medium-High	A	B, D	C, E	F			G
	High	A	B, D	E		C	F	G
Screening Option 3a: Linear Screening as in Figure 1.2	Low a	C, F, G						
	Low b	C, F		G				
	Low-Medium	C, F		G				
	Medium		F	C		G		
	Medium-High			C	F			G
	High					C	F	G
Screening Option 3b: Linear Screening as in Figure 1.3	Low a	C,G						
	Low b	C		G				
	Low-Medium	C		G				
	Medium			C		G		
	Medium-High			C				G
	High					C		G

9.2 Total Costs of the Options

9.2.1 Registration of Intermediates

The general information requirements for the registration of **on-site and transported isolated intermediates** are limited to the information set out in Annex VI, namely (Article 17 and Article 18):

- Identity of the manufacturer;
- Identity of the intermediate;
- Classification of the intermediate;
- Any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;
- A brief general description of the use;
- Details of risk management measures used or recommended.

For on-site isolated intermediates, the information listed above only needs to be provided, "*to the extent that the manufacturer is able to submit it without any additional testing*" (Article 17). However, no such limitation applies to transported isolated intermediates (Article 18).

The 15,000 isolated intermediates considered to be on the EU market were evenly split between transported isolated intermediates and onsite isolated intermediates. Based on this split, Table 9.6 shows the total costs and costs per type by tonnage bands.

Table 9.6: Number of Isolated (Transported and Onsite) Intermediates and Total Registration Costs by Tonnage Bands

	>1,000 tpa	**>100 tpa**	**>10 tpa**	**>1 tpa**	**Total**
Number of intermediates	750	2,250	6,000	6,000	**15,000**
Registration costs in € million					
Substance ID and testing	€ 7.4	€ 22.4	€ 60	€ 60	**€ 150**
Administration and data summarises	€ 1.6	€ 4.8	€ 10.6	€ 9.8	**€ 26.8**
Registration fees	€ 0.8	€ 2.6	€ 6.2	€ 4.6	**€ 14.2**
Total	€ 10	€ 30	€ 76.8	€ 74.4	**€ 191.2**

The average cost to register an intermediate has been estimated at around €13,000, resulting in a total cost to the industry of around €190 million, with 80% of this cost due to the provision of the polymer analytics, 7% due to the Registration fees and 14% due to administration costs linked to the Registration. It has to be noted that for isolated transported intermediates manufactured or imported in quantities above 1,000 tonnes, there will be additional testing costs to provide Annex VII data, in accordance with Article 18(3) of the REACH Regulation.

9.2.2 Number of Polymers to be Registered Under Each Option

Tables 9.7 shows the number of polymers to be included in the Registration dossiers of the constituent monomers after 2015[32] under the extended monomer Registration scenario, while Table 9.8 shows the number of polymers to be registered under the different options in the polymers Registration scenario. Figure 9.2 completes the picture by presenting data on the number of polymers to be registered by tonnage band (scenario I) and the number of polymers to be covered by up-dated monomer Registration dossiers (scenario II) under the different options.

Table 9.7: Polymers included in Monomer Registration – Screening Options 2 and 3

		Polymers Included in Monomer Registration							
Polymer Group (From Screening Option 2)		A	B	C	D	E	F	G	**Total**
Wide Dispersive Use?		-	N	Y	N	Y	N	Y	
CLP Classification for Mixtures?		N	Y	Y	N	N	Y	Y	
Qualify as a PLC?		Y	Y	Y	N	N	N	N	
Screening Option 1: one dimensional screening	**L**	10,100	-	4,300	-	4,300	-	3,300	22,000
	H	33,600	10,100	4,300	10,100	4,300	4,300	3,300	70,000
Screening Option 2: Multidimensional Screening	**L**	-	-	1,400	-	-	-	3,300	7,600
	L-M	-	-	1,400	-	-	4,300	3,300	11,900
	M-H	-	-	1,400	-	4,300	4,300	3,300	16,200
	H	-	-	1,400	3,200	4,300	4,300	3,300	26,300
Screening Option 3a: Linear Screening as in Figure 1.2	**L**	-	-		-	-	-	3,300	3,300
	M	-	-	1,400	-	-	-	3,300	7,600
	H	-	-	1,400	-	-	4,300	3,300	11,900
Screening Option 3b: Linear Screening as in Figure 1.3	**L**	-	-		-	-	-	3,300	3,300
	H	-	-	1,400	-	-	-	3,300	7,600

Notes:
L: Low Option
M: Medium Option
M-H: Medium-High Option
H: High Option

Table A2.1 in Annex 2 presents the percentages of polymers in each group under each different option and Table A2.2 shows the number of polymers to be registered or included in the monomers' Registration dossiers by tonnage bands.

[32] For this study, it is assumed that 2015 would be the date for the introduction of any REACH requirement on polymers.

Table 9.8: Summary of level of Registration and associated requirements for each group identified by each screening option (number of polymers in each group)									
Dossier and Information Requirements		**1 - Minimal**	**2a - Partial**	**2b - Partial - CSA**	**3a - Partial**	**3b - Partial Plus - CSA**	**4a - Full**	**4b - Full - CSA**	
On-site isolated intermediates		All	All	All	All	All	All	All	
Annex VII			>1	>1	1-10	1-10	1-10	1-10	
Annex VIII					>10	>10	10-100	10-100	
Annex IX							>100	>100	
Annex X							>1000	>1000	
CSA				>100		>100		>10	
Screening Option	**Registration Option**	**1 - Minimal**	**2a - Partial**	**2b - Partial - CSA**	**3a - Partial**	**3b - Partial Plus - CSA**	**4a - Full**	**4b - Full - CSA**	**Total**
Screening Option 1: Screening Based on Diffuse/Dispersive Use (D) and Non-Diffuse/Dispersive Use (ND) Only	Low	70,000	0	0	0	0	0	0	70,000
	Low b	48,000	0	22,000	0	0	0	0	70,000
	Low-Medium	0	48,000	22,000	0	0	0	0	70,000
	Medium	0	48,000	0	0	22,000	0	0	70,000
	Medium-High	0	0	0	48,000	22,000	0	0	70,000
	High	0	0	0	0	0	48,000	22,000	70,000
Screening Option 2: Multidimensional Screening	Low a	11,900	0	0	0	0	0	0	11,900
	Low b	8,650	0	3,250	0	0	0	0	11,900
	Low-Medium	66,750	0	3,250	0	0	0	0	70,000
	Medium	33,600	24,500	8,650	0	3,250	0	0	70,000
	Medium-High	33,600	20,170	8,650	4,300	0	0	3,250	70,000
	High	33,600	20,170	4,300	0	4,300	4,300	3,250	70,000
Screening Option 3a: Linear Screening as in Figure 1.2	Low a	11,900	0	0	0	0	0	0	11,900
	Low b	8,650	0	3,250	0	0	0	0	11,900
	Low-Medium	8,650	0	3,250	0	0	0	0	11,900
	Medium	0	4,300	4,300	0	3,250	0	0	11,900
	Medium-High	0	0	4,300	4,300	0	0	3,250	11,900
	High	0	0	0	0	4,300	4,300	3,250	11,900
Screening Option 3b: Linear Screening as in Figure 1.3	Low a	7,575	0	0	0	0	0	0	7,550
	Low b	4,300	0	3,250	0	0	0	0	7,550
	Low-Medium	4,300	0	3,250	0	0	0	0	7,550
	Medium	0	0	4,300	0	3,250	0	0	7,550
	Medium-High	0	0	4,300	0	0	0	3,250	7,550
	High	0	0	0	0	4,300	0	3,250	7,550

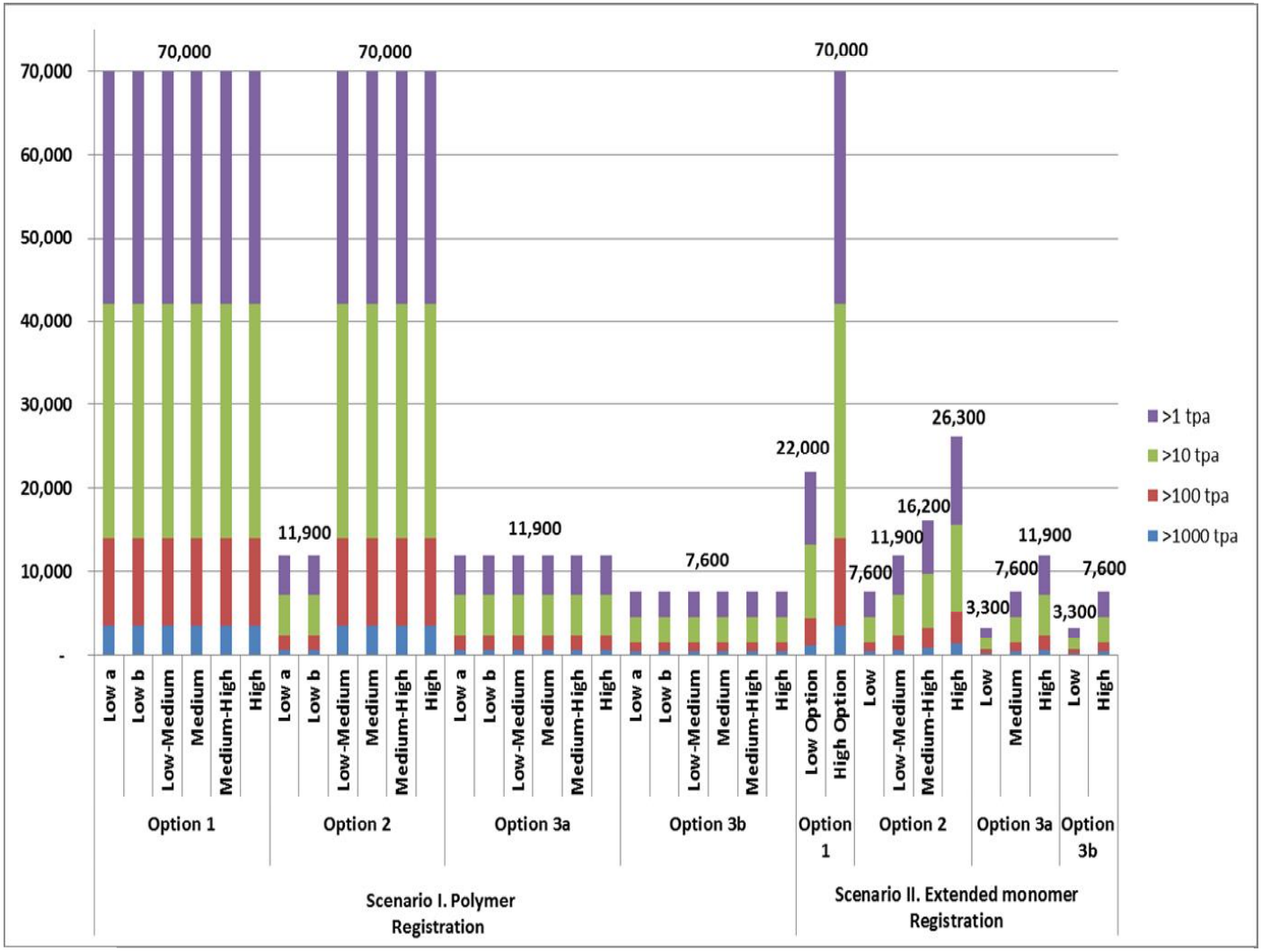


Figure 9.2: Number of polymers to be registered by tonnage band (scenario I) and number of polymers to be covered by up-dated monomer Registration dossiers (scenario II)

As can be appreciated from the Figure, under the first scenario, Option 1 and Option 2 are the ones that require the most polymers to be registered. The first Screening Option, in fact, involves a simple screening approach that divides polymers in terms of dispersive/diffuse uses and non-dispersive/diffuse uses, assigning different information requirements as presented in Table 8.5 for each set. However, all of the polymers need to be registered regardless of whether they involve dispersive/diffuse uses or not. Screening Option 2 is multidimensional and is based on all three of the Screening Criteria set out in Table 8.4 (CLP classification for mixtures, Polymers of Low Concern and Downstream use of substance). Under this screening option, the two low information requirements options prescribe polymers to be registered only if they belong to the Polymer Groups C, F and G (as defined in Table 8.6); in other words if they meet at least one of the three screening criteria (one of their constituent monomers is classified for any human health or environment endpoint under CLP, or they are not identified as "Polymer of Low Concern", or they have dispersive/diffuse uses). As can be seen by Figure 9.2, the numbers that would have to be registered under these low information requirements is significantly smaller at 11,900 than for the higher information requirement options.

As described in Section 8.3.4, Screening Option 3 considers the same three Screening Criteria but employs a stepwise (linear) questioning approach to screen polymers into (a smaller number of) Polymer Groups. Two Screening Sub-options (3a and 3b) have been developed, with these differing in terms of the order in which the questions are posed. Sub-option 3a follows the logical steps presented in Figure 8.2 and results in the same numbers of polymers to be registered as in Option 2 low a and low b. Sub-option 3b follows the logical steps presented in Figure 8.3 and prescribes polymers to be registered only if they have dispersive/diffuse uses and one of their constituent monomers is classified for any human health or environment endpoint, imposing additional information requirements if they do not meet the characteristics of also being identified as a PLC. This approach reduces the numbers to be registered to only 7,600, across all of the information requirements.

The alternative to the above Registration Options for polymers is to adopt a different approach and require monomer Registration dossiers to include consideration of the polymer(s) produced from that monomer. The manufacturers and importers of monomers are currently required to register their monomers in the same way as for any other substance. However, under Article 6(2), monomers may not be registered as isolated intermediates, even when they meet the criteria for such intermediates as set out in Article 3(15).

Under this scenario, the chemical safety report for a monomer Registration would need to include the use of the 'monomer substance' as defined by Article 6(3) within each polymer substance manufactured from that monomer, throughout the lifecycle of those polymer substances.

With respect to screening which monomers must fulfil such requirements, Screening Option 1 for monomers only differentiates between polymers with a dispersive/diffuse use and polymers with no dispersive/diffuse use. The low information requirements option prescribes that information on polymers should be included in the monomers

Registration dossiers just for those polymers with dispersive/diffuse use, where the high information requirements option prescribes that information on polymers should be included for all of the polymers.

As expected, also under this scenario, the screening options have the effect of significantly reducing the number of registered monomers that will need an update of the dossier to include the information on polymers. Interestingly, though, there is significantly more variation in terms of those polymers that would be covered under these options. In these cases, the variations in information requirements interact more fully with the screening criteria to result in changes in the polymer groups that would be covered (see Table 9.4) and hence in the numbers of polymers covered. For all levels of information requirements, Option 2 would result in more polymers being covered by monomer registrations than would either Option 3a or 3b.

9.2.3 Total Costs of the Options

Figure 9.3 provides data on the costs that would be incurred by companies to provide data on the substance ID and the additional tests required under each option, as well as the calculated registration costs and registration fees (see also Annex 2 for more detailed cost tables).

Under the first scenario (separate Registration for polymers), and as can be seen from Figure 9.3, the costs of testing and generating information increase with the amount of information required (although the costs of substance ID remain constant across the options) which, as expected, and constitute the major cost burden. As a result, the relative significance of the registration fees and costs decrease as one moves higher up the information requirements options (again as can be appreciated from Figure 9.3).

From Figure 9.3, it is evident that increased screening on the basis of whether a polymer is likely to meet the criteria for being of low concern (i.e. a PLC) and/or to have dispersive or downstream uses screening has the effect of dramatically decreasing the costs to companies of the potential registration requirements; combining these two criteria with those on the likely classification of the monomer lowers the numbers of polymers that would have to be registered, as noted in the previous subsection.

Turning to the different information requirements, the total costs under the higher registration requirements are estimated at around €22 billion for polymers, while those under the lowest registration requirements (option 3b low) are around €100 million for polymers (see also the more detailed cost tables in Annex 2). This is due to the higher number of tests and the higher costs of the tests as one moves from Annex VII to Annex X. For the monomer registration options, the costs range from €20 million to €330 million.

The estimated costs for the higher registration requirements under Options 1, 2 and 3a are all significant, given that the turnover of the plastics raw material production and converting sectors together are estimated at €307 billion, with imports only

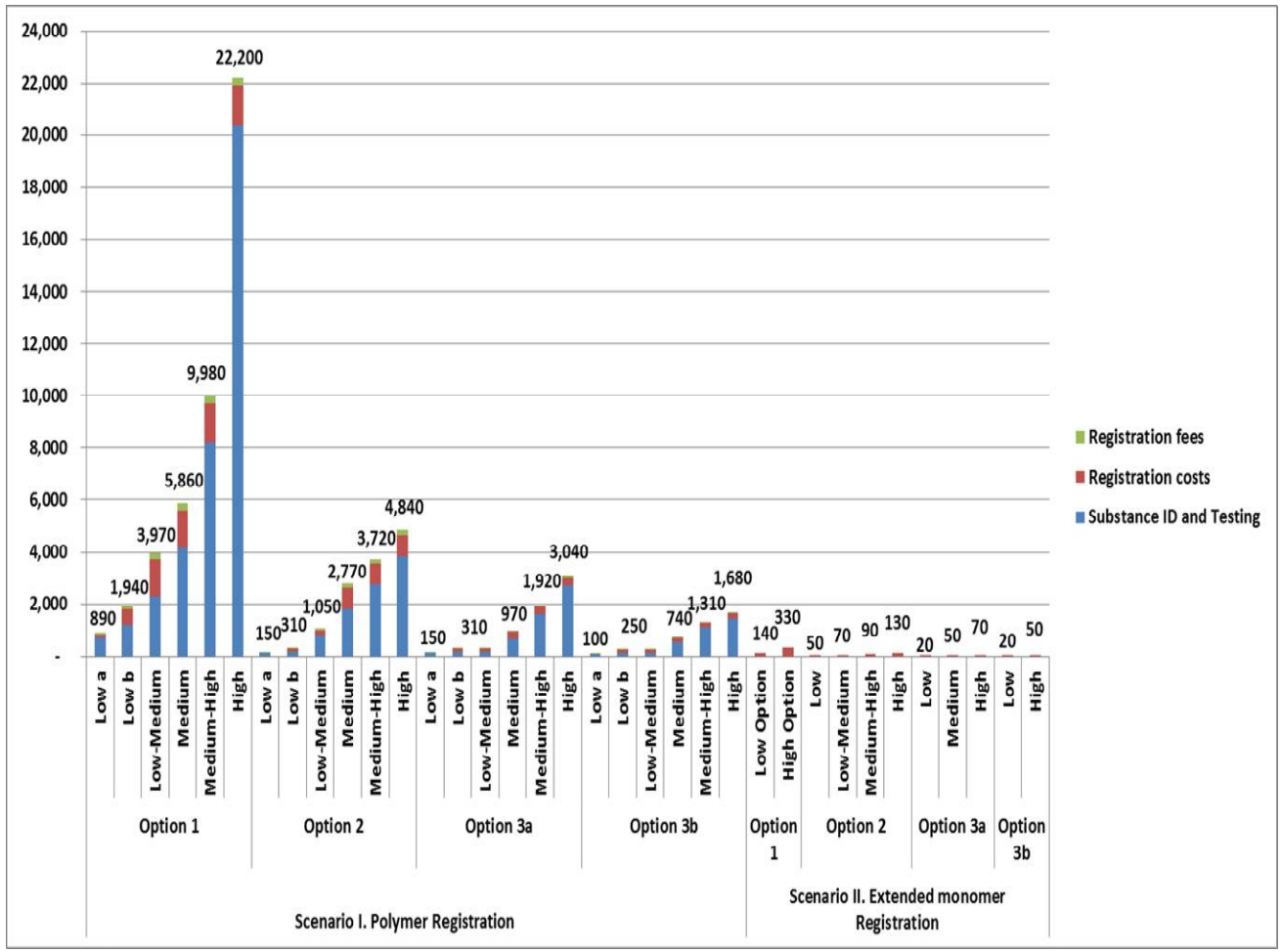


Figure 9.3: Total Costs by Cost Type (€ million)

accounting for a further €1.4 billion. The impacts of these on the sector would depend on the degree to which such costs could be spread over time, assuming that polymer registration requirements were phased as has been the case for other phase-in substances. A more detailed breakdown of these figures by tonnage band are provided in Annex 2.

In comparison to the costs for the first scenario involving polymer registration, requiring industry only to update or extend the monomer Registration dossiers with information on the polymers they are contained within (providing additional exposure scenarios for the polymers) significantly decreases the costs. This is due to the fact that such costs would be incurred across only an estimated 1,400 monomers (of which 1,100 have not yet been registered), rather than a much larger set of polymers. Total costs under the monomer scenario range from €30 million to €300 million. These are essentially lower than those associated with Option 3b, although again this depends on the information requirements (e.g. low or high).

However, it must be recognised that this option would impact on different actors within the polymers supply chain. Although some manufacturers of monomers will also produce polymers, they may not all produce polymers. Similarly, it is clear that not all polymer producers will be monomer producers. Thus, the distribution of costs will vary under the extended monomer options from those under the polymer registration options.

It may therefore be important for a provision similar to that set out in Article 37 to be developed which is specific to polymers. This would include giving downstream users of monomers the right to make known his use and requiring this user to provide sufficient information to allow the manufacturer, importer or downstream user to prepare an exposure scenario, or if appropriate a use and exposure category. Similarly, there should be the potential for a polymer producer to prepare his own chemical safety report, as laid out in Article 37(4) for downstream users of substances and further in Annex XII.

9.2.4 Total Costs by Company Size

Table 7.2 set out our assumptions as to the percentages of polymers that are manufactured by companies of different sizes, with the implications of these in terms of numbers of polymers given in Table 9.9 below.

Table 9.9: Numbers of Polymers Produced by Enterprises of Different Sizes by Tonnage					
	≥1000 tpa	**≥100 tpa/ ≤1,000 tpa**	**≥10tpa/ ≤100 tpa**	**≥1tpa/ ≤10 tpa**	***Total***
Numbers of polymers manufactured or imported by microenterprises	88	262	2,800	7,000	10,150
Numbers of polymers manufactured or imported by small enterprises	262	788	5,600	8,400	15,050
Numbers of polymers manufactured or imported by medium enterprises	1,050	4,200	8,400	8,400	22,050
Numbers of polymers manufactured or imported by large enterprises	2,100	5,250	11,200	4,200	22,750

Data on the numbers of companies by size that are manufacturing plastics and plastic products was given in Table 9.2 (see also Table 3.13). These data suggest in total around 51,000 companies in the sector in the EU, distributed as follows: 63% microenterprises, 22% small companies, 11% medium sized companies, and 4% large companies. However, as also discussed in Section 3, the total figures are likely to include companies that manufacture plastic products rather than those that actually manufacture plastic polymers. Data for the German industry highlight that the ratio of plastics products to plastics manufacture is around 18 to 1. On this basis, it has been calculated that there are roughly 2,800 polymer manufacturers in the EU, with this comprising the following:

- 1,764 micro-enterprises;
- 616 small companies;
- 308 medium sized enterprises; and
- 112 large enterprises.

Based on these assumptions, we have broken the total costs for each option into total costs by company size. These are presented below in Table 9.10. As would be expected from the earlier discussions, the low and low-medium registration requirements result in significantly lower costs than the other options across all of the registration options. These differences in total costs by company size and by option can be more clearly visualized from Figure 9.4 below.

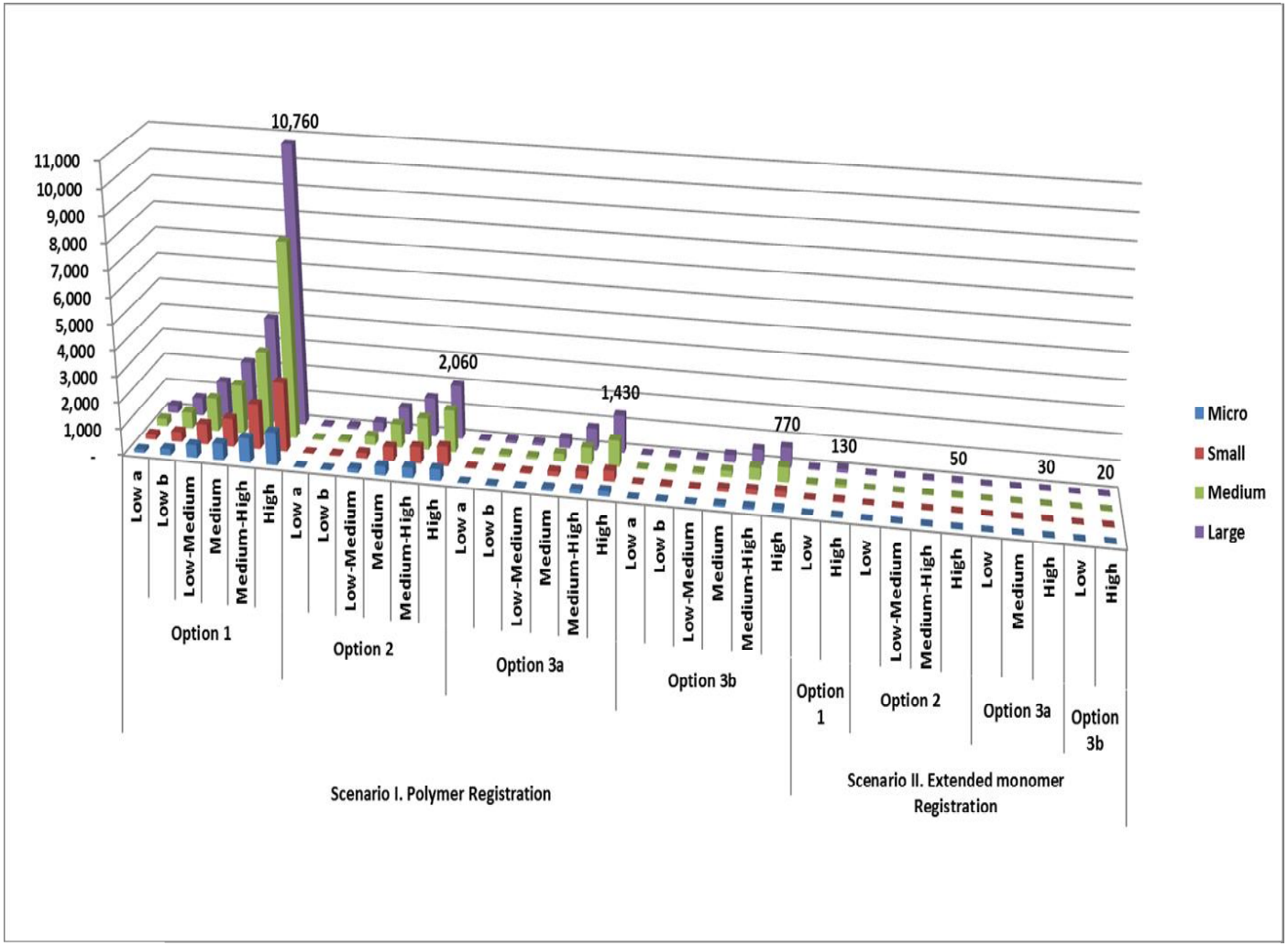


Figure 9.4: Total Costs by Company Size (€ millions)

Table 9.10: Total costs by company size (€ million)					
		Micro	**Small**	**Medium**	**Large**
I. Polymer Registration scenario					
Option 1	**Low a**	127	190	282	293
	Low b	252	384	620	684
	Low-Medium	502	772	1,272	1,422
	Medium	644	1,071	1,885	2,256
	Medium-High	953	1,724	3,225	4,077
	High	1,261	2,645	7,539	10,756
Option 2	**Low a**	22	32	48	50
	Low b	40	61	98	108
	Low-Medium	146	219	332	351
	Medium	343	537	888	1,005
	Medium-High	386	640	1,211	1,481
	High	433	755	1,597	2,056
Option 3a	**Low a**	22	32	48	50
	Low b	40	61	98	108
	Low-Medium	40	61	98	108
	Medium	108	178	314	374
	Medium-High	150	281	636	850
	High	197	396	1,023	1,426
Option 3b	**Low a**	14	21	30	32
	Low b	32	49	81	90
	Low-Medium	32	49	81	90
	Medium	78	132	238	290
	Medium-High	92	175	440	602
	High	120	234	560	766
II. Extended monomer Registration scenario					
Option 1	**Low**	14	23	46	58
	High	35	57	108	132
Option 2	**Low**	5	8	16	20
	Low-Medium	7	11	22	27
	Medium-High	9	15	31	38
	High	14	23	44	53
Option 3a	**Low**	2	3	7	9
	Medium	5	8	16	20
	High	7	11	22	27
Option 3b	**Low**	2	3	7	9
	High	5	8	16	20

From Table 9.10, it becomes clear that Option 1 for polymer registration would place significant cost burdens on companies, with even the lowest registration requirements

resulting in costs between €130 to €200 million; under the higher registration requirements, the costs would rise to above €1 billion for microenterprises alone.

The costs under Options 2 and 3a for the lower registration requirements are the same across the different company sizes, but begin to diverge as the registration requirements increase and more polymers are screened out under Option 3a. The further screening that takes place under Option 3b then reduces the total burden that would be faced by companies. However, it would continue to be significant for the small and microenterprises, considering that these smaller companies are classed as having a turnover of less than €10 million per annum.

9.2.5 Average Cost Per Polymer Registered or Extended Monomer Registration

Figure 9.5 below presents the average costs per polymer and per manufacturer/ importer by company size under each option. Costs range from around €12,700 to register a polymer providing the same information as for isolated intermediates (under Option 1, Low a) to around €320,000 to register a polymer providing all the information up to Annex X with a Chemical Safety Assessment including exposure scenarios (Option 1, High). The average costs per polymer covered by an extended monomer registration dossier ranges from around €2,100 to €33,200, with these costs varying in line with the need to provide additional exposure data, depending on the tonnage band (which determines likely number of downstream uses), substance properties and whether downstream use is classed as dispersive/non-dispersive use.

In assessing the estimates presented in Figure 9.5, it is important to be clear as to what the figures presented for monomer registration dossiers mean. These are not estimates per monomer but estimates per polymer. The latter are presented here as it is more comparable to the other data presented in the Figure, but also because it is relevant to understanding the costs that polymer producers may face if they have to either help support the costs of preparing an extended monomer registration (e.g. under Article 37 type requirements) or in preparing their own CSR; although the figures would be an underestimate of the costs of preparing an own CSR.

If instead one is interested in the average costs per monomer registration, then these would be as follows for the three options:

- Option 1:
  - Low information: €6,375
  - High Information option: €4,750
- Option 2:
  - Low information: €6375
  - Low-medium information: €5510
  - Medium-high information: €5,740
  - High-information: €5,074
- Option 3a:
  - Low information: €6,380
  - Medium information: €6,375
  - High information: €5,510

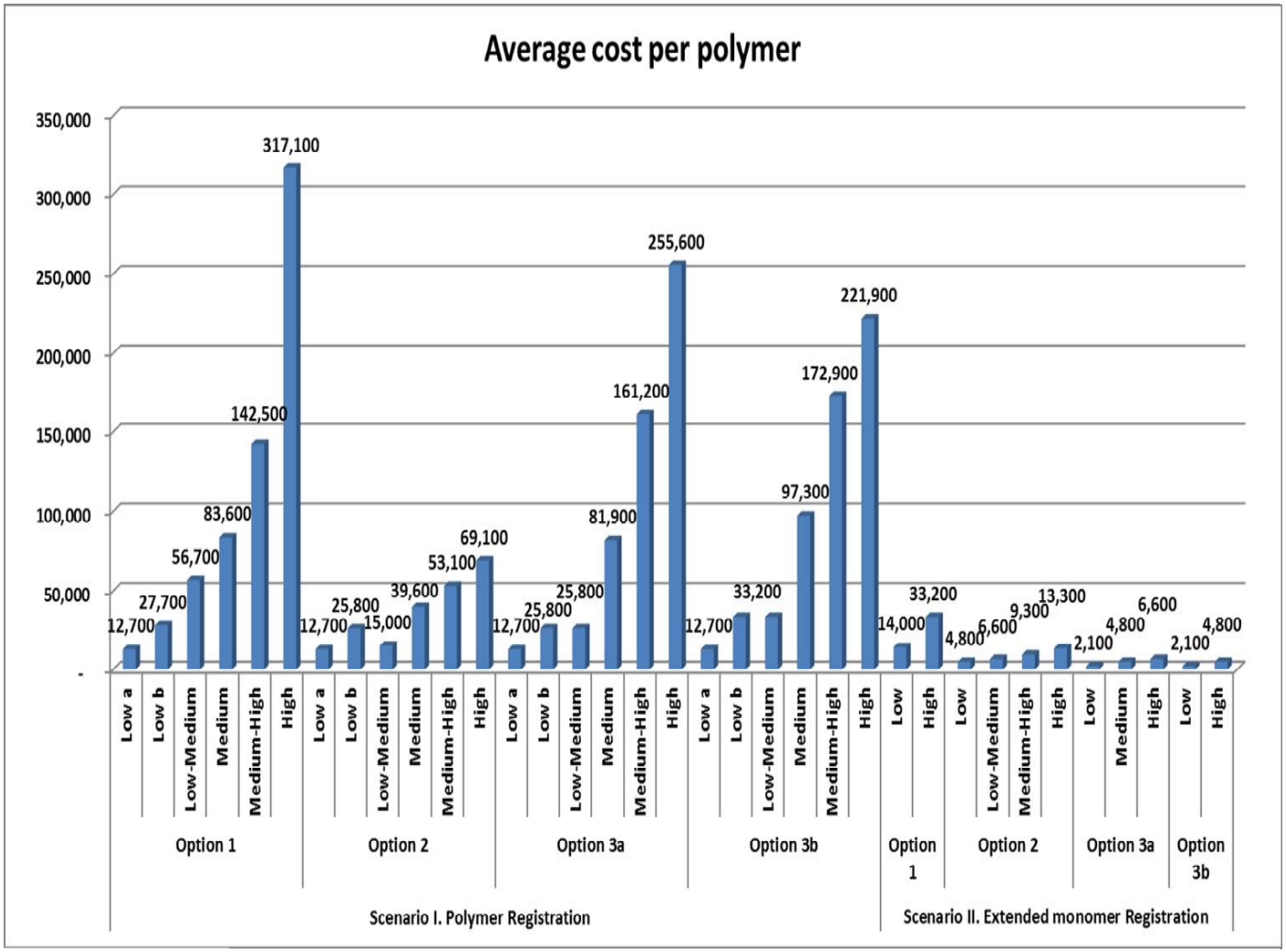


Figure 9.5: Average Cost Per Polymer Registered or Per Polymer Covered by an Extended Monomer Registration Dossier (€)

- Option 3b:
  - Low information: €6,380
  - High information: €4,000

These figures represent the average cost for extending monomer registration dossiers across all tonnage bands. Thus, there will be significant variations from these figures for monomers in the higher tonnage bands depending on the impact of the different screening criteria (see the tables in Annex 2).

More generation, it should be remembered that a lower number of monomer registration dossiers would have to be either up-dated (with 2,000 such dossiers expected to be submitted prior to 2015) or extended compared to the current requirements, than there would be newly required polymer registrations. Furthermore, not all monomer dossiers would need to be up-dated or extended under all of the options, as only some polymers would need to be covered in the dossiers under Options 2 and 3, and under the low information requirements for Option 1. Thus, although the costs per 'registration' appear similar, the total costs vary significantly, as indicated above.

For polymers, it is important to remember that the average cost figures are taken across polymers produced in different tonnages, and which under some of the options would therefore face different information requirements. Given that under the medium high and high registration options these can include full REACH information requirements for some groups of polymers, the variations from the averages may be significant. This can be seen from the more detailed tables provided in Annex 2 to this report.

Case Study for a Small Enterprise Manufacturing or Importing Polymers

Table 9.11 presents estimates of the average total costs to polymer manufacturers for fulfilling the obligations of the different options for a statistical manufacturer's "portfolio". These have been derived by dividing the total predicted number of polymer substances to be manufactured by companies of different size (see Table 9.9) by the number of companies assumed to fall into each size band (see text below Table 9.9).

Drawing on the available data sources, it is assumed here that a typical small company would produce on average 16 polymer substances, with most of these expected to fall in the lower tonnage bands. Based on this figure, for polymer manufacturers or importers, the costs that would arise to the average small company would vary from €33,400 to €4.29 million, depending on the option and registration information requirements.

In interpreting these figures it is important to bear in mind that a small company by definition has a turnover of less than €10 million. As a result, it is clear that the medium to high information requirements may be difficult for a small company to afford under either Option 1 or 2, particularly if they were introduced over a relatively short time period, as these would represent over 10% of annual turnover. In contrast,

Table 9.11: Average Cost per Polymer Registered and per M/I by Company Size (€)						
		Average per polymer	Average cost per M/I by company size			
			Micro	Small	Medium	Large
I. Separate Registration of Polymers						
Option 1	**Low a**	12,700	72,200	308,200	914,200	2,618,200
	Low b	27,700	142,700	623,900	2,014,100	6,106,500
	Low-Medium	56,700	284,600	1,253,600	4,128,300	12,695,000
	Medium	83,600	364,800	1,738,800	6,120,000	20,139,400
	Med-High	142,500	540,100	2,798,600	10,471,200	36,402,100
	High	317,100	714,900	4,294,200	24,476,500	96,035,500
Option 2	**Low a**	12,700	12,300	52,400	155,400	445,000
	Low b	25,800	22,700	99,100	318,100	961,300
	Low-Medium	15,000	82,600	354,900	1,077,000	3,134,500
	Medium	39,600	194,700	872,400	2,883,500	8,970,900
	Med-High	53,100	218,800	1,038,600	3,930,200	13,222,800
	High	69,100	245,200	1,225,500	5,184,000	18,358,900
Option 3a	**Low a**	12,700	12,300	52,400	155,400	445,000
	Low b	25,800	22,700	99,100	318,100	961,300
	Low-Medium	25,800	22,700	99,100	318,100	961,300
	Medium	81,900	61,200	289,600	1,019,300	3,341,600
	Med-High	161,200	85,300	455,800	2,066,100	7,593,500
	High	255,600	111,700	642,700	3,319,900	12,729,500
Option 3b	**Low a**	12,700	7,800	33,400	98,900	283,300
	Low b	33,200	18,200	80,100	261,700	799,700
	Low-Medium	33,200	18,200	80,100	261,700	799,700
	Medium	97,300	44,000	213,900	772,700	2,587,100
	Med-High	172,900	52,300	284,700	1,427,900	5,375,500
	High	221,900	68,100	380,100	1,819,400	6,839,000
II. Extension of Monomer Registration to include Polymers						
Option 1	**Low**	14,000	21,500	102,400	420,200	1,445,500
	High	33,200	55,400	260,600	983,400	3,294,200
Option 2	**Low**	4,800	7,400	35,300	144,800	498,200
	Low-Medium	6,600	10,500	49,500	195,500	664,600
	Med-High	9,300	14,700	69,700	278,100	948,700
	High	13,300	21,800	102,900	396,400	1,337,000
Option 3a	**Low**	2,100	3,200	15,200	62,200	214,100
	Medium	4,800	7,400	35,300	144,800	498,200
	High	6,600	10,500	49,500	195,500	664,600
Option 3b	**Low**	2,100	3,200	15,200	62,200	214,100
	High	4,800	7,400	35,300	144,800	498,200

the lower registration requirements (Low a or Low b) represent 2% to 4% or less of annual turnover, making it more likely that these costs could be borne by the companies if spread over time; this is also the case for the low-medium requirements under Option 2.

The costs per polymer that would have to be registered are higher under Options 3a and 3b than Option 2 and similar to Option 1. Because these costs would only be realised across a smaller number of polymers, the average costs to a micro polymer manufacturer are lower than the average cost per substance under 3b, since not all manufacturers would have polymers meeting the screening criteria. The same is not the case for a small manufacturer. However, it is clear that highest information requirements may not be affordable to small companies under Option 3a, while they may be under Option 3b at the company level. Under Option 3b, the costs associated with the high registration requirements are around 3% of annual turnover.

At the substance level, the costs per polymer registered facing the higher information requirements may no longer make financial sense. As a result, polymer manufacturers may cease production of some polymers under all of the options, although this effect could be less pronounced under Option 2.

Interestingly, if we look at the costs per polymer for an extended monomer registration, the costs are likely to be much more viable for a small polymer manufacturer/importer, as they are less than one tenth those for the polymer registration options. This would be particularly the case if they could be spread over time.

Case Study for a Large Enterprise

The potential percentage of turnover represented by the estimated costs given in Table 9.11 for a large manufacturer/importer of polymers may also be significant. Assuming a large manufacturer with a turnover of around €1 billion, the costs associated with Option 1 vary from less than 1% of turnover (0.3%) to around 9.5% of annual turnover under the Low a and High registration information requirements respectively. Moving down the options, the percentage of annual turnover decreases to around 0.1% of turnover around 4% of turnover under Option 3a, High registration requirements and 1% of turnover under option 3b and High registration requirements.

Again, the extended monomer registration options would all be much more financially viable for a polymer manufacturer/importer than the main polymer registration options.

As indicated by Table 9.9, it is assumed here that large companies manufacture or import around 22,750 of the 70,000 polymers, or around 32.5% of the total; based on NACE data, it is assumed that they comprise around 4% of polymer producers in terms of numbers of companies.

9.2.6 Wider Implications

As for chemical substances, to impose Registration requirements on polymers could be fundamental to ensuring their safe use. However, the inclusion of polymers under REACH could impact the EU polymer manufacturing industry in different ways:

- **Polymer withdrawal**: some manufacturers may consider withdrawing some polymers from the EU market, either due to the financial cost of registering individual polymers under the above options due to the heavy information requirements placed on particular groups, because of a more general rationalisation of their product portfolios to reduce overall costs, or due to the hazardous properties of the polymers. A rationalisation of the product portfolio is likely to occur amongst producers of the most common polymers groups (i.e. standard plastics that makes 90% of the market), with medium and larger companies for example no longer wishing to register low value polymers (up to €2,000 per tonne) with potential hazardous properties. On the other hand, micro and small enterprises could be forced to withdraw some of their polymer products due to the very high costs of testing and registering;

- **Implications of polymer withdrawal on innovation and competitiveness:** polymers withdrawal might impact some of the high value niche products (i.e. engineering plastics and high performance polymers), threatening the innovation and competitiveness of the EU industry, as these polymers permit exceptional end-use applications. Their loss also would be likely to have repercussions on downstream users in strategic sectors for the EU economy. Moreover, the reduced availability and the potential inferior performance of alternatives could affect also "lower value" sectors but have broader impacts in terms of applications. In this regard, screening options identifying and prioritising polymers most likely to have hazardous properties could limit such undesirable effects;

- **Diversion of resources:** the preparation of Registration dossiers for large number of polymers is likely to result in a diversion of financial and human resources that would otherwise be invested in research and development towards covering testing, CSR and other Registration costs, and fees. Moreover, there may also be a diversion of human resources from innovative activities and even from day-to-day activities, as employees would have to dedicate time for the preparation of the dossiers and communication through the supply chain. However, the inclusion of polymers under the REACH Regulation could also have a positive effect on R&D expenditure, due to the research of safer alternatives that should be carry forward by industry;

- **Impacts on SME companies:** as noted in the previous subsection, SMEs would have to plan the preparation of the Registration dossiers and all the required tests well in advance, as they may have difficulty under some of the options finding the financial resources needed to cover all the implied costs.

- **Impacts on ECHA and National Competent Authorities:** if from one side the inclusion of polymers under the REACH Regulation would result in a greater amount of resources for the Agency (in terms of Registration fees), on the other side ECHA (and the Competent Authorities at national level) might not be able to manage effectively the large number of polymers and the linked information. It should be remembered that currently there is no agreement on the number of polymers on the market, with estimate ranging from below 70,000 to 400,000. Moreover, the enforcement of the Regulation on such a high number of polymers could be prohibitive, as it is already proving challenging for phase-in substances alone. Again, the screening options would help in limiting the burden on the Agency.

These impacts would be reduced under the options for the extension of the monomer Registrations to include information on downstream uses of polymers. Under these options, the impacts would not be felt by all polymer producers, only by those which also produce the starting monomers. Given the smaller number of monomers (assumed to be around 1400 in total given that around 330 have been registered to date) than polymers, the costs to those who producer both monomers and associated polymers should be significantly less than associated with the registration of all resulting polymers. However, there would be increased costs to companies that only manufacture the monomers. In some cases, the additional costs of extending CSAs may be such that registrants of monomers are unwilling to support all downstream polymer uses, but it is less likely that there would be significant levels of product withdrawal and the impacts on innovation within the polymer sector are likely to be less.

With respect to ECHA, we assume here that no fees for up-dating monomer dossiers would have to be paid to ECHA given that registrants have already paid fees for the registration of the substance as a monomer. This may or may not be appropriate.

10. RESULTS OF THE OPTIONS APPRAISAL – PREDICTED HEALTH AND ENVIRONMENTAL BENEFITS

10.1 Overview

The 2001 Commission White Paper that set out the Strategy for REACH identified a general lack of knowledge about the properties and uses of existing substances as a major problem, and identified the "*better protection of the environment and human health through appropriate risk management based on adequate information about the dangerous properties of chemicals*" as a key benefit of REACH.[33]

The analysis presented in this report provides a range of outputs which help understand the potential health and environment benefits that could arise from the availability of better information on the properties of polymers. To this end, as well as providing data on costs, the analysis has sought to provide information on:

- the number of previously unclassified substances that would be newly classified as a result of new information stemming from the registration requirements identified;
- the number of already classified substances where additional classifications would be found; and
- the number of PBTs, CMR 1A, 1B, 2 (including impacts on lactation – Lact.) that would be newly identified.

In addition to the identification of new classifications and substances for classification, some of the options examined would introduce Chemical Safety Assessment requirements (either as part of requirements to report new data or simply existing data in the case of the 'minimal' requirements). Here there may be benefits from the formal development of exposure scenarios and the need to report on these and on recommended risk management measures.

Even in the absence of a Chemical Safety Assessment, the identification of new hazardous properties (and hence reclassification) of some polymers may also result in benefits through up-dates of SDS and information on safe use; benefits may also arise from the fact that information on revised classifications will feed into other legislation, triggering risk management requirements.

In terms of estimates of these benefits, as with previous studies on REACH and chemicals regulation in relation to non-polymers, generating information on the benefits of new information requirements requires one to make informed assumptions about the properties (and in particular the dangerous properties) of substances for which there is, at present, little or no information.

In the case of polymers, it is clear from the discussion in the previous Sections that the extent to which polymers and polymer substances may pose either a human health

[33] White Paper on the Strategy for a future Chemicals Policy COM(2001)88 final

or environmental risk remains uncertain; this is largely a reflection of the general lack of publicly available data on these chemicals and, where data are available, difficulty in comparing datasets owing to differences in the criteria used in each.

Section 4 provides an in depth discussion of the available evidence on polymers and what it suggests in terms of their properties and the expected number with properties of concern. This also provides some reassurance that, in general, the proportion of polymers showing classifiable properties is lower than (the high proportion) which might be inferred based on consideration of the monomer(s) content alone. As noted previously, this could be taken as support for PSG statements that their recent study found that the hazards posed by polymers are generally less than that of the respective monomer(s) with only a small subset showing greater risk (generally in relation to environmental rather than human hazards) than would be predicted based on monomer content. However, the PSG statements cannot be substantiated as no results from their work were provided for use in this study (due to stated concerns as to the representativeness of the dataset they considered to the overall European polymer market).

As described in Section 7, the following assumptions have been applied:

- 50% of polymers are expected to have a CLP classification (as a mixture) for health or environment hazards or for both (based on OECD, 2009 and data provided by industry consultees for this and an earlier study). Of these, 25% would be found to have one or more additional classifications assuming a level of testing equivalent to Annex X. Other Annexes would be less effective at identifying these additional classifications and would identify 60%, 70% and 90% of these additional classifications for Annexes VII, VIII and IX respectively;

- 70% of polymers would qualify as being polymers of low concern. Of these, 85% would be found to have one or more classifications assuming a level of testing equivalent to Annex X. Other Annexes would be less effective at identifying these additional classifications and would identify 60%, 70% and 90% of these additional classifications for Annexes VII, VIII and IX respectively; and

- Of the new classifications identified in the above, it is assumed that the hazard profile of the resulting polymers will follow the same distribution as for other substances, such that 2% will have CMR, PBT or vPvB properties.

On the basis of these assumptions, Table 10.1 and Figure 10.1 provide the resulting estimates of the number of polymers that would be newly classified for the first time or that would be found to have to have additional classifications under each of the options.

As would be expected, the high information requirements under Option 1 would identify the greatest number of both newly classified polymers and of additional classifications. Expectedly due to the nature of the screening criteria, Options 3a and 3b would not be expected to newly identify any currently unclassified polymers, yet they would identify additional classifications for already classified polymers. In this

respect, they would fail to identify a significant number of polymers posing either human or environmental hazards (see also the discussion below). They would also identify significantly lower numbers of additional classifications, when compared to either Option 1 or 2.

Table 10.1: Number of Polymers Newly Classified and Number with an Existing Classification having an Additional Classification

		Number of polymers newly classified	Number of polymers with an existing classification that would have additional classification endpoints	Total
Option 1	**Low a**	-	-	-
	Low b	2,637	1,136	3,773
	Low-Medium	8,788	3,297	12,085
	Medium	9,052	3,411	12,463
	Medium-High	9,667	3,627	13,294
	High	10,326	3,874	14,200
Option 2	**Low a**	-	-	-
	Low b	-	488	488
	Low-Medium	-	488	488
	Medium	4,754	3,346	8,100
	Medium-High	4,754	3,447	8,202
	High	4,754	3,561	8,315
Option 3a	**Low a**	-	-	-
	Low b	-	488	488
	Low-Medium	-	488	488
	Medium	-	1,833	1,833
	Medium-High	-	1,934	1,934
	High	-	2,048	2,048
Option 3b	**Low a**	-	-	-
	Low b	-	488	488
	Low-Medium	-	488	488
	Medium	-	1,185	1,185
	Medium-High	-	1,221	1,221
	High	-	1,286	1,286

No similar estimates are provided here for monomers as this analysis is not applicable given that polymer specific information is not generated under the extended monomer registration options.

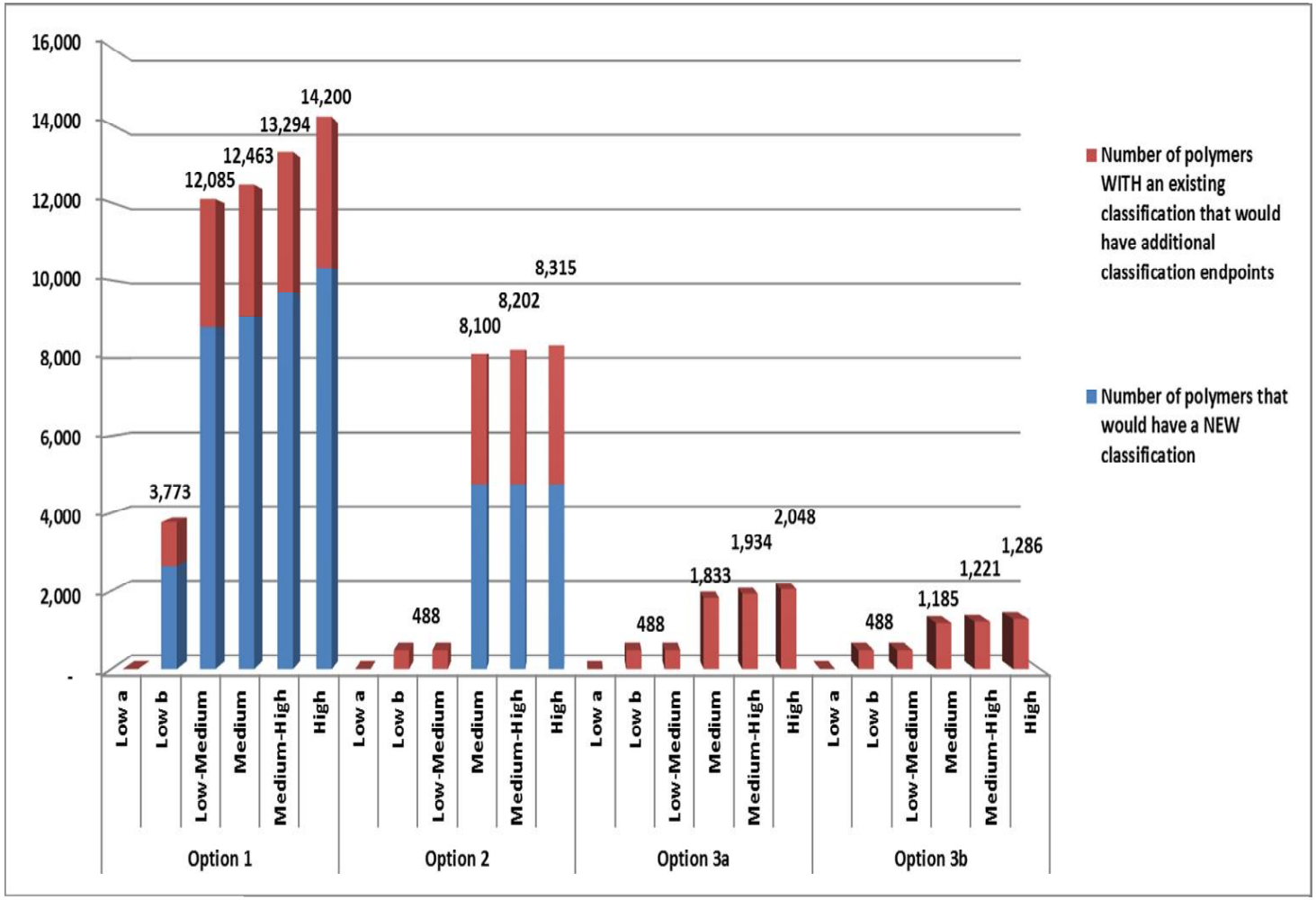


Figure 10.1: Number of Polymers Newly Classified and with Additional Classifications

10.2 Benefits Associated with New Classifications

10.2.1 Identification of Hazardous Polymers

It has always been argued that the generation of new data on the properties of chemicals would result in some proportion of existing (phase-in) classified substances and unclassified substances being found to have previously unidentified hazardous properties. Thus, one of the key premises underlying REACH is that the generation or new data on the properties of substances will lead to improved information and, hence, benefits by (RPA et al, 2012):

- improving the classification of individual chemicals and thereby providing registrants and downstream users with better information on the hazards associated with their use;
- improving the quality of the data available to acting as the basis for preparing exposure scenarios, thereby improving the quality of recommendations on safe use and handling and appropriate risk management measures; and
- improving the data on substance classifications which feeds across into other legislation, with this creating indirect benefits.

Communication of information on both the newly identified properties of polymers and/or through explicit polymer-related advice on risk management measures in Safety Data Sheets (SDS, or extended SDS) should lead to the better control of risks, for example, through the implementation of exposure reducing measures triggered by other legislation (e.g. Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work). Changes in polymer classification, through application of the CLP Regulation, would also be picked up and drawn upon in the other legislation.

Further discussion on such linkages is provided in Part B to this study, in particular, highlighting the fact that the REACH Baseline Study (Oeko-Institut et al, 2011 in draft) found that Registration resulted in substances that were previously unclassified being classified, and substances that had classifications pre-REACH being found to have new classifications as more data became available.

Newly Identifying Polymers with Any Human Health or Environmental Classification

Table 10.1 above provided data on the number of previously unclassified polymers that would be newly identified as requiring one or more classifications under each of the options. Table 10.2 expresses these data as a percentage of the expected maximum number that might be found if Annex X requirements were placed on all polymers (see Annex 2 for details of the expected maximums in numbers).

Table 10.2: Percentage of Expected Maximum of Previously Unclassified Polymers Identified as Requiring a New Classification under Each Option				
	Screening Option 1: Screening Based on Diffuse Use Only	**Screening Option 2: Multi-dimensional Screening**	**Screening Option 3a: Linear Screening**	**Screening Option 3b: Linear Screening**
Low a	0%	0%	0%	0%
Low b	18%	0%	0%	0%
Low-Medium	60%	0%	0%	0%
Medium	62%	32%	0%	0%
Medium-High	66%	32%	0%	0%
High	70%	32%	0%	0%

As discussed above, neither Option 3a nor Option 3b identifies any previously unclassified substances that should be classified, simply because both of these options use a linear questioning approach which excludes those substances with no existing classification from registration. As such, neither of these options is able to provide any of the benefits associated with identifying currently unclassified polymers with hazardous properties.

Of the remaining options, Table 10.2 highlights that screening Option 2 identifies 32% of the expected substances once Medium registration requirements are applied to the various groups that are the outcome of the screening exercise. This is because, in the lower registration requirements, with the exception of group G, all of the groups are subjected to minimal information requirements (akin to on-site isolated intermediates) which only require submission of existing data not generation of new data. As Group G contains only polymers with an existing classification, it is not possible for the option to identify hazardous properties of currently unclassified polymers.

Option 1 is more effective once information requirements above the minimal are included for all polymers (whether diffuse/dispersive uses or not), with the effectiveness increasing to the maximum of 70% as one progresses towards the High information requirements (that involve the same testing requirements as for other substances under REACH).

The Extended Monomer Registration Options do not generate any new information on the properties of polymers and, as such, there are no benefits in terms of the identification of new hazardous properties and hence polymer substance classifications under this option. If polymers are classified following CLP rules for mixtures, they may in any event become newly classified under these. This is an area of key uncertainty.

Identifying Additional Classifications for Polymers with an Existing Classification

Table 10.3 provides data on the percentage of the maximum expected number of already classified polymers which would be identified as needing additional classifications under each of the options.

As can be seen from the tables, both Options 1 and 2 are similarly effective at identifying substances that need additional classification once registration requirements reach 'Medium'. Option 3a identifies almost 30% less than Options 1 and 2 because it excludes Polymer Groups A, B, D and E from registration. Option 3b is less neffective because it also excludes Group F from registration.

Table 10.3: Percentage of Expected Maximum Already Classified Polymers Requiring Additional Classification

	Screening Option 1: Screening Based on Diffuse Use Only	Screening Option 2: Multidimensional Screening	Screening Option 3a: Linear Screening	Screening Option 3b: Linear Screening
Low a	0%	0%	0%	0%
Low b	21%	9%	9%	9%
Low-Medium	60%	9%	9%	9%
Medium	62%	61%	33%	22%
Medium-High	66%	63%	35%	22%
High	71%	65%	37%	23%

Newly Identified Persistent, Bioaccumulative and Toxic (PBT)/Very Persistent and Very Bioaccumulative (vPvB) and CMR 1A, 1B, 2 or Lact. Classifications

Table 10.4 provides the number of polymers that would identified as requiring a new classification as a PBT/vPvB or a CMR 1A or 1B under each option, while Table 10.5 provides an indication of those that would be Newly identified as CMR 1A, 1B and 2 as set. These are either classifications for previously unclassified substances or additional classifications for polymers with an existing classification for another class. Table 10.6 provides the data expressed as a percentage of the expected (i.e. maximum) numbers provided above. The majority of these newly identified substances will be CMRs rather than PBTs or vPvBs.

As can be seen from the tables, Options 1 and 2 are most effective and are able to identify between 40% and 60% of the expected number of PBT, vPvB, CMR 1A and 1B or CMR 2 polymers. Option 1 - High is the most effective, where this option provides the same testing requirements as those for other substances under REACH.

Table 10.4: Number of Polymers Newly Identified as PBT/vPvB or CMR 1A or 1B				
	Screening Option 1: Screening Based on Diffuse Use Only	**Screening Option 2: Multidimensional Screening**	**Screening Option 3a: Linear Screening**	**Screening Option 3b: Linear Screening**
Low a	-	-	-	-
Low b	75	10	10	10
Low-Medium	242	10	10	10
Medium	249	162	37	24
Medium-High	266	164	39	24
High	284	166	41	26

Table 10.5: Number of Polymers Newly Identified as CMR 1A, 1B, or 2				
	Screening Option 1: Screening Based on Diffuse Use Only	**Screening Option 2: Multidimensional Screening**	**Screening Option 3a: Linear Screening**	**Screening Option 3b: Linear Screening**
Low a	-	-	-	-
Low b	226	29	29	29
Low-Medium	725	29	29	29
Medium	748	486	110	71
Medium-High	798	492	116	73
High	852	499	123	77

Table 10.6: Percentage of Expected Maximum Newly Identified PBT/vPvB/CMR 1A, 1B, or 2				
	Screening Option 1: Screening Based on Diffuse Use Only	**Screening Option 2: Multidimensional Screening**	**Screening Option 3a: Linear Screening**	**Screening Option 3b: Linear Screening**
Low a	0%	0%	0%	0%
Low b	19%	2%	2%	2%
Low-Medium	60%	2%	2%	2%
Medium	62%	40%	9%	6%
Medium-High	66%	41%	10%	6%
High	70%	41%	10%	6%

10.3 Chemical Safety Assessment Requirements

10.3.1 Introduction

As noted previously, one of the main aims of REACH is to provide a high level of protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemicals and their uses. One of the key

elements within the Regulation for delivering these benefits is through requirements for the preparation of Chemical Safety Assessments (CSA) as part of the Chemical Safety Report. The preparation of a CSA and communication of the findings of this should lead to:

- uses where adequate control of risks cannot be demonstrated not being supported by the registrant, with this also being communicated in the SDS (although in such cases, under Article 37 downstream users are able to prepare a CSA in accordance with Annex XII of REACH to support their own continued use, unless exempted from so doing);
- risk management measures being (newly) identified and communicated so as to ensure safe use;
- manufacturers learn more about uses and better targeting their information provision towards controlling and reducing risks, as a result of the need to collect information from downstream users in order to prepare the CSA;
- a formal assessment of PBT properties, as this is an explicit requirement within the CSA; and
- advice on waste management becoming more specific in order to ensure safe disposal.

Almost all of the options have CSA requirements for some polymer groups identified by screening. The groups and the total number of CSAs for each option are provided in Table 10.7.

As indicated above, the aim of the exposure assessment carried out as part of a CSA is to enable registrants to identify appropriate risk management measures (RMMs), with these then circulated through the extended SDS. The circulation of such data throughout chemical supply chain is intended to better ensure the safe use of chemicals, thereby delivering human health and environmental benefits by either providing more detailed information or by requiring a higher level of risk management than has previously taken place.

In these cases, a chemical safety assessment and the communication of information to downstream users through extended SDS may be of considerable value in ensuring that workers are adequately protected. This might also help ensure that other legislation, such as requirements under the Chemical Agents Directive or under the Carcinogens and Mutagens Directive (2004/37/EC) can be implemented effectively. Where PBT or vPvB properties trigger the need for a CSA this would include an assessment of these properties, which may help reduce emissions of such substances into the environment (depending on the nature of the uses and current emissions).

Table 10.7: CSA Requirements under the Options and Associated Number of CSAs					
Screening Option	**Registration Option**	**Requirements as for On-site Isolated Intermediates (CSR based on existing data only - all tonnage bands)**		**Testing Requirements and Production of CSA for >100t substances (>10t when marked with *)**	
		Groups	**Number of Polymers**	**Groups**	**Number of Polymers**
Screening Option 1: Screening Based on Diffuse/Dispersive Use (D) and Non-Diffuse/Dispersive Use (ND) Only	Low	All	70,000		
	Low b	ND	60,288	D	1,942
	Low-Medium			D	1,942
	Medium			D	1,942
	Medium-High			D	1,942
	High			D*	5,828
Screening Option 2: Multidimensional Screening	Low a	C, F, G	29,522		
	Low b	C, F	24,977	G	909
	Low-Medium	All except G	65,455	G	909
	Medium	A	6,891	C,E,G	1,770
	Medium-High	A	6,891	C,E,G*	3,588
	High	A	6,891	C,E,G*	3,588
Screening Option 3a: Linear Screening as in Figure 1.2	Low a	C, F, G	29,522		
	Low b	C, F	24,977	G	909
	Low-Medium	C, F	24,977	G	909
	Medium			C,G	1,081
	Medium-High			C,G*	2,899
	High			C,G*	2,899
Screening Option 3b: Linear Screening as in Figure 1.3	Low a	C,G	5,407		
	Low b	C	862		
	Low-Medium	C	862	G	909
	Medium			C, G	1,081
	Medium-High			C, G*	2,899
	High			C, G*	2,899

It should be noted that the extended monomer registration options would also deliver such benefits. Under these options, the monomers linked to the different groups of polymers would need to included CSAs within their registration dossiers. This would have the effect of increasing the level of information provided through the supply chain, including recommended risk management measures, where polymers have hazardous properties. In this respect, if requirements for polymers were phased in after 2015, when additional classifications should be available under CLP, then it would be possible for monomer registrants to use the basis of the CLP classifications for their exposure assessments and the development of risk management recommendations (although it must also be recognised that CLP classification following the mixture rules will not produce DNELs or PNECs to act as the basis for detailed exposure assessment).

10.4 Linkages to Other Legislation

10.4.1 Overview

While it is not the explicit purpose of REACH to deliver information on substances in order to facilitate the implementation of other pieces of EU legislation, the value of information generated under REACH to regulators is recognised under Recital 14, which states that:

> *"Available information, including that generated by this Regulation, should be used by the relevant actors in the application and implementation of appropriate Community legislation, for example that covering products, and Community voluntary instruments, such as the eco-labelling scheme."*

In addition, Recital 21 states that the information yielded on substances under REACH *"may also be used to initiate the authorisation or restrictions procedures under this Regulation or risk management procedures under other Community legislation."*

As such, the increased availability of information on substances and their uses resulting from REACH generates benefits in informing the implementation of other EU legislation. Since this is not an explicit objective of REACH, these may be considered ancillary or indirect benefits.

The remainder of this sub-section describes the potential scope of such ancillary benefits, by identifying to what extent the data requirements of other EU legislation may be met under the options.

10.4.2 The Classification, Labelling and Packaging Regulation

Worker health and safety in particular, but also some environmental and product legislation, relies on hazard classification to trigger a risk assessment. For example, the Carcinogens and Mutagens Directive 2004/37/EC (CMD) relies on the identification of carcinogenic and mutagenic properties to trigger its provisions, without demanding a separate hazard assessment. The CMD currently refers to DSD/DPD classifications for these properties but work is underway to amend the CMD to refer to Carc. or Muta. (1A and 1B) under the CLP Regulation (Regulation (EC) No 1272/2008).

CLP classifications are based on available data. With the exception of data on physicochemical properties, there is no requirement under CLP for the generation of additional information solely for the purposes of classification. However, companies may choose to generate new data while fully respecting Articles 7 and 8 of CLP.

Article 5 (1) of the CLP Regulation provides a list of other data sources and for some substances this may include pre-existing data, and/or data generated under independent studies, or under other EU legislation (e.g. Biocides, Plant Protection Products, Cosmetics, Food Contact Materials legislation). However, for some

chemical substances manufactured or imported into the EU, REACH may represent the main tool for generating data.

Thus, as discussed above, new data generated by REACH should make CLP classifications more reliable. In this respect all Extended Monomer options would result in the generation of no additional information to that already available or required under CLP (i.e. physicochemical data if this does not already exist, as this must be provided for conformance with the CLP Regulation). Options 1 and 2 (with appropriate information requirements) would deliver improved information on hazardous properties for both polymers with and without an existing classification. Similarly, Options 3a and 3b would provide information on new classification endpoints but here only in relation to polymers with an existing classification.

The effectiveness of each polymer registration option in relation to identification of hazardous properties is provided in Table 10.8. As already noted, the Extended Monomer Options would not lead to the identification of any new hazard information.

As any new classification information would be included in a revised SDS, together with any changes to labeling and recommendations for safe use, it would enable downstream users to adapt their handling and use accordingly.

Table 10.8: Effectiveness of Options at Developing New Hazard Data and Classifications

	Screening Option 1: Screening Based on Diffuse Use Only	Screening Option 2: Multidimensional Screening	Screening Option 3a: Linear Screening	Screening Option 3b: Linear Screening
Low a	0%	0%	0%	0%
Low b	19%	2%	2%	2%
Low-Medium	60%	2%	2%	2%
Medium	62%	40%	9%	6%
Medium-High	66%	41%	10%	6%
High	70%	41%	10%	6%

10.4.3 Legislation on the Health and Safety of Workers

Legislation on the health and safety of workers than may benefit from new information on hazardous properties through changes in classification includes:

- Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD);
- the Carcinogens and Mutagens Directive 2004/37/EC (CMD);
- the Young Workers Directive 94/33/EC; and
- The Pregnant and Breastfeeding Workers Directive 92/85/EEC.

The CAD, CMD, Young Workers Directive and Pregnant Workers Directive all require the employer to undertake a risk assessment. The first step of the risk

assessment involves the identification of hazards for which employers will draw on SDS provided by suppliers, as these need to be communicated for all substances independently of their production volumes in order to fulfil the requirements of CLP. Employers then combine this hazard data with exposure data generated for specific workstations to assess the risk to individual workers. The SDS should enable the employer to assess the risk to the health and safety of workers.

As such, having improved information on the hazardous properties of polymers should also improve the ability of employers to assess the risks to their workers of the use of different chemicals and to take action to reduce these. However, it must be remembered that an SDS will include exposure characterisation and handling instructions but will not include more detailed exposure scenarios and risk assessments.

Given that the options will vary with respect to the level and quality of information generated on hazardous properties, the potential benefits in terms of improving employers' ability to protect workers will vary across the options. In relation to CMR and PBT properties, those options that require the generation of information on mutagenicity, reprotoxicity and repeated dose toxicity are likely to lead to the greatest benefits as such classifications trigger specific requirements under the above listed legislation. **As such, those options requiring information equivalent to Annexes VIII and above (Registration Options 'Medium' and above) are likely to the greater benefit)**.

In addition, where there is a requirement for the preparation of a CSA as part of Options (see Section 8), then the exposure assessments produced by registrants in order to fulfil this requirement could be used directly by the employer in order to fulfil his workplace risk assessment obligations under the various worker health and safety legislation.

No attempt is made here to try and quantify the number of future cases of different types of health effects or environmental impacts that may be avoided through the availability of better information on the hazardous properties of polymers. We believe there is too much uncertainty surrounding key assumptions, such as the numbers of polymers being placed on the market, the likelihood of polymers having different hazardous properties, etc. for such calculations to be developed.

Furthermore, it is not possible to derive meaningful estimates of the total population exposed, due to the lack of data on uses and final applications of polymers with unreacted monomers (i.e. superglues) or otherwise hazardous properties. However, using the Structural Business Statistics database of Eurostat, an estimate on the workers population that might be exposed to polymers with unreacted monomers has been provided and presented in Figure 10.2.

For these estimate, employment within four NACE codes has been considered:

- C20.16: manufacture of plastics in primary forms;
- C20.17: manufacture of synthetic rubber in primary forms;

- C22.1: manufacture of rubber products; and
- C22.2: manufacture of plastics products.

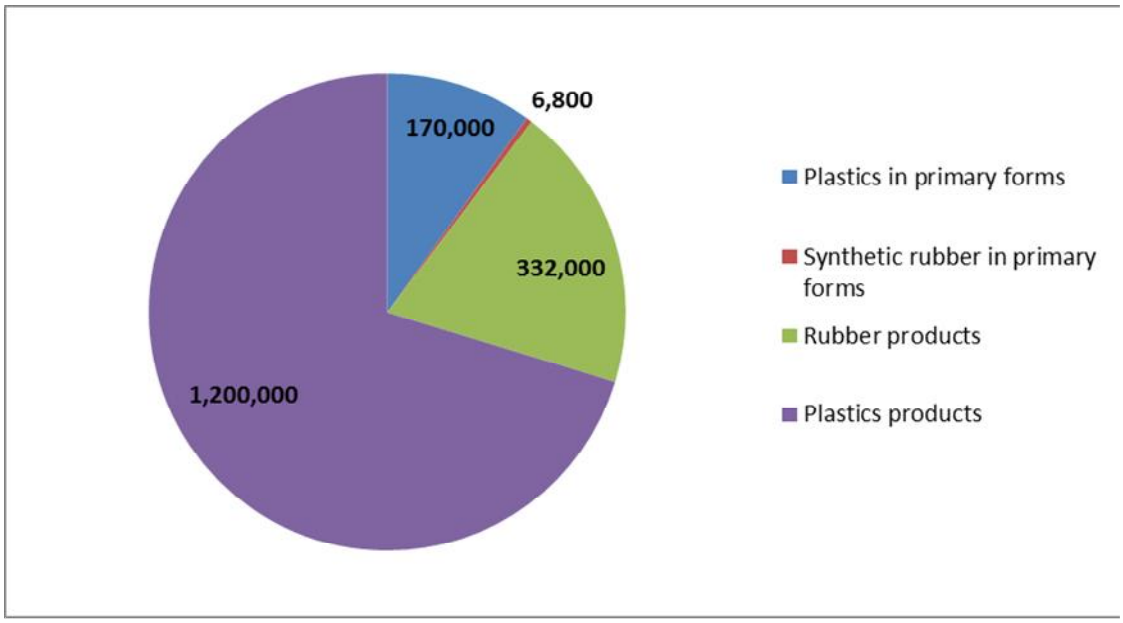


Figure 10.2: Potential exposed workers population

10.4.4 Legislation on the Environment

The implementation of some environmental legislation benefits from the increased availability of data on substances resulting from REACH registration, as well as from the CLP notification requirements. The increased availability of hazard data (as well as data from a CSA where available on environmental risks associated with a particular use) is valuable in determining whether risk management measure should be applied. Hazard data allow for the identification of specific pollutants that may pose a risk to the environment, while data drawn from exposure scenarios – where these are available – can be useful in pointing to potential exposure pathways.

Key sectors of environmental legislation that could benefit from increased information requirements for polymers include waste and water legislation.

- Waste legislation of relevance includes Directive 2008/98/EC (the Waste Framework Directive) establishes a legal framework for the treatment of waste within the Community and the Landfill Directive 1999/31/EC; and

- Water legislation of relevance includes the Water Framework Directive 2000/60/EC (WFD), and its daughter Directives on hazardous substances and groundwater.

10.4.5 Legislation Regulating Products

The chief benefit of REACH registration data to legislation regulating products is derived from the use of that data by producers to identify any risks that their products may pose to consumers. Producers draw on data in SDS on the hazardous properties of an individual substance and associated toxicity endpoints and marry this with information on product use to assess risks. For polymers no toxicity data is required to be generated under REACH, although available data on classifications would need to be reported in SDS.

In order to assess the potential benefits of further information requirements for polymers, one requires information on the extent to which polymers are extensively used in a regulated product group. Within the scope of this study, it is not possible to identify those types of products where the availability of new information to producers would be of greatest value.

11. SUMMARY COMPARISON OF COSTS AND BENEFITS

11.1 Overview

This study has examined a range of options for information requirements for the registration of polymers, plus an option to extend the current registration requirement for monomers to include the risks from the polymers made from them throughout the life cycles of those polymers. These information options have been applied in combination with three screening options so that the level of information requirements is proportionate to the likelihood of risks to human health and/or the environment from exposures to polymers. The information and screening options have been integrated to produce registration options designed to identify how best to minimise costs to industry, including to innovation and competition, while maximising the benefits to human health and the environment.

The options were detailed in Section 8, while the assumptions used to assess the associated costs and to predict the number of substances that would be newly identified as having hazardous properties are set out in Section 7. Sections 9 and 10 provide discussion on the costs and the benefits respectively of the registration options, including the estimated costs to polymer manufacturers/importers and the findings with respect to the numbers of newly identified hazardous polymers. Section 9 also discusses related issues such as the potential impacts of the options on innovation and competition, with a focus on micro and small enterprises.

This section summarises our findings and brings together the information on costs and benefits to enable a comparative assessment.

However, before so doing, we would note that there is a significant, but unquantifiable, level of uncertainty associated with many aspects of the quantitative assessment undertaken for this study. For example, key assumptions regarding the proportion of polymers with specific hazard properties, and the numbers of polymers that would be subject to separate registrations are highly speculative. With regards to these two key assumptions, industry did not provide the data that it had gathered in its own study and which may have helped reduce this uncertainty. Although separate dta were collected and consultation was undertaken with polymer manufacturers not forming part of the PSG, the quantitative assessment presented here should be considered to be indicative only. This issue of uncertainty is addressed further in the sub-sections which follow.

11.2 Total Numbers to be Registered Under the Different Options

A complex range of options has been examined in this study with this including combinations of:

- **Information requirements** which set out what types of information would need to be provided as part of a registration data, with this varying from requirements

as for on-site isolated intermediates to full Annex VII to Annex X information as applies to other substances; and

- **Screening** to target those groups of polymers that would be subject to the registration requirements in terms of the classification of the monomer, whether the polymers may meet criteria for being polymers of low concern (PLC), and the nature of downstream uses and whether these are likely to be classed as dispersive or diffuse.

Varying combinations of these information and screening requirements result in the **polymer** and **extended monomer registration options**, which have been assessed in detail. See Tables 9.3 to 9.5 for summaries of the differences between the options.

The total numbers of polymers to be registered by tonnage band or the number of polymers that would be covered by an extended monomer dossier under the different options are presented in Table 11.1.

11.3 Polymer Hazards

The information available to this study has been sufficient to demonstrate that there are human health and environmental hazards associated with some polymers (Section 4), with the OECD (2009) finding that over 50% of polymers it considered posed environmental hazards for example. Data obtained from the Classification and Labelling Inventory (CLI), although representing only a small proportion of polymers, suggest that the hazard profile of polymers may be similar to the profile for all substances in the CLI. When the hazard profile of those polymers notified to date is compared to a limited sample of key monomers, the monomers were found to be more likely to have CMR properties and are more likely to be hazardous to the aquatic environment (acute and chronic).

Industry has indicated that a significant proportion of polymers are placed on the market for further polymerisation without meeting the criteria for being an intermediate, as defined by REACH (PSG, *pers. comm.*, cf. Section 2). In order for these polymers to be capable of further polymerisation, they typically include levels of monomer above the threshold for the classification of mixtures based on individual substance classifications under CLP, plus oligomers. This would appear to support arguments that a significant proportion of polymers may have properties that pose hazards to human health and the environment, including CMR properties.

It must be noted though that at this time only a small percentage of polymers would appear to have been notified to the CLI (at around 1,100 when using the search term "polymer"). This discrepancy with the assumed level of hazard and the assumed number of polymers may be due to the factors listed here, probably in combination.

Table 11.1: Number of polymers to be registered by tonnage band (scenario I) and number of polymers covered by extended monomer dossiers (scenario II)						
		>1000 tpa	**>100 tpa**	**>10 tpa**	**>1 tpa**	**Total**
I. Separate registration for polymers						
Option 1	**Low a**	3,500	10,500	28,000	28,000	70,000
	Low b	3,500	10,500	28,000	28,000	70,000
	Low-Medium	3,500	10,500	28,000	28,000	70,000
	Medium	3,500	10,500	28,000	28,000	70,000
	Medium-High	3,500	10,500	28,000	28,000	70,000
	High	3,500	10,500	28,000	28,000	70,000
Option 2	**Low a**	600	1,800	4,750	4,750	11,900
	Low b	600	1,800	4,750	4,750	11,900
	Low-Medium	3,500	10,500	28,000	28,000	70,000
	Medium	3,500	10,500	28,000	28,000	70,000
	Medium-High	3,500	10,500	28,000	28,000	70,000
	High	3,500	10,500	28,000	28,000	70,000
Option 3a	**Low a**	600	1,800	4,750	4,750	11,900
	Low b	600	1,800	4,750	4,750	11,900
	Low-Medium	600	1,800	4,750	4,750	11,900
	Medium	600	1,800	4,750	4,750	11,900
	Medium-High	600	1,800	4,750	4,750	11,900
	High	600	1,800	4,750	4,750	11,900
Option 3b	**Low a**	400	1,150	3,000	3,000	7,550
	Low b	400	1,150	3,000	3,000	7,550
	Low-Medium	400	1,150	3,000	3,000	7,550
	Medium	400	1,150	3,000	3,000	7,550
	Medium-High	400	1,150	3,000	3,000	7,550
	High	400	1,150	3,000	3,000	7,550
II. Extension of monomer Registration to include polymers (polymers covered)						
Option 1	**Low**	1,100	3,300	8,800	8,800	22,000
	High	3,500	10,500	28,000	28,000	70,000
Option 2	**Low**	400	1,100	3,000	3,000	7,600
	Low-Medium	600	1,800	4,800	4,800	11,900
	Medium-High	800	2,400	6,500	6,500	16,200
	High	1,300	3,900	10,500	10,500	26,300
Option 3a	**Low**	200	500	1,300	1,300	3,300
	Medium	400	1,100	3,000	3,000	7,600
	High	600	1,800	4,800	4,800	11,900
Option 3b	**Low**	200	500	1,300	1,300	3,300
	High	400	1,100	3,000	3,000	7,600

1. Many polymer substances do not have "polymer" (or poly) in the chemical name under which they have been notified. There is some support for this argument as a search of the Japanese PolyInfo database found that only 19,000 of the 35,000 polymers included within had the phrase "poly" in the name. However, this also means that a greater percentage do.

2. The findings of the OECD (2009) study are misleading and only a relatively small percentage of polymer substances are hazardous to human health or the environment, and the proportion of polymers that have properties warranting classification are lower than assumed here.

3. Some polymer manufacturers may consider themselves to be downstream users of notified polymers, not manufacturers of new polymers and have not therefore notified their polymers to the CLI.

4. Some polymer manufactures may consider themselves to be producing mixtures of polymer and monomer, particularly where the polymer contains high concentrations of monomers for further polymerisation, and/or high concentrations of monomers acting as solvents.

5. More than one polymer has been grouped under a single entry in the CLI.

All five of the factors listed above have been derived from discussions with chemical manufacturers (including monomer and polymer producers) and with the PSG (pers. comm.) during this study. However, industry was unable to estimate the extent of factors one to three and were unwilling to provide details of data held by the PSG that of relevance to factor four.

As a result, a range of assumptions were made for the purposes of the assessment carried out here to predict the numbers of polymers that may be newly identified as having different properties. Based on these, the expected numbers of polymers to be found as having new or additional classifications was calculated, with these figures given in Table 11.2 below.

11.4 Polymer Substance Identification

The number of 'polymers' subject to registration under the different options would be dependent upon the ability of registrants to be able to group similar polymers for the purposes of registration (i.e. determine sameness). In principle, this is an issue faced by registrants of other complex substances but industry has indicated its belief that this issue will be greater for potential polymer registrants (PSG, *pers. comm.*). However, industry has expressed the opinion that all the criteria for determining polymer substance identification and grouping ready for registration are available and that it would take approximately two years for this process to be completed.

Table 11.2: Expected Numbers of Newly Classified or Additionally Classified Polymers					
Polymer Group	**>1000 tpa**	**>100 tpa**	**>10 tpa**	**>1 tpa**	**TOTAL**
Previously Unclassified Polymers that would require New Classification (if tested according to Annex X requirements)					
A	336	1009	2689	2689	**6723**
B	0	0	0	0	**0**
C	0	0	0	0	**0**
D	277	832	2,219	2,219	**5,547**
E	119	356	951	951	**2,377**
F	0	0	0	0	**0**
G	0	0	0	0	**0**
Total	**732**	**2,197**	**5,859**	**5,859**	**14,647**
Already Classified Polymers that would require Additional Classification (if tested according to Annex X requirements)					
A	0	0	0	0	**0**
B	126	378	1009	1009	**2,522**
C	54	162	432	432	**1080**
D	0	0	0	0	**0**
E	0	0	0	0	**0**
F	54	162	432	432	**1,080**
G	41	122	325	325	**813**
Total	**275**	**824**	**2,198**	**2,198**	**5,495**
Polymers that would require Additional Classification as PBT, vPvB or CMR 1A, 1B or 2 (if tested according to Annex X requirements)					
A	20	61	161	161	**403**
B	8	23	61	61	**151**
C	3	10	26	26	**65**
D	17	50	133	133	**333**
E	7	21	57	57	**143**
F	3	10	26	26	**65**
G	2	7	20	20	**49**
Total	**60**	**181**	**483**	**483**	**1209**

The implication of the above though is that it has been impossible in the analysis carried out above to make any assumptions as to the number of group registrations rather than individual polymer registrations that may exist under the different polymer registration options. As a result, it may be appropriate to consider the cost estimates presented in Section 9 of this report as worst case estimates – i.e. they assume that each polymer would be registered in its own right rather than as part of a broader group which would enable cost savings.

This is important. As discussed below (and in detail in Section 10 of this report), Options 1 and 2 are the most effective in identifying new hazardous properties but may also be less affordable for industry than some of the other options, if one assumes that all polymers are registered individually. If, instead, polymers are registered in groups comprising several substances, then Options 1 and 2 should become much more affordable, with this resulting in reduced impacts in terms of the diversion of funds from research and development and hence innovation. This is particularly true if grouping continues to enable joint registration of polymer substances.

To achieve this suggests that no registration requirements should be introduced until industry has been given the time to complete its proposed polymer substance identification and grouping process. This suggests that any future registration of polymers would allow at least two years for substance identification and grouping and a further two years for the preparation of registration dossiers (i.e. a minimum of four years between the implementation of registration provisions and the requirement to submit registration dossiers).

11.5 Extending Monomer Registrations

Currently, monomer registrants may not submit a registration dossier with the reduced information requirements set for isolated intermediates, even where these monomers meet the criteria for such intermediates under REACH. The vast majority of key monomers identified by this study were found to have already been registered and it is therefore to be expected that significant numbers of monomers, including all monomers produced in quantities of 100 tonnes or more per registrant per year will have been registered by the time that any registration provisions could come into force for polymers. It is not known the extent to which some or all of the registered tonnage of these monomers meets the criteria for isolated intermediates.

In comparison to the polymer registration options, extending the requirements for monomer registrations results in significantly lower costs. In these cases, it is assumed that registrants would need to update (if already registered) or expand (if not registered) their chemical safety assessments and extended safety data sheets, as well as the overall chemical safety report. However, the costs of doing this across the assumed 10,000 monomers is, as one would expect, lower than the costs of submitting registrations for an estimated 70,000 polymer substances. The costs would be borne by a different set of actors though, with monomer manufacturers rather than polymer producers bearing the costs; clearly there will be some overlap but the extent of this is not known.

The key difference between the extended monomer registration and the polymer registration options is that the latter would be expected to identify some new hazardous properties both for already classified and currently unclassified polymers. The extended monomer registrations will have to rely on classifications developed under CLP for polymers to act as the basis for the identification of hazardous properties. This may result in some newly classified polymers, but with a lack of test data on individual polymers, such classifications may not be reliable (they may under or over classify). Even so, if a requirement for such classifications to be passed upstream to monomer registrants existed, and for these registrants to then extend their CSAs and CSRs to account for any hazardous polymers within their exposure assessments and extended safety data sheets, then there may still be benefits from the communication of better data on the safe use of polymers through the supply chain.

If registration is to be required for polymers, then it should be noted that registrants of monomers that meet the criteria for isolated intermediates will have incurred unnecessary costs from being required to submit a full registration rather than a registration dossier for an intermediate. Furthermore, some registrants that have registered substances for use as monomers will have had to include the volume supplied for use as a monomer, and thus may have incurred the additional costs of registering above a higher tonnage threshold. As these costs have already been incurred (sunk costs) and, as the review of the polymer registration was written into the REACH text, they could essentially be considered to be due to the normal implementation of REACH.

11.6 Costs and Benefits

11.6.1 Estimated Total Costs

Section 9 provides data on the costs that would be incurred by companies to provide data on the substance ID and the additional tests required under each option, as well as the calculated registration costs and registration fees. These are summarized here in Figure 11.1 (which is a repeat of Figure 9.3). As expected, the costs of testing and generating information increase with the amount of information required (although the costs of substance ID remain constant across the options) which, as expected, constitute the major cost burden.

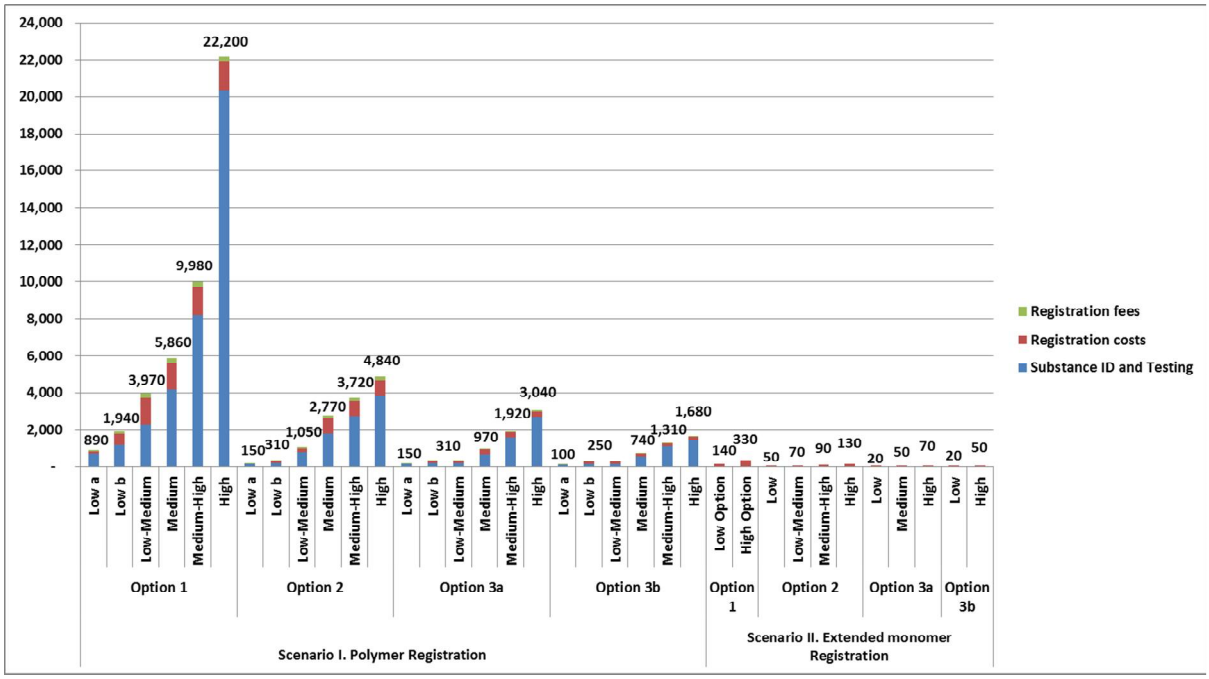


Figure 11.1: Total costs for options and by cost type (€ million)

As the options relying on an increased level of screening depend on whether a polymer is likely to meet the criteria for being of low concern (i.e. a PLC) and/or to have dispersive or downstream uses, the costs to companies decrease significantly; combining these two criteria with those on the likely classification of the monomer lowers the numbers of polymers that would have to be registered. The total costs under Option 1 and the higher information requirements are estimated at around €22 billion for polymers, while those under the lowest registration requirements (option 3b low) are around €100 million for polymers. This is due to the higher number of tests and the higher costs of the testing requirements associated with the different requirements under the Options. For the monomer registration options, the costs range from €20 million to €330 million.

The estimated costs for the higher registration requirements under Options 1, 2 and 3a are all significant, given that the turnover of the plastics raw material production and converting sectors together are estimated at €307 billion, with imports only accounting for a further €1.4 billion. The impacts of these on the sector would depend on the degree to which such costs could be spread over time, assuming that polymer registration requirements were phased as has been the case for other phase-in substances.

11.6.2 Average Costs Per Substance

In this respect, it is also useful to consider the average cost per polymer registered. This is illustrated in Figure 11.2, with Section 9 detailing the underlying numbers.

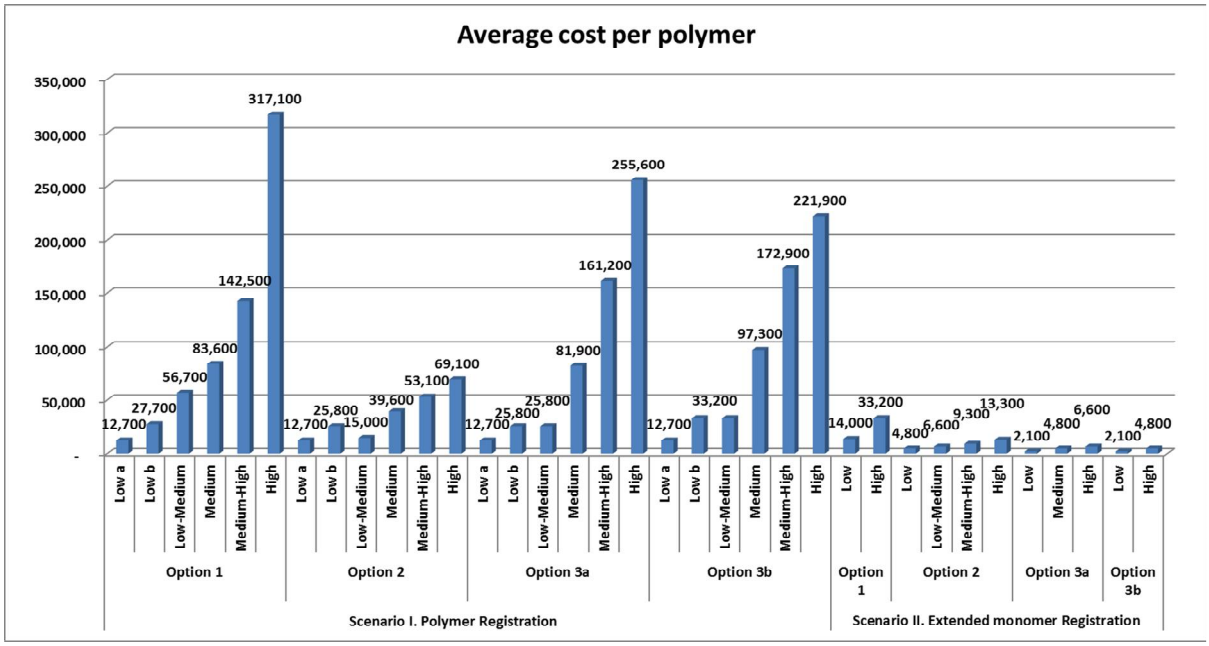


Figure 11.2: Average cost per polymer registered or per extended monomer Registration dossier (€)

Average costs range from around €12,700 to register a polymer providing the same information as for isolated intermediates (under Option 1, Low a) to almost €320,000 to register a polymer providing all the information up to Annex X with a Chemical Safety Assessment including exposure scenarios. The average costs per polymer for producing the exposure information needed to extend a monomer registration dossier are estimated at between €2,100 and €33,200, with these costs varying depending on substance properties, tonnage band and whether downstream use is classed as dispersive/non-dispersive use.

It is important to remember that these average cost figures are taken across polymers produced in different tonnages, with different classifications (including none) and which under some of the options would therefore face different information requirements. Given that under the medium high and high registration options these can include full REACH information requirements for some groups of polymers, the variations from the averages may be significant for some polymers.

11.7 Cost-Effectiveness

From the discussion provided in Section 10 on effectiveness, as one increases information requirements and number of polymers required to generate information, so this is accompanied by more extensive and reliable information on the hazard properties of the polymers. At the same time, however, it is also accompanied by an increase in the costs of implementing the option. As such, a comparison of the costs of requirements with their effectiveness provides useful information on the benefits of options in relation to cost and the incremental costs and benefits of moving up

through the options. Table 11.3 provides a summary of the cost-effectiveness of the different polymer registration options in newly identifying hazardous properties.

As can be seen from the Table, under Option 2 and the Medium registration requirements (which equate to all substances requiring at least the information set out in Annex VII) around 60% of the newly classified substances are likely to be identified. Increasing the requirements above this achieves only small increases in the percentage of substances newly identified but significant increases in the associated costs, and appears not to produce an increase in the cost-effectiveness of the option. Thus, measuring cost-effectiveness only in terms of identification of newly hazardous substances, Option 2, Medium information has a cost of €0.58 million per new substance for classification; the cost per substance identified increases markedly as one progresses from this to the higher information Options. The same is the case for Option 1.

Because Options 3a and 3b screen in part on the basis of existing substance classifications, they do not identify any currently unclassified substances needing a new classification. However, for substances that are already classified, they do result in the new identification of substances with PBT, vPvB, and CMR properties. They identify fewer though than Options 1 and 2 because of the screening out of substances which currently do not hold any classifications. As a result, they are less cost-effective in identifying polymers with these properties of high concern.

This analysis is not applicable to the extended monomer registration options as they do not require the generation of any information on the classification of the polymers, rather they place obligations on including the polymer uses in the monomer CSA.

Table 11.3: Average Cost per New Classification (Million Euros per Substance Identified)

	Screening Option 1: Screening Based on Diffuse Use Only	**Screening Option 2: Multidimensional Screening**	**Screening Option 3a: Linear Screening**	**Screening Option 3b: Linear Screening**
New Substance with Classification Identified				
Low a	None Identified	None Identified	None Identified	None Identified
Low b	0.74	None Identified	None Identified	None Identified
Low-Medium	0.45	None Identified	None Identified	None Identified
Medium	0.65	0.58	None Identified	None Identified
Medium-High	1.03	0.78	None Identified	None Identified
High	2.15	1.02	None Identified	None Identified
Substance with Newly Identified or Additional PBT, vPvB and CMR 1A, 1B, 2 Classification				
Low a	None Identified	None Identified	None Identified	None Identified
Low b	8.6	10.5	10.5	8.6
Low-Medium	5.5	35.8	10.5	8.6
Medium	7.8	5.7	8.9	10.4
Medium-High	12.5	7.6	16.5	17.9
High	26.1	9.7	24.8	21.8

The above analysis highlights that the benefits that would be expected from the registration of polymers through the identification of new hazardous properties, and the communication of these through the supply chain, will vary across the options. As stated above, it is assumed that polymers marketed for further polymerisation are more likely to be hazardous and, by their nature, these are more likely to be used in industrial or professional settings. Therefore, any human health benefits are likely to be greater for workers than for the general public.

11.8 Other Factors

The above discussion has considered the estimated total costs of each option as well as the potential human health and environmental benefits in terms of the effectiveness of identifying hazards associated with the use of polymers. There is a series of other factors which should also be taken into account. These can be summarised as follows:

- **Internal market**: REACH is an internal market regulation, and is intended, inter alia, to ensure that there are no barriers to trade across the EU in terms of variations in the requirements of Member States on the registration and use of polymers. As a result, if no initiative on polymers would be carried forward at the European level, Member States may introduce their own legislative initiatives, introducing a distortion into the internal market.

- **Wider health and environmental benefits**: It has not been possible to quantify the potential benefits from the introduction of registration requirements for polymers. However, it is clear that some polymers do have hazardous properties and thus that there may be impacts on both workers and downstream users (including the general public) through exposures to these, although this will depend on the degree to which these properties are already classified and labeled, the level of such exposures, and the extent to which risk management measures are already adopted.

- **Innovation**: The issue of innovation was examined in Section 9. Clearly, the lower the costs to industry the lower the likely knock-on effects for innovation, assuming that there remains a level playing field across the EU with regard to national requirements. This suggests that either extended monomer registration or Screening Option 3b may have the lowest impact on innovation, followed by Option 3a and Option 2. Given the significant increases in costs associated with Option 1, this option is assumed to give rise to the most significant impacts on innovation. However, the costs presented above may be significant overestimates if industry is able to find approaches to the grouping of polymers for registration purposes; this possibility could not be taken into account in our analysis.

  Nevertheless, the withdrawal of substances from the market, for example, in response to the total costs of registration could have knock-on effects for the level of innovation in downstream user sectors. This is because polymer withdrawal may remove critical inputs from the market or may result in costly reformulation

activities, with these acting as a diversion of research and development expenditure in the affected sectors.

- **Competitiveness**: Competitiveness concerns arise at three different levels. The first is the potential impact which registration costs may have on the ability of micro, small and medium sized enterprises to continue the manufacture and supply of high performance polymers within the EU, as discussed in Section 9.

  At the second level, the costs of registering polymers and the need for registrants to pass these downstream to their customers may increase the costs of producing other goods and services in the EU. This may therefore impact on the competitiveness of the polymer manufacturing sector (in terms of extra-EU exports) as well as downstream user sectors in placing their products on the global market. Such potential impacts should be minimal under the lower information requirement options (low a, low b and low-medium).

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ANNEX 1

APPROACHES TO THE RISK ASSESSMENT OF POLYMERS

A1.1 Approach to Polymer Assessment in Europe: Dangerous Substances Directive (DSD) 67/548/EEC (Annex VII D) – the 'Family Approach'

Directive 67/548/EEC, the Dangerous Substances Directive (DSD) with its subsequent amendments, has provided the historic basis for regulating the classification, packaging and labelling of dangerous substances within Europe. The 6th Amendment (79/831/EEC) of the DSD established the procedures on the notification of new substances within the Community from September, 1981 (COM, undated). Introduced in the 6th Amendment, Annex VIID established the information requirements for the technical dossier referred to in Article 12 that are specific to polymers; this established reduced test data requirements for polymers across the various tonnage categories (see Annex 2 of EC, undated) and established the concept that polymers may be grouped together, including an option to adopt a 'family approach'. Such a grouping of polymers was permitted at two levels based on establishment of either a narrow (under a definition of a polymer 'substance') or a wider range of defining characteristics (i.e. as a polymer family) for which the underlying assumption is that, in principle, members of a family will possess a similar hazard profile. This modification of the approach to notification of polymers allowed for multiple industry notifiers to, if they wished, submit a single technical dossier to cover data requirements for multiple polymers.

The criteria used to establish either a narrow range defining a polymer 'substance' or a polymer 'family' are considered below.

A1.1.1 Notification as a Substance

For polymers, definition of substance in 67/548/EEC is interpreted as "a narrow group of (co)polymers of similar composition and/or similar molecular weight (Mn) values, even if the small variations are due to deliberate alterations to the process conditions, as long as the process itself remaining unchanged". Thus, for group notifications the variations in composition must be within the following specified limits:

(a) for homopolymers, molecular weight may vary by up to three-fold;

(b) for co-polymers where
  (i) molecular weight remains approximately constant (within two-fold) and composition varies by ±10% absolute; or
  (ii) composition is approximately constant (±3% absolute) and molecular weight varies up to three-fold.

Notification was based on the total tonnage of polymers falling within the definition of the 'substance'.

A1.1.2 Notification as a Family

Where notifiers wished to submit a notification for a number of polymers that showed a range of molecular weights or compositions which exceeded the definitions used to define a 'substance', the option was provided to adopt a 'family approach'.

For polymers, a family was defined as *a group of polymers/substances [i.e. either homopolymers or copolymers as defined above], in which one parameter, e.g. the number average molecular weight, Mn, is "fixed" while one (N.B. one) other (e.g. the composition) is allowed to vary, due to the differing ratios of monomer units, over a relatively large range.* Importantly, use of the term 'fixed' here means that this parameter is confined to a narrow range of values that are consistent with the possibly wide variation of the variable parameter.

For the purposes of notification, the approach adopted was for the notifier(s) to submit technical dossiers addressing two representative substances selected from each extreme of the parameters considered to define the family. The basis for this was that - in order to avoid extensive testing – an assumption was made that, within a given family, those polymers of lower molecular weight would be more likely to pose the greater hazard (toxicological or ecotoxicological) than those of higher molecular weight because of the differences in solubility and mobility. Thus, examination of the properties for these two representative substances would inform on the variation in hazardous profile that would be anticipated for that family.

For example, data submission requirements could be - for a family for which composition was fixed but molecular weight varied (i.e. homopolymers) - that the number average molecular weight would be defined and dossiers prepared for a substance from each end of the number weight range. Test data would be needed for the required endpoints appropriate for the low molecular weight polymer (because of its presumed greater potential hazard) for the tonnages considered while the precise data needs for the high molecular weight substance would depend upon the hazard profile established for the low molecular weight polymer. That is, only those hazard endpoints found to raise concerns regarding the hazard posed by the low weight polymer would need to be assessed for the high weight polymer.

Under certain circumstances, if there is evidence that there are differences in the effects profiles seen for representative members within a family (as defined in terms of either molecular weight or composition range), further testing might be necessary to establish the profile of other representative members.

A1.1.3 No Longer Polymers

Brief mention should also be made of the 'no longer polymers' (NLP) group of substances for completeness. There were substances that were once considered as polymers (and so were not listed on EINECS) and were also not notified under the original (6^{th} Amendment) of the new substances legislation. However, the introduction of a new definition of a 'polymer' during 1993 resulted in these

substances no longer being considered to be polymers. However, they were permitted to remain exempt from notification under the new substances regulations.

To qualify as a NLP, a substance must have been on the market between 18th September 1981 and 31st October 1993 inclusive, and was required to satisfy the requirement that they were considered polymers under the reporting rules of EINECs. However, they were no longer considered as polymers under the 7th Amendment (92/32/EEC)[34].

A1.1.4 Approach to hazard characterisation of polymers under DSD

Standard Requirements

In principle, under the requirements of Annex VII D[35], dossiers submitted for polymers should include the datasets necessary to comply with the so called 'base set' (Annexes VII and VIII) as well as several polymer specific test requirements that inform on substance identity, physicochemical properties and – to some extent – hazards; these are summarised in Table A1.1). The requirements relating to data on number-average molecular weight, molecular weight distribution, identity and concentrations of starting monomers and other substances bound in the polymer) allow confirmation that the polymer complies with the definition for polymers in Directive 67/548/EEC. Further, requirements relating to endgroups, reactive functional groups, the identity and percentage of main impurities and non-reacted monomers, together with statements that are required regarding the intended environmental degradability are intended to inform on potential hazard based on the assumption that any hazard would be mainly attributable to the presence of low molecular weight and soluble components; additional investigations might also be necessary on a case-by-case basis.

Thus, under DSD, the data requirements for notification of a polymer – be it as a 'substance' or 'family' - differed somewhat from those defined for other (non-polymer) substances.

Reduced Test Package (RTP)[36]-Polymers

In some instances, the information requirements described above may be further reduced for some polymers that were considered of low concern (i.e. RTP- polymers). This reduced test package applied in the case of substances' that are considered to possess high number-average molecular weight, low content of low molecular weight species and have a low solubility/extractivity, since these are assumed to be non-

34 For further information, see Internet site http://www.hse.gov.uk/reach/definitions.htm.

35 Commission Directive 93/105/EC of 25 November 1993 laying down Annex VII D, containing information required for the technical dossier referred to in Article 12 of the seventh amendment of Council Directive 67/548/EEC, available from (http://www.reachteam.eu/english/legislation/docs/launchers/launch-93-105-EC.html).

36 Reduced Test Package (RTP), as defined by Commission Directive 93/105/EC of 25 November 1993 laying down Annex VII D, containing information required for the technical dossier referred to in Article 12 of the seventh amendment of Council Directive 67/548/EEC.

bioavailable. This was based on an assumption that, for non-bioavailable substances (as defined by: high molecular weight; <1% of species with molecular weight <1000; and that show low water extractivity) would not be able to elicit systemic effects that would be of toxicologically and/or ecotoxicologically relevant.

The concept of reduced data requirements for RTP-polymers was further elaborated post-Annex VII D, such that even in situations where a polymer broke one of the three defining criteria, it might still be considered for regulatory purposes as a RTP-polymer or accorded similar status based on argumentation on a case-by-case basis that balances the presumed - but still low - bioavailability against a knowledge of the properties of the component monomers. Overall, the reduced test package for RTP-polymers comprised most of the physicochemical tests and the common declarations as to manufacturer, notifier, identity of the substance and information on the substance. Determination of melting range could be combined with (polymer-specific) testing for thermal stability by DTA or DSC (e.g. OECD Test Guideline 113), though testing requirements remained for explosive properties and auto-flammability. In any event, however, the 'escape' clause was very likely to apply with regard to explosive properties, structural and physical characteristics of the polymer (reactive functional groups, while bioavailable metals and aerodynamic particle size must also to be taken into account. However, if scientific justification was provided, such tests could be omitted.

On a case-by-case basis but without causing a delay in acceptance of a notification, Competent Authorities could subsequently request additional toxicity and ecotoxicity test data to address any concerns that arose with regard to the presence of reactive groups, structural/physical characteristics or information on the properties possessed by low molecular weight components of the polymer or in relation to human or environmental exposures. In particular, for human health, inhalation toxicity test data might be requested where exposure by this route has been identified as being possible while additional ecotoxicity investigations might also potentially be required to address concerns regarding light-stability or long-term extractivity.

Table A1.1: Summary of Information Requirements Relating to Hazard for Polymers under DSD					
Polymers with Standard Test Package			**Polymers with Reduced Test Package**		
Quantity Produced	**Type of Data**	**Endpoint**	**Quantity Produced**	**Type of Data**	**Endpoint**
<100 kg/y or total of <500 kg (Annex VII C, and Annex VII D, C.1.3.)	Basic information	As for reduced test package	<100 kg/y or total of <500 kg ≥100 kg/y or total of ≥500 kg	Basic information	Identity of manufacturer and the identity of the notifier (location of the production site or, when sole representative, identity and the addresses of the importers)
	Substance identity	As for reduced test package, plus: Number-average molecular weight (molecular weight distribution, identity & concentration of starting monomers/other substances that will be bound in polymer, and indication of end groups & identity/ frequency of reactive functional groups) identity of non-reacted monomers; and % non-reacted monomers		Substance identity	Name (IUPAC nomenclature, other names and CAS name/number, if available); Molecular structural formula (number-average molecular weight, molecular weight distribution, identity & concentration of starting monomers/other substances that will be bound in polymer, and indication of end groups & identity/ frequency of reactive functional groups); Composition of substance (Degree of purity (%), nature of impurities, including by-products [identity of non-reacted monomers], % (significant) main impurities [% non-reacted monomers], if stabilizing agent or inhibitor or other additives, the nature, approx ppm or %, spectral data and GPC); and Methods of detection and determination (a full description of the methods used or the appropriate bibliographical references)
	Information on the Substance	As for reduced test package, plus statement of relevant information where the polymer has been developed to be environmentally degradable		Information on the substance	Production[3] (technical processes, and exposure estimates to working environment and environment); Proposed uses[3] ; • Types of uses – description of the function and desired effects (technological process(es) related to the use of the substance (where known), exposure estimate(s) related to the use (where known) [working environment/ environment], form under which the substance is marketed [substance, preparation, or product], and concentration of the substance in marketing preparations and products (where known); • Fields of application with approximate breakdown

Table A1.1: Summary of Information Requirements Relating to Hazard for Polymers under DSD					
Polymers with Standard Test Package			**Polymers with Reduced Test Package**		
Quantity Produced	**Type of Data**	**Endpoint**	**Quantity Produced**	**Type of Data**	**Endpoint**
					(industries, farmers and skilled trades, or use by the public at large); • Where known and where appropriate, the identity of the recipients of the substance; and • Waste quantities and composition of waste resulting from the proposed uses (where known); Estimated production and/or imports for each of the anticipated uses or fields of application; • Overall production and/or imports in tonnes per year (first calendar year and following calendar years); and • Production and/or imports expressed as %, broken down by types of use and fields of application (first calendar year and following calendar years); Recommended methods and precautions (handling, storage, transport, fire, other dangers, and susceptibility of polymer powder to explode, if relevant); Emergency measures in case of spillage, and injury to persons (e.g. poisoning); and Packaging
	Physicochemical	State of the substance at 20 oC and 101.3 kPa; Flash-point; and Flammability		Physico-chemical	State at 20° C/101.3 kPa; Melting range; Relative density; Water extractivity; and Flammability.
	Toxicological	Acute toxicity (one route)		Toxicological	None
	Ecotoxicological	None		Ecotoxicological	None
	Possibility of rendering substance harmless	None		Possibility of rendering substance harmless	None
<1t/a or total of <5t/a,	Basic information	As for lower tonnages		Basic information	As for lower tonnages

Table A1.1: Summary of Information Requirements Relating to Hazard for Polymers under DSD					
Polymers with Standard Test Package			**Polymers with Reduced Test Package**		
Quantity Produced	**Type of Data**	**Endpoint**	**Quantity Produced**	**Type of Data**	**Endpoint**
but ≥100 kg/a or total quantities ≥500 kg/a (Annex VII B, and Annex VII D, C.1.2)	Substance identity	As for lower tonnages		Substance identity	As for lower tonnages
	Information on the Substance	As for lower tonnages		Information on the Substance	As for lower tonnages
	Physicochemical	As for lower tonnages, plus: Melting point; Boiling point; Water solubility; Partition coefficient n-octanol/water; and Water extractivity		Physicochemical	As for lower tonnages
	Toxicological	As for lower tonnages, plus: Skin irritation; Eye irritation; and Mutagenicity (bacteriological reverse mutation test with and without metabolic activation)		Toxicological	As for lower tonnages
	Ecotoxicological	Biotic degradation		Ecotoxicological	As for lower tonnages
	Possibility of rendering substance harmless	None		Possibility of rendering substance harmless	None
≥1 t/a or total of ≥5t/a (Annex VIIA, and Annex VII D, C.1.1.)	Basic information	As for lower tonnages	≥1 t/y or total of ≥5t (Annex VII D, C.2.1.)	Basic information	As for lower tonnages
	Substance identity	As for lower tonnages		Substance identity	As for lower tonnages
	Information on the Substance	As for lower tonnages		Information on the substance	As for lower tonnages

Table A1.1: Summary of Information Requirements Relating to Hazard for Polymers under DSD					
Polymers with Standard Test Package			**Polymers with Reduced Test Package**		
Quantity Produced	**Type of Data**	**Endpoint**	**Quantity Produced**	**Type of Data**	**Endpoint**
	Physicochemical	As for lower tonnage range, plus Relative density; Vapour pressure; Surface tension; Explosive properties; Self-ignition temperature; Oxidising properties; Granulometry; and The possibility of further tests in certain cases e.g. light-stability test where polymer is not light stabilised, or long-term extractivity (leachate test)		Physico-chemical	As for lower tonnages, plus: Explosive properties; Auto-flammability; Particle size (where risk from inhalation); Thermal stability; and Extractivity (water and cyclohexane)
	Toxicological	As for lower tonnages, plus: Acute toxicity (two routes); Skin sensitisation; Repeat dose toxicity (one route); Non-bacteriological test to detect chromosome aberrations or damage; Screening for reprotoxicity; and Toxicokinetics		Toxicological	May be requested by MS CAs, on a case-by-case basis
	Ecotoxicological	As for lower tonnages, plus: Acute toxicity (fish); Acute toxicity (daphnia); Growth inhibition (algae); Bacterial inhibition; Abiotic degradation; and Absorption/desorption screening test		Ecotoxicological	May be requested by MS CAs, on a case-by-case basis

Table A1.1: Summary of Information Requirements Relating to Hazard for Polymers under DSD					
Polymers with Standard Test Package			**Polymers with Reduced Test Package**		
Quantity Produced	**Type of Data**	**Endpoint**	**Quantity Produced**	**Type of Data**	**Endpoint**
	Possibility of rendering substance harmless	As for reduced test package		Possibility of rendering substance harmless	For industry/skilled trades; and For the public at large. To cover recycling, neutralisation of unfavourable effects, destruction, and others
Notes. 1. Source: EC (undated). 2. Annex VII D of DSD states that, *If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authorities. Appropriate available information on the properties of the monomer(s) may be taken into account for the assessment of the properties of the polymer.* 3. Sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the production process.					

A1.2 Approach to Polymer Assessment in Europe: Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

As previously explained in Section 2, the focus of the regulatory requirements of polymers under REACH is significantly different from that under DSD and relates to regulation of the monomers and other substances which are chemically bound to the polymer. Importantly, the polymer itself is not required to be registered.

The critical requirement is thus that the monomer substance(s) or any other substance(s) chemically bound to the polymer must be registered by the supplier or another actor up the supply chain. Under such a scenario, there is no obligation on a manufacturer/importer of a polymer to register either the polymer or the monomer substances or any other bound substances. Where the monomer is not registered in a particular supply chain, the manufacturers/importers of a polymer would need to register the monomer substance(s) or any other substance(s) themselves, subject to the following limitations: 1) the polymer in question must contain ≥2% w/w of the monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s); and 2) the total amount of the monomer or other substance(s) must amount to ≥1 t/a.

A1.3 Approach to Polymer Assessment in Other Jurisdictions

A1.3.1 Australia

From 2002, the Australian government worked to reform their approach to the regulation of low regulatory concern chemicals, including development of a reduced registration requirement for polymers that meet their criteria for being considered of low concern (low regulatory concern polymers, LRCP; Commonwealth of Australia, 2007). Under the latest version of the Industrial Chemicals (Notification and Assessment) Act 1989 (Commonwealth of Australia, 2011), a *polymer of low concern* (PLC) is defined as a polymer that:

(a) either has:
  (i) number average molecular weight >1000; or
  (ii) number average molecular weight ≤1000 and other characteristics as prescribed by regulations and

(b) has a low charge density; and
(c) is not a hazardous chemical; and
(d) does not dissociate readily; and
(e) under the conditions of use, is stable; and
(f) has other characteristics as prescribed by the regulations.

The 'National Industrial Chemicals Notification and Assessment Scheme' (NICNAS) has established extensive criteria that define PLCs. Overall, the regulation established seven classes on the basis of the following main characteristics:

1. Number average molecular weight >1000 and <10,000;
2. Number average molecular weight ≥10,000;
3. Number average molecular weight ≤10,000;
4. Low charge density;
5. When polymer does not dissociate readily;
6. When polymer is stable;
7. Other characteristics based on chemical composition (e.g. presence of certain elements) and water absorption capacity.

The underlying characteristics defining each of these 7 classes of low concern polymer are summarised in Table A1.2.

Table A1.2: Summary of Criteria Used to Define a Polymer of Low Concern under NICNAS

Main Criteria	**Qualifying Characteristics**
Number average molecular weight >1000 & <10,000	Meeting average molecular weight criteria and: <10% by mass of molecules with MWt <500; and <25% by mass of molecules with MWt <1000; and consists only of low concern reactive functional groups (as per column 2, Table A1.3)
	Meeting average molecular weight criteria but including reactive functional groups of moderate concern (as per column 3, Table A1.3) if: groups have combined functional group equivalent weight of >1000; and must include no high concern reactive functional groups (as per column 4, Table A1.3)
	Meeting average molecular weight criteria but includes reactive functional groups of high concern (as per column 4, Table A1.3) if: groups have combined functional group equivalent weight >5000
Number average molecular weight ≥10,000	Meeting average molecular weight criteria and : <2% by mass of molecules with MWt <500; and <5% by mass of molecules with MWt <1000
Number average molecular weight ≤ 1000	Meeting average molecular weight criteria and : made from a prescribed reactant; or polymer has molecules containing 2 or more carboxylic acid ester linkages (one or more of which link internal monomer units)
Polymer of low charge density	Not cationic (i.e. has not net +ve charged atoms or associated groups covalently bonded to polymer molecule) and unlikely to become cationic in aqueous environments of pH >4 and < 9
	A solid not soluble or dispersible in water and only used in its solid phase
	A polymer with 1 or more cationic groups, with total combined functional group equivalent weight of any cationic group at least 5000
Polymer does not dissociate readily	A polymer of low concern is defined as a polymer that does not dissociate readily if it is not likely to become cationic in an aquatic environment that has a pH value greater than 4 and less than 9

Table A1.2: Summary of Criteria Used to Define a Polymer of Low Concern under NICNAS	
Main Criteria	**Qualifying Characteristics**
Stable polymer	A low concern polymer is stable under the conditions in which it is used if, under those conditions, it does not readily break down by any process, including the following: depolymerisation; hydrolysis; photodegradation; thermal degradation
Other qualifying characteristics	integral part of composition has at least 2 of following: carbon; hydrogen; nitrogen; oxygen; silicon; or sulphur
	Does not contain as an integral part (except as impurity) an atomic element other than: aluminium as the monatomic counterion, Al3+; bromine as the monatomic counterion, Br ; bromine covalently bound to carbon; calcium as the monatomic counterion, Ca2+; carbon; chlorine as the monatomic counterion, Cl ; chlorine covalently bound to carbon; fluorine covalently bound to carbon; hydrogen; iodine as the monatomic counter ion, I ; iodine covalently bound to carbon; magnesium as the monatomic counterion, Mg2+; nitrogen; oxygen; potassium as the monatomic counterion, K+; silicon; sodium as the monatomic counterion, Na+; sulphur; < 0.2% by weight of any combination of: boron; copper; iron; lithium; manganese; nickel; phosphorus; tin; titanium; zinc; or zirconium
	Capable of absorbing own weight in water and number average molecular weight <10,000

Table A1.3: Concern Level Associated with Particular Chemical Functional Groups		
Low Concern	**Moderate Concern**	**High Concern**
Aliphatic hydroxyl Butenedioic acid; Carboxylic acid; Blocked isocyanates (includes ketoxime-blocked isocyanates); Conjugated olefinic groups in naturally occurring fats, oils or carboxylic acids; Halogens except reactive halogen-containing groups (e.g. benzylic or allylic); Thiols; Unconjugated nitriles; and Unconjugated olefinic considered 'ordinary' (i.e. not specifically activated by being part of larger functional group or other influence)	Conjugated olefinic groups not contained in naturally occurring fats, oils and carboxylic acids	Acid anhydrides; Acid halides; Aldehydes; Aldimines; Allyl ethers; Alkoxysilanes; α or β-Lactones; Aziridines; Carbodimides; Cyanates; Epoxides; Halosilanes, Hemiacetals; Hydrazines; Hydrosilanes, Isocyanates, Isothiocyanates; Ketimines; Partially hydrolysed acrylamides; Pendant acrylates; Methacrylates; Methylolamides; Methylolamines; Methylolureas; Unsubstituted o- or ρ-phenolic hydroxyl; Vinyl sulfones & analogous compounds; Reactive functional groups not of low or moderate concern

The Commonwealth of Australia (2007) suggested a number of potential changes to the system including, in the case of polymers and low-concern-polymers that do not meet the formal criteria for PLC, that there may be instances in which it is nonetheless unnecessary to undertaking a complete risk assessment. Examples, include substances falling within other classes of low hazard polymers, where it is an analogue of a PLC, or polymers already assessed by other regulatory systems. Typically, such polymers were suggested to include:

- Polymers of classes considered of low hazard;
- Polymers chemically similar to polymers already assessed by NICNAS;
- Use of a consolidated notification (i.e. where more than one polymer is notified/assessed together); and
- Polymers previously assessed by other regulatory schemes.

In the case of low hazard polymers meeting the criteria detailed above for number-average molecular-weight ≤1000, it is proposed that to qualify as 'low concern' they should also meet certain hazard criteria (see Table A1.2). Commonwealth of Australia (2007) also proposed that that if a polymer had been assessed by another

Competent Authority from a recognised jurisdiction, that risk assessment should be considered. While noting that no schemes from other jurisdictions were as yet approved, the Canadian system (considered below) was considered likely to be acceptable. Mention was also made of the ongoing efforts within OECD to identify classes of polymer which would be of 'low regulatory concern'.

Table A1.4: Criteria for Defining Low Hazard for Polymers of Number Average Molecular-Weight ≤1000

Property	**Qualifying Criteria**
Flammability	Not a dangerous goods or meeting R10 criteria
Persistence/ bioaccumulation	Should not meet the criteria
Other chemical or physical properties	Not a dangerous goods
Acute toxicity	Not hazardous: Oral LD50 = >2000 mg/kg bwt; Dermal LD50 = >2000 mg/kg bwt; Inhalation LD50 = >5 mg/l/4 hrs (aerosols/particulates) or >20 mg/l/4 hr (gas/vapour)
Skin irritation	Not hazardous or meeting R38 (irritating to skin) criteria
Eye irritation	Not hazardous or meeting R36 (irritating to eyes) criteria
Sensitisation	Not hazardous
Mutagenicity	Not hazardous
Carcinogenicity	Not hazardous
Reproductive/Developmental toxicity	Not hazardous
Acute aquatic toxicity	Not harmful and will not cause long-term adverse effects: EC_{50}/ IC_{50}/ LC_{50} = >100 mg/L
National Occupational Health & Safety Commission (NOHSC)	Not a Type I ingredients (i.e. not carcinogenic, mutagenic, teratogenic, skin or respiratory sensitiser, very corrosive, corrosive, toxic or very toxic, harmful substance causing irreversible effects after acute exposure, or harmful substance causing serious damage to health after repeated/ prolonged exposure); or No exposure standard set by NOHSC; and Not present in quantities exceeding lowest cut-off level specified by NOHSC
Source: NICAS (2007)	

A1.3.2 Canada

From July 1994, polymers in Canada have been controlled under the Canadian Environmental Protection Act and its various amendments (Department of Justice, 2012a). Under this Act, the New Substances Notification Regulation was promulgated; provisions for chemicals and polymers were most recently revised in October 2005 (Department of Justice, 2012b).

The Canadian Environmental Protection Act, 1999 requires the screening assessments of substances, including polymers that meet certain categorization criteria to determine whether they present a risk to the environment or to human health. Approximately 4300 substances were identified as priorities for further action and polymers account for a substantial portion of the substances identified as priorities.

Criteria have been developed to address polymers on the Domestic Substances List (DSL)[37] that were identified as priorities (Environment Canada/Health Canada, 2012). Under the Regulations, the term 'polymer' is defined as a substance that consists of:

(a) molecules characterized by the sequence of one or more types of monomer units;
(b) greater than 50% by weight of molecules having three or more monomer units that are covalently bound to one or more other monomer units or reactants;
(c) less than 50% by weight of molecules of the same molecular weight; and
(d) molecules distributed over a range of molecular weights whose differences in molecular weights are primarily attributable to differences in the number of monomer units.

The Regulations also divide polymers into three major categories:

1) Polymers and biopolymers used for research and development, as contained site-limited intermediate or contained export-only substances;
2) Reduced regulatory requirement polymers, and
3) Polymers and biopolymers used for any other purpose.

For the first of these types (those used for research and development, as contained site-limited intermediate or contained export-only substances), information requirements for polymers exceeding a 10,000 kg/annum threshold are summarised in Table A1.4. For the second of the polymer types, polymers that meet the requirements set out in Table A1.5, there are reduced regulatory requirements (Department of Justice, 2012b). For polymers exceeding 1000 kg, the information must be provided as set out in Table A1.6 or, if the substance is a biopolymer, then the information in Table A1.7.

Table A1.4: Information Requirements for Polymers and Biopolymers Used for Research and Development, as Contained Site-limited Intermediate or Contained Export-only Substances

Information	Clarification of Requirement
Type of substance	Specifying if research and development substance, contained site-limited intermediate substance or contained export-only substance
New substances pre-notification consultation number	If assigned/ known
Chemical name	As per rules of International Union of Pure and Applied Chemistry or Chemical Abstracts Service
Trade name(s)/ synonyms	If known
CAS registry number	If assigned
Molecular formula of polymer	-
Structural formula of the polymer	If possible; if not, partial structural formula

[37] The Domestic Substances List (DSL) is an inventory of approximately 23 000 substances manufactured in, imported into or used in Canada on a commercial scale and present in Canada between January 1, 1984 and December 31, 1986. With few exemptions, all substances not on this list are considered new and must be reported prior to importation or manufacture In addition, a Non-Domestic Substances List (NDSL) based on the United States Environmental Protection Agency's (USEPA) Toxic Substances Control Act (TSCA) Chemical Substances Inventory for 1985, and contains more than 58 000 entries. Substances that are not on the DSL but are listed on the NDSL are subject to lesser information requirements.

Table A1.4: Information Requirements for Polymers and Biopolymers Used for Research and Development, as Contained Site-limited Intermediate or Contained Export-only Substances	
Information	**Clarification of Requirement**
Number average molecular weight and maximum concentration (as % of residual constituents with MWt <500 and residual constituents with MWt <1 000	For contained site-limited intermediate substances and contained export-only substances
Target number average molecular weight (Mn) of polymer	For research and development substances.
Known impurities (and concentration by weight)	-
Polymer composition (and concentrations by weight)	Including constituents uch as monomers/other reactants, additives, stabilizers and solvents present when tested,
Material safety data sheet	If available
Physical state of polymer	-
Statement if polymer is formulated for dispersal in water	-
Exposure data	Anticipated annual quantity manufactured/imported (as applicable); Anticipated uses; Anticipated concentration in products/ in end-use products (if known); Expected modes for transportation/ storage; Size/type of container for transport/ storage; Environmental components into which release is anticipated; Anticipated releases municipal wastewater systems; Methods for destruction or disposal; Whether significant public exposure to polymer (considering concentration, duration, frequency and circumstance of exposure and limiting factors) For site-limited intermediate substances only, location of use
Other	Summary of other data on polymer held by manufacturer/ importer or to which they should access, that are relevant to environmental/human health hazard and exposure assessment
Other Competent Authorities with an interest	Other government agencies notified of manufacture/ import of the polymer and, if known, relevant reference number and outcome of risk assessment and risk management actions arising
Souce: Department of Justice (2012b)	

Table A1.5: Requirements for Reduced Regulatory Requirement Polymers	
Size Criteria	**Exclusions**
Polymer has a number average molecular weight > 10,000 daltons and: < 2% of its components have molecular weights < 500 daltons, and < 5% of its components having molecular weights < 1,000 daltons	A cationic polymer or a polymer that is reasonably expected to become cationic in a natural aquatic environment, except (a) a polymer whose cationic group has a combined equivalent weight > 5 000 daltons; or (b) a polymer that is a solid material, that is not soluble or dispersible in water and that will be used only in the solid phase, such as polymers that can be used as ion exchange

Table A1.5: Requirements for Reduced Regulatory Requirement Polymers	
Size Criteria	**Exclusions**
	beads. A polymer designed, or expected, to substantially degrade, decompose or depolymerize[38], including polymers that could substantially degrade, decompose or depolymerize after manufacture and use, even though they are not intended to do so. A polymer that has, as an integral part of its composition, only one or none of the following atomic elements: carbon, hydrogen, nitrogen, oxygen, silicon and sulphur. A polymer that has any atomic elements other than carbon, hydrogen, nitrogen, oxygen, silicon, sulphur, fluorine, chlorine, bromine or iodine covalently bound to carbon; any monoatomic counter ions other than chlorine, bromine, iodine, sodium, divalent magnesium, trivalent aluminium, potassium or divalent calcium; or $\geq$ 0.2% by weight of any atomic element (or combination of): lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin or zirconium
Polymer has a number average molecular weight > 1 000 daltons and $\leq$ 10 000 daltons and: < 10% of its components having molecular weights < 500 daltons and < 25% of its components having molecular weights < 1 000 daltons	As above plus A polymer: that has reactive functional groups other than carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups that are considered "ordinary"39, butenedioic acid groups, blocked isocyanates including ketoxime-blocked isocyanates, thiols, unconjugated nitrile groups, halogens excluding reactive halogen groups such as benzylic or allylic halides, and conjugated olefinic groups present in naturally occurring fats, oils and carboxylic acids, in combined equivalent weights of less than 5 000 daltons; or in which the only reactive functional groups present are part of acid halides, acid anhydrides, aldehydes, hemiacetals, methylolamides, methylol-amines, methylol-ureas, alkoxysilanes with alkoxy greater than C2-alkoxysilanes, allyl ethers, conjugated olefins, cyanates, epoxides, imines, unsubstituted positions ortho or para to phenolic hydroxyl, in combined equivalent weights of less than 1 000 daltons
A polymer that is a polyester manufactured solely from the following reactants (or their anhydrous forms): 1. Monobasic Acids and Natural Oils 2. Dibasic and Tribasic Acids and Esters 3. Polyols 4. Modifiers	Reactants or their anhydrous forms that include both 1-butanol and fumaric or maleic acid

[38] Degradation, decomposition and depolymerization refer to the types of changes that convert a polymeric substance into simpler, smaller substances, through processes including but not limited to oxidation, hydrolysis, attack by solvents, heat, light and microbial action.

[39] Not specially activated either by being part of a larger functional group, such as a vinyl ether, or by other activating influences, for example, strongly electron-withdrawing sulfone group with which the olefinic groups interact.

Table A1.6: Information Requirements for Polymers in Quantities >1000kg	
Information	**Clarification of Requirement**
Type of substance	Specifying if a reduced regulatory requirement polymer; a polymer on the NDSL; a polymer with all of its reactants on the DSL or the NDSL; or a polymer with one or more reactants not on either the DSL or NDSL.
New substances pre-notification consultation number	If assigned/ known
Chemical name	As per rules of International Union of Pure and Applied Chemistry or Chemical Abstracts Service
Trade name(s)/ synonyms	If known
CAS registry number	If assigned
Molecular formula of polymer	
Structural formula of the polymer	If possible; if not, partial structural formula
The reaction scheme	For reduced regulatory requirement polymers unless it is a polyester manufactured solely from listed reactants.
Number average molecular weight and maximum concentration (as % of residual constituents with MWt <500 and residual constituents with MWt <1 000	
Known impurities (and concentration by weight)	
Polymer composition (and concentrations by weight)	Including constituents such as monomers/other reactants, additives, stabilizers and solvents present when tested,
Material safety data sheet	If available
Exposure data	Anticipated annual quantity manufactured/imported (as applicable); Anticipated uses
Other	Summary of other information and data on polymer held by manufacturer/ importer or to which they should access, that are relevant to environmental/human health hazard and exposure assessment
Other Competent Authorities with an interest	Other government agencies notified of manufacture/ import of the polymer and, if known, relevant reference number and outcome of risk assessment and risk management actions arising
Information from Department of Justice (2012b)	

Table A1.7: Additional Information Requirements for Biopolymers in Quantities >1000kg	
Information	**Clarification of Requirement**
Identification of the organism (production organism) and organ form which biopolymer is isolated.	Includes synonyms, common and superseded names, if known; and its source and history.
Any known adverse environmental or human health effects associated with exposure to the production organism.	-
The concentration of the viable production organism in the biochemical or biopolymer and, if known, in end-use products.	-

Polymers and biopolymers on the NDSL polymers and biopolymers on the NDSL or all of whose reactants are on the DSL or NDSL in a quantity greater than 10,000 kg should provide the information in Table A1.8. Polymers and Biopolymers not on the NDSL in quantities greater than 10 000 kg require the information in Table A1.9.

Table A1.8: Information Requirements for Certain Polymers in a Quantity > 10,000kg						
Tonnage	**General**	**Physicochemical Data**	**Environmental Data**	**Health Data**	**Exposure Information**	**Other Information**
10,000 kg	Information in Table 3ac (unless already submitted)	Physical state; polymer formulated for dispersal in water; water extractability measured at several pHs; octanol-water partition coefficient; hydrolysis rate as a function of pH (unless the polymer has a water extractability at pH 7 of less than or equal to 2%) identification of the products of the hydrolysis, if known	Acute toxicity test for the most sensitive species: fish, daphnia or algae; if the sensitivity is unknown, an acute algae toxicity test	Oral toxicity test ; Certain test information	Expected modes for its transportation and storage; description of the size and type of container used; anticipated releases into municipal wastewater systems; methods for its destruction or disposal; historical and other likely uses; factors limiting environmental exposure; whether it is released to the aquatic environment > 3 kg per day, per site, if the public is anticipated to be significantly exposed to the polymer	A summary of all other relevant information and test data identifying hazards to the environment and human health
50,000 kg and polymer released to aquatic environment in >3 kg per day per site (averaged monthly) after wastewater treatment				Data from a repeated-dose mammalian toxicity test of at least 28 days duration, plus certain experimental information; mutagenicity data from an in vitro test, with and without		

Table A1.8: Information Requirements for Certain Polymers in a Quantity > 10,000kg						
Tonnage	**General**	**Physicochemical Data**	**Environmental Data**	**Health Data**	**Exposure Information**	**Other Information**
				metabolic activation		
50,000 kg and public exposure				Data from repeated-dose mammalian toxicity test of at least 28 days; mutagenicity data from in vitro test with and without metabolic activation; data from in vitro for chromosomal aberration test with and without metabolic activation in mammalian cells or data from a previously existing in vivo mammalian test		

Table A1.9: Information Requirements for Certain Polymers in a Quantity > 10,000kg					
General	**Physicochemical Information**	**Health information**	**Environmental Information**	**Exposure Information**	**Other Information Required**
Information in Table 3ac (unless already submitted)	Physical state; polymer formulated for dispersal in water; water extractability measured at several pHs; octanol-water partition coefficient; hydrolysis rate as a function of pH (unless the polymer has a water extractability at pH 7 of less than or equal to 2%) identification of the products of the hydrolysis, if known	Information sufficient to assess skin irritation; Data from a skin sensitization test; Data from one repeated-dose mammalian toxicity test of at least 28 days duration; Mutagenicity data including: in vitro test with and without metabolic activation for gene mutations; in vitro test, with and without metabolic activation for chromosomal aberrations; and in vivo mammalian test, for chromosomal aberrations or gene mutations		Expected modes for its transportation and storage; description of the size and type of container used; anticipated releases into municipal wastewater systems; methods for its destruction or disposal; historical and other likely uses; factors limiting environmental exposure. Data on if it is released to the aquatic environment > 3kg per day per site, if the public is anticipated to be significantly exposed to the polymer	Summary of all other relevant information and test data identifying hazards to the environment and human health

A1.3.3 Japan

In Japan, the **Chemical Substances Control Law (CSCL)** was implemented on 16 April 1974, while the latest amendments entered into force on 1st April 2011 (METI, 2011). Under this legislation, there is a recognition that some polymers are of low concern where they pose no risk of causing damage to human health or the habitat of flora and fauna in the human living environment (Notification No. 2 of 2009 by the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry and the Ministry of the Environment). These polymers are simply defined as:

> *Any chemical substance composed of an aggregation of those molecules that are produced by linkages of one or more types of monomeric units, in which the total weight of those molecules that are composed of 3 or more linkages makes up 50% or more of the weight of the whole substance and the total weight of those molecules with identical molecular weight is less than 50% of the weight of the whole substance;*
>
> *and*
>
> *Any chemical substance whose number average molecular weight is 1,000 or more.*

For new polymers falling under this definition only minimal information requirements – to justify status - are needed, and as such these substances are effectively exempt from mandatory notification of manufacture and/or import. Thus, in order to qualify as a polymer of low concern, the substance must meet the following criteria:

1. Number average molecular weight of 1,000 or more;
2. No observed changes in weight under acid or alkali conditions;
3. Includes no metal (except for Na, Mg, Ca and K); and
4. Insoluble in water or organic solvents.

In order to justify the claim, the following data must be submitted by the importer or manufacturer, after which – if judged satisfactory by the Ministry - no further information is required: molecular weight distribution; physicochemical property data; solubility in acid, alkali conditions and in water and organic solvents.

For existing polymers that are recognized as either equivalent to non-hazardous determination under a High Molecular Flow Scheme or that can be shown to satisfy the criteria for confirmation of new polymers as of low concern, then notification is not required.

Figure A1.1 outlines the decision tree that governs the test requirements that apply to polymers in Japan. In addition to those considered of low concern (discussed above), further exemptions may apply for those polymers that are produced or imported at ≤10 tonnes per annum that do not meet the requirements for PLC, test data is required

unless it can be demonstrated that there is a low presence of species of molecular weights ≤ 800. However, such testing could still be requested if concerns are identified based on structure, although this is considered unlikely to be the case if the species of molecular weight ≤ 800 daltons are only present at < 1 % by weight (SoCMA, 2012).

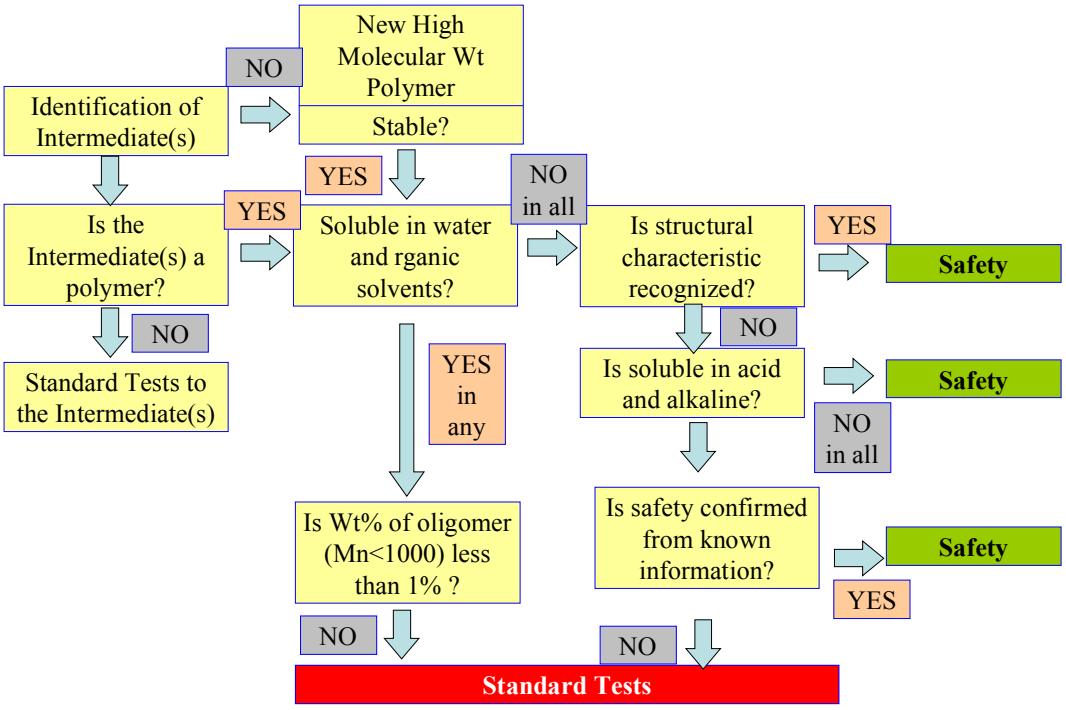

Figure A1.1: Polymer Test Scheme for Japan

A1.3.3 United States of America

In the USA, the 1976 Toxic Substances Control Act (TSCA), Section 5 requires the Environment Protection Agency (EPA) to review new substances before they are manufactured or imported (pre-manufacture notification process). If EPA determines that a new substance may present a risk to human health or the environment or if there is insufficient information, EPA may limit the manufacture, processing, distribution, use, or disposal of the substance (US EPA, 1997).

From 1979 until 1984, all new polymer substances were subject to the full pre-manufacture reporting requirements until the EPA determined certain polymers were unlikely to present a risk to human health or the environment along with relevant criteria (polymer exemption rule).

Since the EPA established the polymer exemption rule, they have reviewed over 10,000 polymer submissions and have re-evaluated the criteria to increase the number of polymers qualifying for exemption.

For a new chemical substance to be eligible for exemption under the amended rule, it must meet the requirements set out in Table A1.10.

Table A1.10: Requirements for Polymers	
Substance Criteria	**Detailed Requirements**
Must meet the definition of a polymer	> 50 percent of molecules must be composed of a sequence of at least 3 monomer units plus at least one additional monomer unit or other reactant. The amount of polymer molecules of any one molecular weight cannot exceed 50 weight percent
Must not be specifically excluded from the polymer exemption	Cationic polymers and those polymers which are reasonably anticipated to become cationic in the natural aquatic environment are excluded from the exemption and may not be manufactured under it. Polymer must integrate at least two of: C, H, N, O, S, Si; only F, Cl, Br and I are permitted as an integral part of the polymer and Cl-, Br-, I-, Na+, Mg+2, Al+3, K+ and Ca+2 as counter ions. < 0.20 % of Li, B, P, Ti, Mn, Fe, Ni, Cu, Zn, Sn, and Zr are permitted. The polymer is not permitted to be designed or reasonably anticipated to substantially degrade, decompose, or depolymerise. A polymer may contain at more than two percent by weight only those reactants and monomers that are either: on the TSCA Chemical Substance Inventory, granted a section 5 exemption, (a low-volume exemption; a polymer exemption under the 1984 rule; etc.), excluded from reporting or a non-isolated intermediate. Water-absorbing polymers with number-average molecular weight > 10,000 daltons are excluded from exemption
Must meet one of the (e)(1), (e)(2), or (e)(3) criteria	The polymer must have a MW > than 1,000 daltons and < 10,000 daltons. The polymer must contain < 10 percent oligomer content of molecular weight below 500 daltons and < 25 percent oligomer content of molecular weight below 1,000 daltons. The polymer must have either: no reactive functional groups; only low-concern functional groups; or it must have a functional group equivalent weight (FGEW) above threshold levels for moderate- and high-concern functional groups. The polymer must have a MWs $\geq$ 10,000 daltons and an oligomeric content < 2% molecular weight 500 daltons, and < 5% of molecular weight < 1,000 daltons. There are no functional group restrictions but the substance must not be excluded from exemption. Exemption of manufactured or imported polyesters which have been prepared exclusively from a list of identified feedstocks; each monomer or reactant in the chemical identity of the polymer (charged at any level) must be on the list

In 2010, the US Environmental Protection Agency published guidance on the assessment of polymers (US EPA, 2010). US EPA (2010) takes the PLC principle a step further and outlines the following criteria for the division of polymers into three categories:

- **Category 1**: Polymers with low molecular weight (MWn <1,000);
- **Category 2**: Polymers with high molecular weight (MWn >1,000) and large low molecular weight (LMW) material composition (≥25% with MW <1,000; ≥10% with MW <500); and

- **Category 3**: Polymers with high molecular weight (MWn >1,000) and minimal LMW material (<25% with MW <1,000; <10% with MW <500).

These categories are used to identify whether a risk assessment (or screening) may focus on the polymer alone or whether oligomers and/or monomers may also need to be addressed. It may be possible to assess Category 1 polymers without reference to oligomers or monomers. Category 2 polymers may be mostly assessed like Category 1 polymers but the potential for oligomers to result in increased toxicity should also be considered. Category 3 polymers would again be mostly assessed like a Category 1 polymer but additional assessment may be required to address concerns for the monomer.

The US EPA (2010) identifies the following physicochemical properties for which it is important to have information when estimating the likely hazards of polymers:

> monomers from which the polymer is created, and relative mole fraction of each monomer;
> molecular weight (MW) distribution;
> number average molecular weight (MWn) in Daltons and how it was determined;
> oligomer content of the polymer (i.e. percentages with MW ≤1,000 and MW ≤500);
> physical form;
> equivalent weight of any reactive functional groups (RFG) and/or cationic charge density, which can be determined from the structure;
> particle size distribution;
> swellability; and
> water solubility or dispersability – polymers that form micro emulsions or gels may be mistaken for soluble, but may not be truly soluble.

For polymers with MWn >1,000 it may be assumed that vapour pressure $<10^{-8}$ mm Hg and Henry's Law constant $<10^{-8}$ atm-m^3/mol.

Based on physicochemical information, assessments should be carried out for environmental fate, acute toxicity, and human health hazards.

Environmental Fate Estimations

The most important parameters to evaluate in the fate assessment of polymers are electronic charge (density being secondary), MWn, and solubility/dispersability.

Vapor Pressure – Polymers with MWn >1000 generally have a vapor pressure of $<10^{-8}$ mm Hg. This indicates that the chemical is likely to exist solely as particulate matter in the atmosphere. As particulate matter, atmospheric oxidation is not expected to be a significant route of environmental removal.

Henry's Law Constant – Due to the large size and low vapor pressure of most polymers, those with MWn >1000 generally have Henry's Law constant of $<10^{-8}$ atm-

m3/mol. Due to this, volatilization from water or moist soil is not expected to occur at an appreciable rate, with half-lives for volatilization of >1 year.

Bioconcentration Factor (BCF) – Due to the large size and insolubility of most polymers, they are typically of low concern for bioconcentration. Those with MWn >1,000 will typically be of low concern.

Soil Adsorption and Mobility

Cationic, amphoteric, nonionic – These polymers will generally absorb strongly to soil and sediment.

Anionic polymers – Anionic polymers usually have low sorption to soil. However, due to large size and weight parameters, these materials may still have low mobility in soil.

Publicly Owned Treatment Work (POTW) removal – Removal of polymers in sewage treatment is dependent primarily on solubility, but may be influenced by binding potential for sludge.

Biodegradation – The vast majority of polymers are essentially non-biodegradable. While some exceptions exist, these polymers are usually specifically designed to be biodegradable materials (to replace more resistant polymers as a more environmentally friendly alternative). Often, to substantiate this claim, biodegradation studies are available on these biodegradable types of polymers. In the case of highly degradable polymers, assessment of the degradation products may be warranted.

Hydrolysis – Hydrolysis of susceptible groups on polymers is solubility dependent. Polymers with poor water solubility may have reduced susceptibility to hydrolysis.

Aquatic Toxicity Estimations

Average Molecular Weight (MWn), Monomer, and Low Molecular Weight (LMW) Material Composition Categories – When assessing polymers that fit into Category 1, it may be relevant to find a discrete representative structure with MW of <1,000 and assess this structure using methods of aquatic hazards estimation. Polymers that fit into Category 2 above may require assessment of the polymer itself, but further assessment of the low molecular weight components of the polymer mixture may also be needed to fully characterize the aquatic hazard. Polymers that contain large amounts of residual monomers may require assessment of the monomer to fully characterize the aquatic hazards associated with the mixture.

Insoluble Polymers – Insoluble polymers are not expected to be toxic unless the material is in the form of finely divided particles. Most often, the toxicity of these polymer particles does not depend on a specific reactive structural feature, but occurs from occlusion of respiratory organs (e.g. gills). For these polymers, toxicity typically occurs only at high concentration; acute toxicity values are generally >100 mg/L and chronic toxicity values are generally >10 mg/L (low toxicity).

Nonionic Polymers – These polymers are generally of low concern for aquatic hazard, due to negligible water solubility. However, two exceptions exist:

- nonionic polymers that have monomers blocked in such a way as to use the polymer as a surfactant or dispersant, which may cause toxicity to aquatic organisms.
- nonionic polymers with significant oligomer content (i.e., ≥25% with MW <1,000; ≥10% with MW <500), which may be a concern on the basis of bioavailability of the LMW material.

Anionic Polymers – Polyanionic polymers with MWn >1,000 that are soluble or dispersible in water may pose a concern for direct or indirect toxicity. These polymers are further divided into 2 subclasses:

Poly(aromatic acids), which generally are of moderate hazard concern to aquatic organisms with acute LC50/EC50 values between 1 mg/L and 100 mg/L;

Poly(aliphatic acids), which generally exhibit low toxicity toward fish and daphnid with LC50 values >100 mg/L.

Cationic Polymers – Cationic polymers that may pose a concern for aquatic hazard are those that have a net positive charge or that may become cationic in the environment. The most common atoms that may have net positive charge include, but are not limited to, nitrogen (ammonium), phosphorus (phosphonium), and sulfur (sulfonium); with nitrogen constituting the cationic atom in >99% of polymers.

Human Health Hazard Estimations

For *Non-Cancer Human Health Hazard*, the approach for assessing potential human health concerns posed by a polymer depends on the type and availability of toxicity data. In most cases, there is a paucity of data, which precludes adequate evaluation of the polymer itself, and requires an assessment based on information available for, e.g., analogous polymer, chemical class, or the constituent monomer(s).

However, a hierarchical approach is often used in evaluating the human health effects of polymers by an assessment based on:

- toxicity data for the polymer or an analogous polymer;
- chemical class information;
- residual monomers;
- molecular weight for high molecular weight polymers;
- swellability.

Assessment based on toxicity data for the polymer or analogous polymer – For some polymers, adequate toxicity data exist in the literature or are supplied by the submitter for assessing the potential health effects of the polymer. In this case, systemic effects, as well as portal of entry effects, are thoroughly evaluated based on data for the

polymer itself. In the absence of adequate data on the polymer, or to fill specific data gaps, the assessment will be based on structurally related analogous polymers having adequate toxicity information.

Assessment based on chemical class information – Often, either no toxicity data are available or the data may be inadequate for thorough evaluation of the health effects of the polymer. For these polymers, several lines of evidence are used in parallel:

the assessment may be based on the toxicity information available for the same chemical class of the polymer to assess;

the toxicity of a polymer may also be evaluated based on its intended use, and consider the toxicity information available based on functional effects;

consider the presence of reactive functional groups (RFGs) on the side chains: a key consideration is whether these side chains are likely to have biological functions in the context of their presence on a larger molecule (since they may not be available for interaction with the same cellular targets as a small molecule would be with the same structure);

if the polymer is expected to undergo hydrolysis (in the environment, under physiological conditions such as the acidic pH of the stomach, or enzymatically), the evaluation of the health effects should take into consideration the toxicity data available for the hydrolysis product(s);

in other instances, the size or chemical properties (e.g., solubility) of the polymer will raise the question regarding its bioavailability. Typically, polymers with molecular weight > 1000 are considered to be of limited bioavailability. However, if it is known, or if there is evidence to suggest that the polymer is not bioavailable, the evaluation will be limited to consideration of portal of entry effects.

Assessment Based On Residual Monomers –It may also be appropriate to develop an assessment based on the toxicity information of the low molecular weight species or residual monomers if they exist in a product at significant quantities (e.g., >10%).

Lung Effects Of High Molecular Weight Polymers – Polymers with MWn of >10,000 are generally of concern only for lung effects. For concerns specific to lung toxicity, these polymers are typically divided into 3 classes with associated qualitative hazard concerns used to identify inhalation concerns:

Soluble polymers of MWn 10,000-13,000 are not expected to exhibit lung toxicity because they can rapidly clear from the respiratory tract, preventing lung overload. However, soluble polymers of MWn >13,000 may have the potential to cause lung overloading effects. Polymers that are soluble as well as swellable (tea bag test shows loss of material) are considered soluble for the determination of lung effect concerns;

Insoluble polymers present concerns with MWn >10,000 for the potential to cause lung overloading. Studies have shown irreversible lung damage as a result of respiration of polymer particles with MWn >70,000. Additional concerns exists for ultra-fine particles with significant amounts of <10 micron material.

Swellable polymers can absorb their weight or greater in water have serious health concerns for fibrosis and/or cancer.

Cancer Human Health Hazard – The potential human health cancer concerns for polymers can be assessed using input on basic properties, structural features, and components of the polymer. Not all of these properties are required for a polymer, however, and more data input will obviously lead to a more accurate assessment of the potential carcinogenic effects. The basic information required is as follows:

- Average molecule weight (MWn);
- Presence of covalently linked repeating units;
- Quantity of residual polymer >2%;
- Quantity of oligomer (MW ≤500) >2%
- Presence of Beryllium (Be), Cadmium (Cd), Chromium (Cr), Nickel (Ni), Arsenic (As), Antimony (Sb)
- Is the polymer crosslinked?
- Presence of any reactive functional groups (RFGs) on the polymer or unreacted monomers;
- Water solubility of the polymer;
- Is the polymer expected to be inflammatory?
- Is the polymer expected to accumulate in soft tissues?
- Expected routes of exposure (ingestion, injection, and/or inhalation);
- Whether the polymer is going to be in a form that is easily respirable.

A1.4 Role of the OECD in the International Development of Polymer Risk Assessment and Regulation

The OECD has been actively engaged in the development of hazard and risk assessment approaches for polymers since the initial meeting of the OECD Expert Group on Polymer Definition in January 1990 (OECD, undated). Of particular relevance here, however, is the work of the Expert Group during 2007-8 to examine the application of the US concept of 'polymers of low concern' (PLC; see above), through a detailed analysis of data for 205 polymers submitted to the OCED by National Authorities. This followed a meeting in March 2007 that proposed a definition for PLC's as *"Polymers of low concern are those deemed to have insignificant environmental and human health impacts. Therefore, these polymers should have reduced regulatory requirements."* The output of this work was published the following year (OECD, 2009) and is summarised below.

A1.4.1 Criteria Used to Identify Polymers of Concern

Consideration of the range of criteria adopted by Member States to define polymers of low regulatory concern demonstrated that, although subject to national variations, the principle criteria applied are:

- **Number-average Molecular Weight:** ≥1,000 Da is the most generally used criterion though subject to considerable national variation in the associated limits applied with respect to the presence of low molecular weight unreacted monomers and oligomers allowed (e.g. USA, Canada and Australia defined weight % of oligomer content cut-offs that varies with polymer molecular weight but Japan has a single cut-off of <1% based on the toxicity of polymers with the highest oligomer content); and

- **Reactive Functional Groups (RFG):** The presence or absence of specific RFGs are used by several authorities and are defined through their association with toxicity of polymers. The limits for RFG are frequently linked to the dilution of each RFG in the polymer, expressed as a functional group equivalent weight (FGEW);

Other less widely used criteria included:

- Polymer stability;
- Polymer solubility (in water and other solvents);
- Chemical class (referred to here as polymer type);
- Residual monomer content; and
- Human health hazard classification (used as the main comparator in the study).

As noted above, the data supporting the analyses were drawn from datasets provided by various Authorities and were found to be highly variable in nature, necessitating considerable interpretation and adoption of a number of assumptions (without the possibility of validation) so as to allow assembly of a set suitable for comparison. For example, polymers were assigned to 13 simplified Polymer classes (including a 'mixed' class containing polymers which had characteristics of multiple classes and a 'other' class where definitive assignment was not possible based on the available information). With regard to classification of levels of human and environmental concerns, a simplified scheme for grouping under health concern and ecotoxicological concern (based only on data for fish, Daphnia, or algae) was adopted (Table A1.11).

Table A1.11: OECD Health and Ecotoxicological Concern Criteria

Type of Concern	Concern Level	Basis
Human Health	1. No toxicity	
	2. Low	None or minor observed effects; Low acute toxicity (LD50 >1000 mg/kg); and Mild/ slight irritancy
	3. Potential	Moderate-high acute toxicity (LD50 ≤1000 mg/kg); mild irritancy; +ve skin sensitisation (including limited evidence); Any +ve mutagenicity/ genotoxicity test;

Table A1.11: OECD Health and Ecotoxicological Concern Criteria		
Type of Concern	**Concern Level**	**Basis**
		NOAEL ≤750 mg/kg/day; Any other positive test result
Ecotoxicity	0.	No data
	1. Low	EC50 or LC50 = >100 mg/L
	2. Moderate	EC50 or LC50 = 1<100 mg/L
	3. High	EC50 or LC50 = <1 mg/L
Source: OECD (2009)		

A1.4.2 Performance of Criteria for Distinguishing between PLC and Non-PLC Polymers

Of the available dataset, 142 polymers had toxicological data available suitable for consideration (see Table A1.12). Of these 109 (53%) were assignable as being 'low health concern' while 33 polymers (16%) showed potential health concerns which were based upon a diverse set of toxic endpoints. The relationship between assessed PLC status and identified toxic concerns was complex. Thus the main health concern identified for those polymers considered as PLC was sensitisation[40]; other endpoints showed no marked trend across the two categories of polymer. Also, 100 polymers (48.8%) out of 205 were suitable for evaluation of ecotoxic concern. Here analyses identified clear differences between the distribution of levels of concern for PLC and non-PLC polymers, although the analysis was somewhat limited as only 6 polymers (all defined as non-PLC) were assignable to the 'high ecotoxic concern' category.

Table A1.12: Potential Concerns Identified for PLC and Non-PLC Polymers		
Endpoint	**PLC**	**Non-PLC**
Human Health		
Acute toxicity	0	1
Irritancy	6	6
Repeat dose	4	9
Sensitisation	5	1
Mutagenicity	5	6
Ecotoxicity[1]		
Low	45	13
Moderate	13	23
High	0	6
Note 1: Maximum score from taxonomic classes considered. Source: OECD (2009).		

The strength of the correlations found between each of the criteria (i.e. number-average molecular weight, etc.) that have been used by various regulatory bodies and the health and/or ecotoxicological concerns as derived in this exercise were considered.

Number-average Molecular Weight

[40] For 2 of 5 PLC polymers under the 'sensitisation' endpoint, only "limited evidence" was reported and data quality was inadequate to establish robustly the extent to which the assignment was justified. The issue of data quality also limited the robustness of assessments for other endpoints as well.

With regard to the relationship between molecular weight and degree of health concern, it was apparent that polymers for which there was potential health concern were more prevalent at molecular weights below 2000 Da (Figures A1.2 and A1.3, taken from OCED, 2009). Molecular weight criteria are, however, frequently applied in association with sub-criteria on the levels of oligomers present and the influence of oligomer content was also considered for polymers of low or potential health concern; this identified a statistically significantly higher mean oligomeric content in polymers of potential health concern with, for those of potential concern, an increased incidence of higher oligomer content at 5% for <1000 Da and 2% for <500 Da oligomer content (Figure 5.3). Detailed analysis showed the oligomer content profile to be even for polymers in the low health concern grouping while for those of potential health concern, there was an increased incidence of higher oligomer content, beginning at 5% for <1000 Da and 2% for <500 Da oligomeric content. Indeed, most potential health concern polymers were found to have molecular weights of <10,000 Da and an oligomer content of >1%.

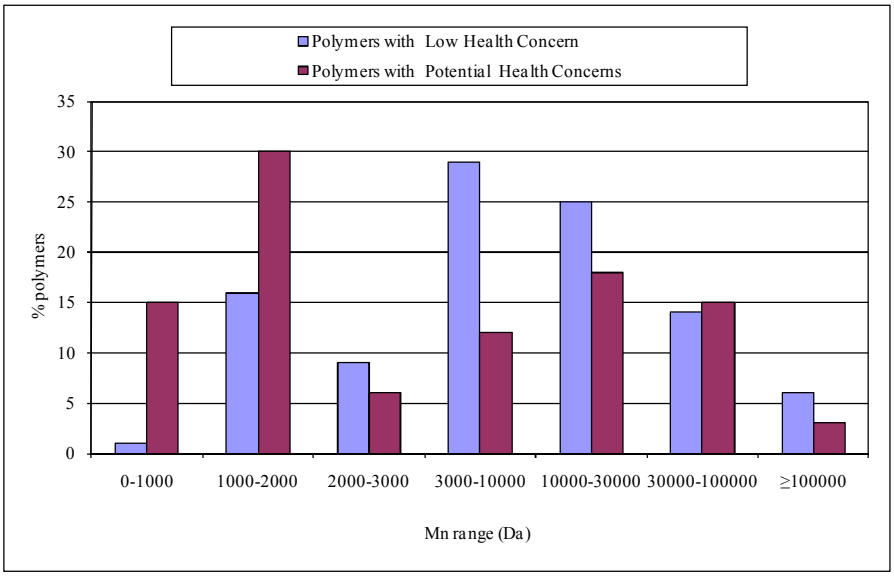

Figure A1.2: Polymer Health Concern Rating based on Mn

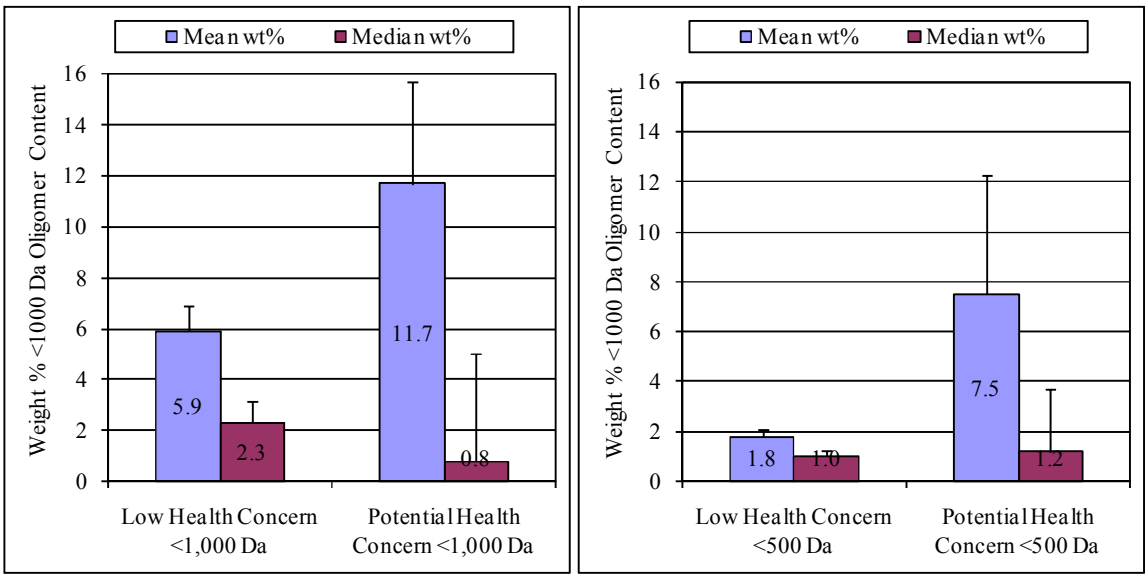

Figure A1.3: Oligomer Content of Polymers with Different Levels of Health Concern

Similar relationship patterns were noted in the associations seen between weight and ecotoxic concern (based on maximum ecotoxic concern). Indeed, most of the polymers qualifying as of 'moderate' or 'high' ecotoxicological concern again had molecular weights <2000 Da. For oligomer context, concern also increased progressively with rising content of <1000 Da oligomeric species (Figure A1.4, taken from OECD, 2009).

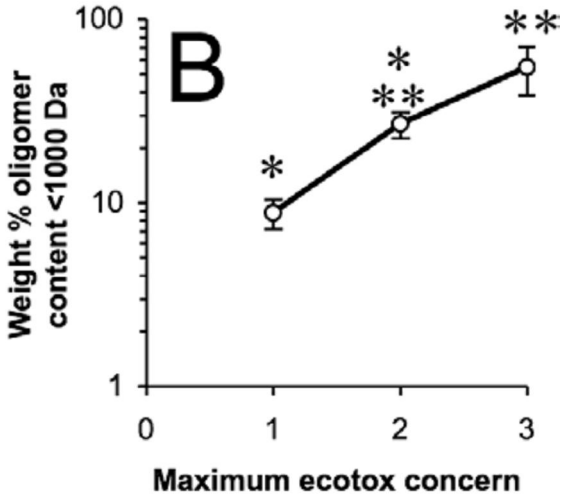

Figure A1.4: Analysis of Relationship between Ecotoxicity Concern and Oligomer Content

Reactive Functional Group

Although observation of the dataset appeared to suggest that more polymers in the potential health concern dataset contained RFGs than for the low health concern

dataset, average RFG ratings were not significantly different (p >0.1) between categories, suggesting that no strong associations can be inferred from this study.

Polymer Solubility

Only solubility in water was considered. Polymers of low health concern were found to distribute mainly (43.5%) among those with very low solubility (<10 mg/L) while the proportion of polymers with no or potential concerns were similar for those of very high solubility (>10,000 mg/L). However, those of intermediate solubility (i.e. 10<10,000 mg/L) included 62.5% of polymers of potential health concern (see Figure A1.5).

A tendency towards higher water solubility was observed for those polymers of moderate or high ecotoxicological concern, although no differences attained a level of statistical significance.

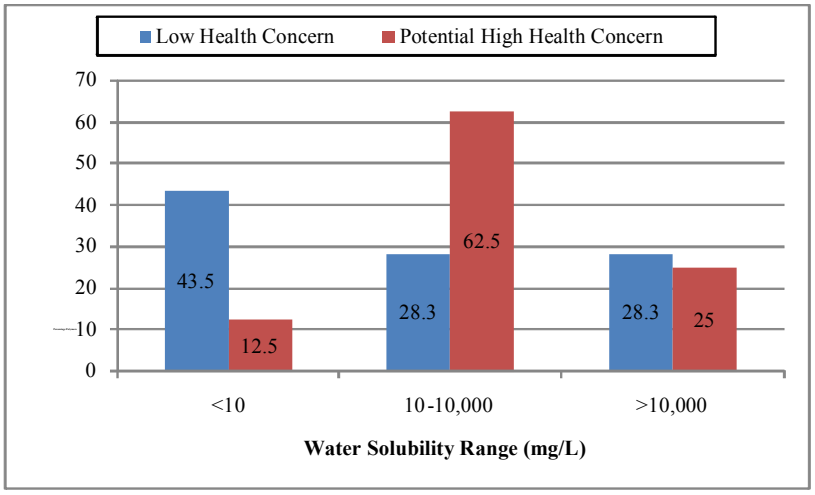

Figure A1.5: Distribution of Polymers by Water Solubility
(Numbers normalised as % of total in each concern group)

Chemical Class (i.e. Polymer Type)

Consideration of the distribution of health concerns for the various chemical classes of polymer for which data were available appeared to suggest that polyesters, polysaccharides, siloxanes and silicones did not associate with health concern (Figure A1.6, taken from OECD, 2009). However, the authors note that, except for polyesters, there were insufficient data to draw firm conclusions, although they do comment that for some classes (e.g. polyacrylates) the apparent number with health concerns may reflect a tendency to contain residual toxic monomers. This final point reflects the need to account for monomers and reaction by-products that are toxic.

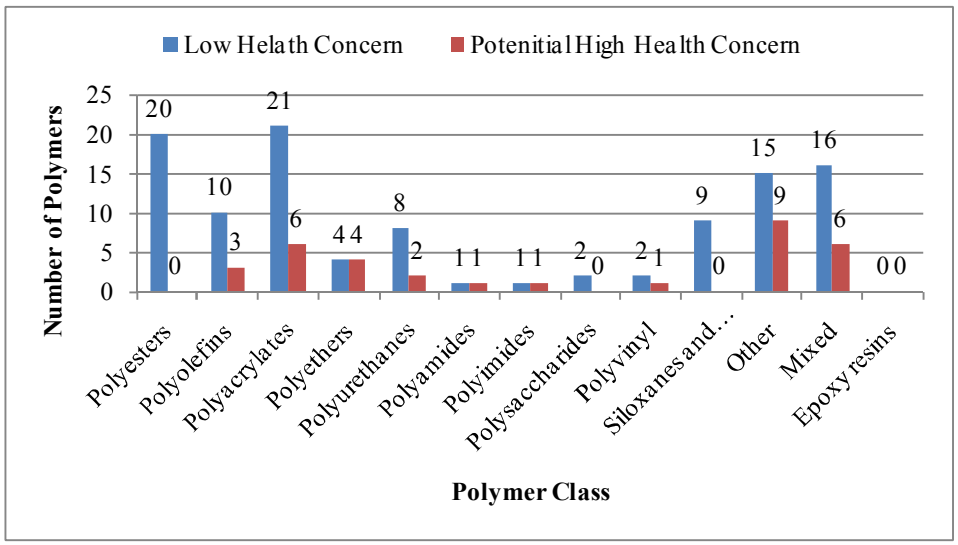

Figure A1.6: Distribution of Low or Potential Health Concerns Amongst Different Chemical Classes of Polymers

When the significance for health concern, of molecular weight was considered for the individual classes of polymer, it was apparent that some chemical classes were composed of mainly lower molecular weight polymers (e.g. some polyethers where identified) while, for only some chemical classes, there appeared to be a tendency for polymers of low molecular weight to associate with a potential health concern (e.g. polyethers and polyurethanes); such an association was not apparent for other classes (e.g. polyolefins and polyacrylates). Regrettably, limitations in data quantity and quality precluded more meaningful analysis.

Residual Monomer Content

Unreacted monomer(s) were present in 147 of the polymers (71.7%), 41 did not contain any residual monomer (20%) while this parameter was uncertain in 17 cases (8.3%). Since no information was available as to the identity, level or hazard profile of the residual monomers, no analysis was possible.

Final Notes

Other factors that may influence whether or not a polymer should be treated as a PCL were considered in OECD (2009), but there was insufficient data for conclusions to be drawn, e.g. with respect to ionicity of polymers soluble in water and degradation potential.

A1.4.3 Overview of OCED Conclusions

Overall, OECD (2009) provides a degree of confidence that – provided sufficient data are available – use of the PLC criteria allows the identification of polymers with only insignificant/limited health or ecotoxic concerns, and suggests that this is a useful

concept that may allow the adoption of a reduced regulatory requirement for PLC-compliant polymers.

Nonetheless, the study also highlighted that there are issues regarding data availability to establish the hazard posed by polymers. In particular, deficiencies were noted in the data on reactive functional groups, polymer class and residual monomers, the rationale for classification of health effects, and a polymer's PLC/non-PLC status. The extent to which such data may be necessary to support registration, therefore warrants consideration.

Specific observations that arose from this investigation included: concern regarding risk to human health and/or the environment appears to be inversely correlated with number average molecular weight; oligomer content may associate with human health and/or the environment concerns, particularly in the case of polymers containing >5% of <1,000 Da oligomers or >2% of <500 Da oligomers; no allowable oligomer content limit was discernable for polymers of molecular weight 1000-10,000 Da (i.e. <25% for <1000 Da species and <10% for <500 Da species); number average molecular weight used in conjunction with oligomer content, suggests those of potential health concern most likely to show weights of less than 10,000 Da and an oligomer content of >1%; there is evidence suggesting polyesters may show inherently low toxicity; RFGs (particularly amino and epoxide groups & un-substituted positions ortho- to a phenolic hydroxyl) appear to be more common in polymers with potential health or (eco)toxicological concern; limited evidence suggests polymers with water solubilities of 10-10,000 mg/L may be of most human health concern; limited evidence suggests a possible correlation between water solubility and (eco)toxicological concern for polymers with water solubility of >10 mg/L.

In conclusion, the study adds support to the hypothesis that polymers meeting the PLC criteria are likely to have insignificant human health or environmental impacts is thus supported, and suggests that reduced regulatory requirements might be appropriate for such polymers.

Box A1.1: Issues for Further Consideration

1. Concern regarding access to hazard data on polymers supports the registration of polymers under REACH.2. Use of some PLC criteria may be justified for excluding/reducing registration requirements for PLCs.
3. Evidence shows that PCL criteria based on molecular weight and oligomer content is robust.
4. There is a need for further research on the value of unreacted monomer content and some of the other PLC criteria to identify inherently low hazard polymers

A1.5 Recent Academic Approach

Alongside the national and international developments in polymer risk assessment within a regulatory context, some academic research has also been recently published in this area.

A1.5.1 Methodology of Lithner et al.: Composition-based Polymer Ranking

Lithner *et al.* (2011a,b & c) proposed a ranking and assessment method for polymers based on application of the harmonised hazard classifications (using CLP classifications) for the substances that contribute to that polymer.

Briefly, the CLP hazard classifications of constituents (monomers and additives) were assigned to one of five levels of perceived significance (ranging from **I** – low significance (e.g. physicochemical hazards such as oxidising agents) to **V** – high significance (e.g. carcinogenicity or mutagenicity)) and a nominal hazard grade score was assigned to each level (at intervals of 10-fold between levels). The polymers that were considered in the paper had been prioritised for consideration based on annual global production volumes and, for each polymer prioritised for consideration, the various hazard classifications established for each of the constituents of the polymer were identified; the substances considered at this stage comprised not just the monomer but also additive and other agents. A composite score was then determined for each polymer, based upon summation of the hazard classification scores of the individual constituents adjusted for the quantity of that constituent present in the polymer (expressed as a percentage by weight, wt.%). Separate environmental and health composite 'hazard' scores were then determined for each polymer and the results ranked to identify those of greatest concern.

Although representing a somewhat novel approach that draws on readily available information on the CLP classification of substances, and using these to assess and rank the relative risks that might potentially associated with a particular polymer, there are several concerns with regard to its suitability. For example, the method has only been demonstrated in relation to consideration of both monomers and additives, and does not address some important properties such as PBT, vPvB or endocrine disruption (since these are not directly addressed within the CLP classification system). It also essentially constitutes only a ranking tool addressing the properties of individual constituents (which might actually no longer be present after polymerisation), rather than considering the polymer itself. Also, no criteria for what score would warrant further regulatory action can be derived given that the comparative "hazard" scores used appear to have been derived on a somewhat arbitrary basis. Furthermore, this approach has yet to be independently critically compared with existing approaches arising from authoritative national or international bodies.

Given these reservations, no further consideration will be given to this method at this time.

ANNEX 2:

SUPPLEMENTARY COST DATA

Table A2.1: Summary of level of Registration and associated requirements for each group identified by each screening option (percentage of polymers in each group)									
Dossier and Information Requirements		**1 - Minimal**	**2a - Partial**	**2b - Partial - CSA**	**3a - Partial**	**3b - Partial Plus - CSA**	**4a - Full**	**4b - Full - CSA**	
On-site isolated intermediates		All	All	All	All	All	All	All	
Annex VII			>1	>1	1-10	1-10	1-10	1-10	
Annex VIII					>10	>10	10-100	10-100	
Annex IX							>100	>100	
Annex X							>1000	>1000	
CSA				>100		>100		>10	
Screening Option	**Registration Option**	**1 - Minimal**	**2a - Partial**	**2b - Partial - CSA**	**3a - Partial**	**3b - Partial Plus - CSA**	**4a - Full**	**4b - Full - CSA**	**Total**
Screening Option 1: Screening Based on Diffuse/Dispersive Use (D) and Non-Diffuse/Dispersive Use (ND) Only	Low	100%	0%	0%	0%	0%	0%	0%	100%
	Low b	69%	0%	31%	0%	0%	0%	0%	100%
	Low-Medium	0%	69%	31%	0%	0%	0%	0%	100%
	Medium	0%	69%	0%	0%	31%	0%	0%	100%
	Medium-High	0%	0%	0%	69%	31%	0%	0%	100%
	High	0%	0%	0%	0%	0%	69%	31%	100%
Screening Option 2: Multidimensional Screening	Low a	17%	0%	0%	0%	0%	0%	0%	17%
	Low b	12%	0%	5%	0%	0%	0%	0%	17%
	Low-Medium	95%	0%	5%	0%	0%	0%	0%	100%
	Medium	48%	35%	12%	0%	5%	0%	0%	100%
	Medium-High	48%	29%	12%	6%	0%	0%	5%	100%
	High	48%	29%	6%	0%	6%	6%	5%	100%
Screening Option 3a: Linear Screening as in Figure 1.2	Low a	17%	0%	0%	0%	0%	0%	0%	17%
	Low b	12%	0%	5%	0%	0%	0%	0%	17%
	Low-Medium	12%	0%	5%	0%	0%	0%	0%	17%
	Medium	0%	6%	6%	0%	5%	0%	0%	17%
	Medium-High	0%	0%	6%	6%	0%	0%	5%	17%
	High	0%	0%	0%	0%	6%	6%	5%	17%
Screening Option 3b: Linear Screening as in Figure 1.3	Low a	11%	0%	0%	0%	0%	0%	0%	11%
	Low b	6%	0%	5%	0%	0%	0%	0%	11%
	Low-Medium	6%	0%	5%	0%	0%	0%	0%	11%
	Medium	0%	0%	6%	0%	5%	0%	0%	11%
	Medium-High	0%	0%	6%	0%	0%	0%	5%	11%
	High	0%	0%	0%	0%	6%	0%	5%	11%

Table A2.2: Number of polymers to be registered by tonnage band (scenario I) and number of polymers covered by extended monomer dossiers (scenario II)						
Screening	**Registration**	**>1000 tpa**	**>100 tpa**	**>10 tpa**	**>1 tpa**	**Total**
I. Separate Registration for Polymers						
Option 1	**Low a**	3,500	10,500	28,000	28,000	70,000
	Low b	3,500	10,500	28,000	28,000	70,000
	Low-Medium	3,500	10,500	28,000	28,000	70,000
	Medium	3,500	10,500	28,000	28,000	70,000
	Medium-High	3,500	10,500	28,000	28,000	70,000
	High	3,500	10,500	28,000	28,000	70,000
Option 2	**Low a**	600	1,800	4,750	4,750	11,900
	Low b	600	1,800	4,750	4,750	11,900
	Low-Medium	3,500	10,500	28,000	28,000	70,000
	Medium	3,500	10,500	28,000	28,000	70,000
	Medium-High	3,500	10,500	28,000	28,000	70,000
	High	3,500	10,500	28,000	28,000	70,000
Option 3a	**Low a**	600	1,800	4,750	4,750	11,900
	Low b	600	1,800	4,750	4,750	11,900
	Low-Medium	600	1,800	4,750	4,750	11,900
	Medium	600	1,800	4,750	4,750	11,900
	Medium-High	600	1,800	4,750	4,750	11,900
	High	600	1,800	4,750	4,750	11,900
Option 3b	**Low a**	400	1,150	3,000	3,000	7,550
	Low b	400	1,150	3,000	3,000	7,550
	Low-Medium	400	1,150	3,000	3,000	7,550
	Medium	400	1,150	3,000	3,000	7,550
	Medium-High	400	1,150	3,000	3,000	7,550
	High	400	1,150	3,000	3,000	7,550
II. Extension of Monomer Registration to include Polymers (polymers covered)						
Option 1	**Low**	1,100	3,300	8,800	8,800	22,000
	High	3,500	10,500	28,000	28,000	70,000
Option 2	**Low**	400	1,100	3,000	3,000	7,600
	Low-Medium	600	1,800	4,800	4,800	11,900
	Medium-High	800	2,400	6,500	6,500	16,200
	High	1,300	3,900	10,500	10,500	26,300
Option 3a	**Low**	200	500	1,300	1,300	3,300
	Medium	400	1,100	3,000	3,000	7,600
	High	600	1,800	4,800	4,800	11,900
Option 3b	**Low**	200	500	1,300	1,300	3,300
	High	400	1,100	3,000	3,000	7,600

Table A2.3: Polymer Option Substance ID and Testing - Costs of Requirements (€ Million)					
Screening Option 1: One Dimensional					
Registration Option	>1000 tpa	>100 tpa	>10 tpa	>1 tpa	Total
Low a	35.0	105.0	280.0	280.0	700.0
Low b	60.0	180.0	479.9	479.9	1,199.8
Low-Medium	114.5	343.7	916.7	916.7	2,291.6
Medium	269.6	807.4	2,153.2	916.7	4,146.9
Medium-High	608.3	1,820.3	4,854.5	916.7	8,199.8
High	6,309.1	8,260.7	4,854.5	916.7	20,341.0
Screening Option 2: Multidimensional					
Low a	6.0	17.8	47.6	47.6	119.0
Low b	9.7	28.9	77.2	77.2	192.9
Low-Medium	38.7	116.1	309.6	309.6	774.0
Medium	99.3	297.7	793.9	611.0	1,802.0
Medium-High	395.4	688.2	1,037.1	611.0	2,731.6
High	777.8	1,176.8	1,280.2	611.0	3,845.7
Screening Option 3a: Linear					
Low a	6.0	17.8	47.6	47.6	119.0
Low b	9.7	28.9	77.2	77.2	192.9
Low-Medium	9.7	28.9	77.2	77.2	192.9
Medium	42.5	127.0	338.7	155.8	664.0
Medium-High	338.5	517.5	581.9	155.8	1,593.7
High	720.9	1,006.1	825.0	155.8	2,707.8
Screening Option 3b: Linear Screening					
Low a	3.8	11.4	30.3	30.3	75.8
Low b	7.5	22.5	59.9	59.9	149.7
Low-Medium	7.5	22.5	59.9	59.9	149.7
Medium	35.4	105.8	282.1	99.2	522.6
Medium-High	301.0	405.1	282.1	99.2	1,087.5
High	331.5	496.3	525.3	99.2	1,452.2

Table A2.4: Polymer Option Registration Costs (€ Million)					
Screening Option 1: One Dimensional					
Registration Option	>1000 tpa	>100 tpa	>10 tpa	>1 tpa	Total
Low a	7.6	22.7	49.2	46.0	125.4
Low b	91.1	167.7	189.2	163.5	611.4
Low-Medium	211.9	382.8	443.2	372.7	1,410.7
Medium	214.6	390.9	464.8	372.7	1,443.0
Medium-High	220.5	408.6	512.0	372.7	1,513.7
High	235.1	437.8	549.3	372.7	1,594.8
Screening Option 2: Multidimensional					
Low a	1.3	3.9	8.4	7.8	21.3
Low b	13.7	25.3	29.1	25.2	93.2
Low-Medium	19.9	44.1	69.9	63.4	197.3
Medium	114.9	212.2	258.1	216.6	801.8
Medium-High	116.1	215.1	267.8	216.6	815.7
High	117.5	218.5	272.1	216.6	824.7
Screening Option 3a: Linear					
Low a	1.3	3.9	8.4	7.8	21.3
Low b	13.7	25.3	29.1	25.2	93.2
Low-Medium	13.7	25.3	29.1	25.2	93.2
Medium	41.3	74.3	82.6	67.1	265.4
Medium-High	42.6	77.3	92.4	67.1	279.3
High	44.0	80.7	96.6	67.1	288.4
Screening Option 3b: Linear Screening					
Low a	0.8	2.5	5.3	5.0	13.6
Low b	13.2	23.9	26.0	22.4	85.5
Low-Medium	13.2	23.9	26.0	22.4	85.5
Medium	30.0	53.6	56.7	45.4	185.8
Medium-High	30.7	54.9	62.2	45.4	193.3
High	31.2	56.5	66.5	45.4	199.7

Table A2.5: Polymer Option Fees (€ Million)					
Screening Option 1: One Dimensional					
Registration Option	>1000 tpa	>100 tpa	>10 tpa	>1 tpa	Total
Low a	4.1	11.9	29.0	21.5	66.6
Low b	27.9	35.1	44.4	21.5	129.0
Low-Medium	80.0	85.8	78.0	21.5	265.3
Medium	80.0	85.8	78.0	21.5	265.3
Medium-High	80.0	85.8	78.0	21.5	265.3
High	80.0	85.8	78.0	21.5	265.3
Screening Option 2: Multidimensional					
Low a	0.7	2.0	4.9	3.7	11.3
Low b	4.2	5.5	7.2	3.7	20.6
Low-Medium	7.7	15.4	31.3	21.5	75.8
Medium	43.6	50.4	54.5	21.5	169.9
Medium-High	43.6	50.4	54.5	21.5	169.9
High	43.6	50.4	54.5	21.5	169.9
Screening Option 3a: Linear					
Low a	0.7	2.0	4.9	3.7	11.3
Low b	4.2	5.5	7.2	3.7	20.6
Low-Medium	4.2	5.5	7.2	3.7	20.6
Medium	13.6	14.6	13.3	3.7	45.1
Medium-High	13.6	14.6	13.3	3.7	45.1
High	13.6	14.6	13.3	3.7	45.1
Screening Option 3b: Linear Screening					
Low a	0.4	1.3	3.1	2.3	7.2
Low b	4.0	4.7	5.4	2.3	16.4
Low-Medium	4.0	4.7	5.4	2.3	16.4
Medium	8.7	9.3	8.4	2.3	28.7
Medium-High	8.7	9.3	8.4	2.3	28.7
High	8.7	9.3	8.4	2.3	28.7

Table A2.6: Polymer Option Total Costs (€ Million)					
Screening Option 1: One Dimensional					
Registration Option	>1000 tpa	>100 tpa	>10 tpa	>1 tpa	Total
Low a	46.7	139.6	358.2	347.5	892.0
Low b	179.0	382.8	713.5	665.0	1,940.2
Low-Medium	406.4	812.4	1,437.9	1,310.9	3,967.6
Medium	564.2	1,284.1	2,696.0	1,310.9	5,855.2
Medium-High	908.7	2,314.8	5,444.5	1,310.9	9,978.8
High	6,624.1	8,784.4	5,481.8	1,310.9	22,201.1
Screening Option 2: Multidimensional					
Low a	7.9	23.7	60.9	59.1	151.6
Low b	27.6	59.7	113.4	106.0	306.7
Low-Medium	66.3	175.6	410.8	394.5	1,047.2
Medium	257.8	560.3	1,106.5	849.1	2,773.6
Medium-High	555.0	953.7	1,359.4	849.1	3,717.1
High	938.8	1,445.7	1,606.7	849.1	4,840.3
Screening Option 3a: Linear					
Low a	7.9	23.7	60.9	59.1	151.6
Low b	27.6	59.7	113.4	106.0	306.7
Low-Medium	27.6	59.7	113.4	106.0	306.7
Medium	97.4	216.0	434.6	226.5	974.5
Medium-High	394.7	609.3	687.5	226.5	1,918.1
High	778.5	1,101.3	934.9	226.5	3,041.3
Screening Option 3b: Linear Screening					
Low a	5.1	15.1	38.8	37.6	96.5
Low b	24.7	51.1	91.3	84.6	251.6
Low-Medium	24.7	51.1	91.3	84.6	251.6
Medium	74.1	168.7	347.3	147.0	737.0
Medium-High	340.3	469.4	352.8	147.0	1,309.5
High	371.3	562.1	600.2	147.0	1,680.6

Table A2.7: Total Estimated Costs for the Different Polymer Options by Cost Types (€ million)					
Screening	**Registration**	**Substance ID and testing**	**Registration costs**	**Registration fees**	**Total costs**
I. Separate Registration for Polymers					
Option 1	**Low a**	700	300	70	1,070
	Low b	920	500	90	1,510
	Low-Medium	2,290	1,300	270	3,860
	Medium	3,110	1,400	270	4,780
	Medium-High	8,200	1,500	270	9,970
	High	20,340	1,500	270	22,110
Option 2	**Low a**	300	100	30	430
	Low b	400	200	40	640
	Low-Medium	800	400	80	1,280
	Medium	2,520	1,300	250	4,070
	Medium-High	5,340	1,300	250	6,890
	High	9,600	1,300	250	11,150
Option 3a	**Low a**	300	100	30	430
	Low b	400	200	40	640
	Low-Medium	400	200	40	640
	Medium	1,350	600	110	2,060
	Medium-High	4,170	600	110	4,880
	High	8,430	600	110	9,140
Option 3b	**Low a**	50	30	10	90
	Low b	160	110	20	290
	Low-Medium	160	110	20	290
	Medium	560	140	20	720
	Medium-High	1,350	150	20	1,520
	High	1,420	150	20	1,590
II. Extension of Monomer Registration to include Polymers (polymers covered)					
Option 1	**Low Option**	0	140	0	140
	High Option	0	330	0	330
Option 2	**Low**	0	50	0	50
	Low-Medium	0	70	0	70
	Medium-High	0	90	0	90
	High	0	130	0	130
Option 3a	**Low**	0	20	0	20
	Medium	0	50	0	50
	High	0	70	0	70
Option 3b	**Low**	0	20	0	20
	High	0	50	0	50

Table A2.8: Total Costs by Company Size for the Polymer Options (€ million)					
		Micro	**Small**	**Medium**	**Large**
I. Separate Registration for Polymers					
Option 1	**Low a**	130	190	280	290
	Low b	250	380	620	680
	Low-Medium	500	770	1,270	1,420
	Medium	640	1,070	1,880	2,260
	Medium-High	950	1,720	3,230	4,080
	High	1,260	2,650	7,540	10,760
Option 2	**Low a**	20	30	50	50
	Low b	40	60	100	110
	Low-Medium	150	220	330	350
	Medium	340	540	890	1,000
	Medium-High	390	640	1,210	1,480
	High	430	750	1,600	2,060
Option 3a	**Low a**	20	30	50	50
	Low b	40	60	100	110
	Low-Medium	40	60	100	110
	Medium	110	180	310	370
	Medium-High	150	280	640	850
	High	200	400	1,020	1,430
Option 3b	**Low a**	10	20	30	30
	Low b	30	50	80	90
	Low-Medium	30	50	80	90
	Medium	80	130	240	290
	Medium-High	90	180	440	600
	High	120	230	560	770
II. Extension of Monomer Registration to include Polymers (polymers covered)					
Option 1	**Low Option**	10	20	50	60
	High Option	30	60	110	130
Option 2	**Low**	-	10	20	20
	Low-Medium	10	10	20	30
	Medium-High	10	20	30	40
	High	10	20	40	50
Option 3a	**Low**	-	-	10	10
	Medium	-	10	20	20
	High	10	10	20	30
Option 3b	**Low**	-	-	10	10
	High	-	10	20	20

Table A2.9: Average cost per polymer registered (or extended monomer Registration dossier)						
		Average per polymer	Average cost per M/I by company size			
			Micro	Small	Medium	Large
I. Separate Registration of Polymers						
Option 1	**Low a**	**€ 15,700**	83,000	362,000	1,133,000	3,386,000
	Low b	**€ 21,900**	112,000	495,000	1,590,000	4,823,000
	Low-Medium	**€ 55,800**	282,000	1,240,000	4,060,000	12,448,000
	Medium	**€ 67,700**	317,000	1,455,000	4,941,000	15,738,000
	Med-High	**€ 141,700**	538,000	2,785,000	10,404,000	36,157,000
	High	**€ 316,000**	711,000	4,274,000	24,389,000	95,715,000
Option 2	**Low a**	**€ 15,700**	35,000	153,000	478,000	1,428,000
	Low b	**€ 22,600**	49,000	215,000	692,000	2,100,000
	Low-Medium	**€ 18,600**	97,000	424,000	1,347,000	4,058,000
	Medium	**€ 57,500**	279,000	1,255,000	4,186,000	13,101,000
	Med-High	**€ 98,400**	379,000	1,886,000	7,286,000	25,159,000
	High	**€ 159,500**	441,000	2,416,000	12,177,000	45,954,000
Option 3a	**Low a**	**€ 15,700**	35,000	153,000	478,000	1,428,000
	Low b	**€ 22,600**	49,000	215,000	692,000	2,100,000
	Low-Medium	**€ 22,600**	49,000	215,000	692,000	2,100,000
	Medium	**€ 69,300**	136,000	625,000	2,132,000	6,817,000
	Med-High	**€ 166,500**	235,000	1,256,000	5,232,000	18,874,000
	High	**€ 311,200**	298,000	1,786,000	10,123,000	39,669,000
Option 3b	**Low a**	**€ 15,700**	6,000	28,000	88,000	261,000
	Low b	**€ 53,400**	20,000	90,000	301,000	934,000
	Low-Medium	**€ 53,400**	20,000	90,000	301,000	934,000
	Medium	**€ 132,700**	40,000	202,000	753,000	2,600,000
	Med-High	**€ 280,400**	51,000	301,000	1,668,000	6,490,000
	High	**€ 294,100**	54,000	320,000	1,746,000	6,782,000
II. Extension of Monomer Registration to include Polymers						
Option 1	**Low**	**€ 56,300**	14,000	21,500	102,400	420,200
	High	**€ 275,500**	33,200	55,400	260,600	983,400
Option 2	**Low**	**€ 31,300**	4,800	7,400	35,300	144,800
	Low-Medium	**€ 119,000**	6,600	10,500	49,500	195,500
	Med-High	**€ 139,000**	9,300	14,700	69,700	278,100
	High	**€ 226,700**	13,300	21,800	102,900	396,400
Option 3a	**Low**	**€ 26,300**	2,100	3,200	15,200	62,200
	Medium	**€ 31,300**	4,800	7,400	35,300	144,800
	High	**€ 119,000**	6,600	10,500	49,500	195,500
Option 3b	**Low**	**€ 26,300**	2,100	3,200	15,200	62,200
	High	**€ 31,300**	4,800	7,400	35,300	144,800

Table A2.10: Expected Number of Previously Unclassified Polymers that would require New Classification (if tested according to Annex X requirements)					
Polymer Group	**>1000 tpa**	**>100 tpa**	**>10 tpa**	**>1 tpa**	**TOTAL**
A	336	1009	2689	2689	**6723**
B	0	0	0	0	**0**
C	0	0	0	0	**0**
D	277	832	2,219	2,219	**5,547**
E	119	356	951	951	**2,377**
F	0	0	0	0	**0**
G	0	0	0	0	**0**
Total	**732**	**2,197**	**5,859**	**5,859**	**14,647**

Table A2.11: Expected Number of Already Classified Polymers that would require Additional Classification (if tested according to Annex X requirements)					
Polymer Group	**>1000 tpa**	**>100 tpa**	**>10 tpa**	**>1 tpa**	**TOTAL**
A	0	0	0	0	**0**
B	126	378	1009	1009	**2,522**
C	54	162	432	432	**1080**
D	0	0	0	0	**0**
E	0	0	0	0	**0**
F	54	162	432	432	**1,080**
G	41	122	325	325	**813**
Total	**275**	**824**	**2,198**	**2,198**	**5,495**

Table A2.12: Expected Number of Polymers that would require Additional Classification as PBT/CMR 1A, 1B, 2 or Lact. (if tested according to Annex X requirements)					
Polymer Group	**>1000 tpa**	**>100 tpa**	**>10 tpa**	**>1 tpa**	**TOTAL**
A	20	61	161	161	**403**
B	8	23	61	61	**151**
C	3	10	26	26	**65**
D	17	50	133	133	**333**
E	7	21	57	57	**143**
F	3	10	26	26	**65**
G	2	7	20	20	**49**
Total	**60**	**181**	**483**	**483**	**1209**

Table A2.13: Number of previously unclassified substances requiring new classification				
	Screening Option 1: Screening Based on Diffuse Use Only	**Screening Option 2: Multi-dimensional Screening**	**Screening Option 3a: Linear Screening**	**Screening Option 3b: Linear Screening**
Low a	0	0	0	0
Low b	2637	0	0	0
Low-Medium	8788	0	0	0
Medium	9052	4754	0	0
Medium-High	9667	4754	0	0
High	10326	4754	0	0
Expected number	14,647			

Table A2.14: Percentage of expected maximum previously unclassified substances requiring new classification				
	Screening Option 1: Screening Based on Diffuse Use Only	**Screening Option 2: Multi-dimensional Screening**	**Screening Option 3a: Linear Screening**	**Screening Option 3b: Linear Screening**
Low a	0%	0%	0%	0%
Low b	18%	0%	0%	0%
Low-Medium	60%	0%	0%	0%
Medium	62%	32%	0%	0%
Medium-High	66%	32%	0%	0%
High	70%	32%	0%	0%

Table A2.15: Number of already classified substances requiring additional classification				
	Screening Option 1: Screening Based on Diffuse Use Only	**Screening Option 2: Multidimensional Screening**	**Screening Option 3a: Linear Screening**	**Screening Option 3b: Linear Screening**
Low a	0	0	0	0
Low b	1136	488	488	488
Low-Medium	3297	488	488	488
Medium	3411	3346	1833	1185
Medium-High	3627	3447	1934	1221
High	3874	3561	2048	1286
Expected Number	5,495			

Table A2.16: Percentage of Expected Maximum already classified substances requiring additional classification				
	Screening Option 1: Screening Based on Diffuse Use Only	**Screening Option 2: Multidimensional Screening**	**Screening Option 3a: Linear Screening**	**Screening Option 3b: Linear Screening**
Low a	0%	0%	0%	0%
Low b	21%	9%	9%	9%
Low-Medium	60%	9%	9%	9%
Medium	62%	61%	33%	22%
Medium-High	66%	63%	35%	22%
High	71%	65%	37%	23%

Table A2.17: No. of substances newly requiring PBT/vPvB CMR 1A, 1B, 2 or Lact. Classification				
	Screening Option 1: Screening Based on Diffuse Use Only	**Screening Option 2: Multidimensional Screening**	**Screening Option 3a: Linear Screening**	**Screening Option 3b: Linear Screening**
Low a	0	0	0	0
Low b	226	29	29	29
Low-Medium	725	29	29	29
Medium	748	486	110	71
Medium-High	798	492	116	73
High	852	499	123	77
Expected Nunber	1,209			

Table A2.18: Percentage of Expected Maximum PBT/vPvB/CMR 1A, 1B, 2 or Lact. Classification				
	Screening Option 1: Screening Based on Diffuse Use Only	**Screening Option 2: Multidimensional Screening**	**Screening Option 3a: Linear Screening**	**Screening Option 3b: Linear Screening**
Low a	0%	0%	0%	0%
Low b	19%	2%	2%	2%
Low-Medium	60%	2%	2%	2%
Medium	62%	40%	9%	6%
Medium-High	66%	41%	10%	6%
High	70%	41%	10%	6%

Table A2.19: Total number of substances found to have additional (previously unknown) classifications				
	Screening Option 1: Screening Based on Diffuse Use Only	**Screening Option 2: Multidimensional Screening**	**Screening Option 3a: Linear Screening**	**Screening Option 3b: Linear Screening**
Low a	0	0	0	0
Low b	3773	488	488	488
Low-Medium	12085	488	488	488
Medium	12463	8100	1833	1185
Medium-High	13294	8202	1934	1221
High	14200	8315	2048	1286
Expected Nunber	20,142			

Table A2.20: Effectiveness of Options at Developing New Hazard data and Classifications				
	Screening Option 1: Screening Based on Diffuse Use Only	**Screening Option 2: Multidimensional Screening**	**Screening Option 3a: Linear Screening**	**Screening Option 3b: Linear Screening**
Low a	0%	0%	0%	0%
Low b	19%	2%	2%	2%
Low-Medium	60%	2%	2%	2%
Medium	62%	40%	9%	6%
Medium-High	66%	41%	10%	6%
High	70%	41%	10%	6%