# REVIEW OF REACH WITH REGARD TO THE REGISTRATION REQUIREMENTS FOR POLYMERS AND 1 TO 10 TONNE SUBSTANCES

**070307/2011/602175/SER/D3**

## Final Report
## Executive Summary

**Prepared for**

**European Commission**
**DG Environment**

**December 2012**

RPA
gnosys
milieu
ENVIRONMENTAL LAW & POLICY
ARCHE
ASSESSING RISKS OF CHEMICALS

# Review of REACH with regard to the Registration Requirements on Polymers and 1 to 10 Tonne Substances

**070307/2011/602175/SER/D3**

# Executive Summary

## December 2012

prepared for

European Commission
DG Environment

by

**Risk & Policy Analysts Limited**
Farthing Green House, 1 Beccles Road, Loddon, Norfolk, NR14 6LT
Tel: 01508 528465 Fax: 01508 520758
Email: post@rpaltd.co.uk

| **RPA REPORT - ASSURED QUALITY** | | |
|---|---|---|
| RPA Project Ref: | J762 | |
| Approach: | In accordance with the agreed work plan | |
| Report Status: | Final | |
| Report Prepared by: | Meg Postle (RPA)<br>Philip Holmes (RPA)<br>Marco Camboni (RPA)<br>Anthony Footitt (RPA)<br>Nigel Tuffnell (RPA) | Mark Blainey (Milieu)<br>Gary Stevens (GnoSys)<br>Amy Pye (GnoSys)<br>Frederik Verdonck (Arche)<br>Catherine Ganzleben (Milieu)<br>Florent Pelsy (Milieu) |
| Report approved for issue by: | Meg Postle, Director | |
| Date: | 6 December 2012 | |

# 1. Background to the Study

## 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).

## 1.2 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] 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).

| **Table 1: Summary of Reviews Required under Article 138 of REACH** | |
|---|---|
| **Summary of Review** | **Deadline** |
| Chemical Safety Assessment/Report exemptions for substances manufactured/ imported in quantities less than 10 tonnes per company.<br><br>CMRs Cat. 1 or 2 under Directive 67/538/EEC (Cat 1A or Cat 1B under Regulation (EC) No 1272/2008) | 1 June 2019<br><br>1 June 2014 |
| Consider registration of polymers | As soon as practicable |
| 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) |
| Annexes I, IV and V | 1 June 2008 |
| Annex XIII | 1 December 2008 |
| Scope of REACH regarding overlaps with other EU legislation | 1 June 2012 |
| Endocrine disrupting chemicals | 1 June 2013 |
| Communication on additional dangerous substances in articles | 1 June 2019 |
| Promotion of non-animal testing | 1 June 2019 |

Article 138(1) states that:

> *By 1 June 2019, the Commission shall carry out a review to assess whether or not to extend the application of the obligation to perform a chemical safety assessment and to document it in a chemical safety report to substances not covered by this obligation because they are not subject to registration or subject to registration but manufactured or imported in quantities of less than 10 tonnes per year. However, for substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1 or 2, in accordance with Directive 67/548/EEC, the review shall be carried out by 1 June 2014. When carrying out the review the Commission shall take into account all relevant factors, including:*
>
> *(a) the costs for manufacturers and importers of drawing up the chemical safety reports;*
> *(b) the distribution of costs between actors in the supply chain and the downstream user;*
> *(c) the benefits for human health and the environment.*
>
> *On the basis of these reviews, the Commission may, if appropriate, present legislative proposals to extend this obligation.*

With respect to polymers, the review of specific concern for this element of the study are those required under Article 138(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.*

Article 138(3) places further obligations were placed on the Commission in relation to substances registered in quantities greater than or equal to one tonne and less than 10 tonnes per year per manufacturer or importer (1 to 10 tonne substances):

> *The report, referred to in Article 117(4), on the experience acquired with the operation of this Regulation shall include a review of the requirements relating to registration of substances manufactured or imported only in quantities starting at 1 tonne but less than 10 tonnes per year per manufacturer or importer. On the basis of that review, the Commission may present legislative proposals to modify the information requirements for substances manufactured or imported in quantities of 1 tonne or more up to 10 tonnes per year per manufacturer or importer, taking into account the latest development, for example in relation to alternative testing and (quantitative) structure-activity relationships ((Q)SARs).*

This study was carried out in response to these obligations. Part A focuses on the review in relation to polymers, while Part B focuses on 1 to 10 tonne substances which are registered only in that tonnage band. This second assessment responds to the obligations set out under Article 138(1) and (3).

# 2. Part A: Review of the Exemption of Polymers from Registration Requirements

## 2.1 Aims of the Study

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) was to review the exemption from registration requirements for polymers.

Our work started by reviewing the current requirements with regard to the registration of polymers, monomers, and other polymer constituents under REACH. Information on polymers is then presented, together with data on the industry that manufactures and uses them. The report then considers the potential hazards posed by polymers and compares these with those posed by monomers and other substances.

The results of the previous impact assessment on polymers is reviewed, and from this and information gathered for this study, a series of assumptions are developed to act as the basis for the impact assessment carried out for this component of the study.

A complex array of policy options was developed and then assessed using a model developed for this study and specific to this component of the work. This model provides estimates of the costs associated with each of the policy options, together with predictions of the numbers of polymers that would be newly identified as having hazardous properties, as well as the number already classified and which may have additional classifications identified.

A summary of the key findings is given below.

## 2.1 The 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.

In practice, this study 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 were 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 were 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 and the variations in their requirements are summarised in Tables 2 to 4.

Table 2 sets out the different groupings adopted for polymers meeting varying screening criteria. Table 3 provides a summary of the options considered for the extension of the current Monomer Registration requirements. Table 4 provides a summary of the polymer registration options, with this highlighting the complexity of the options considered as part of this study. Reference to the main report may be required to understand fully the variations in the registration requirements associated with low, medium and high sub-options.

| Table 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 |

| Table 3: Polymers included in Monomer Registration | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **Polymers Included in Monomer Registration** | | | | | | | |
| **Polymer Group** | | 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 variant 1** | **Low** | - | - | - | - | - | - | G | **G** |
| | **Medium** | - | - | C | - | - | - | G | **C+G** |
| | **High** | - | - | C | - | - | F | G | **C+F+G** |
| **Screening Option 3b: Linear Screening variant 2** | **Low** | - | - | | - | - | - | G | **G** |
| | **High** | - | - | C | - | - | - | G | **C+G** |

Before providing a summary of the conclusions of this work, it is important to 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 data were collected and consultation was undertaken with polymer manufacturers, the quantitative assessment presented here should be considered to be indicative only.

| **Table 4: 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 |

## 2.3 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, 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.*). 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.

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 higher percentage probably 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 5 below.

**Table 5: 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** |

## 2.4 Total Numbers to be Registered under the Different 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 6.

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 6: 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 |

| **Table 6: 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** |
| **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 |

The implication of the above though is that it has been impossible in the analysis carried out here 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 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, 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).

## 2.5 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.

## 2.6 Costs and Benefits

### *Estimated Total Costs*

Figure 1 presents estimates of 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. As expected, the costs of testing and generating information increase with the amount of information

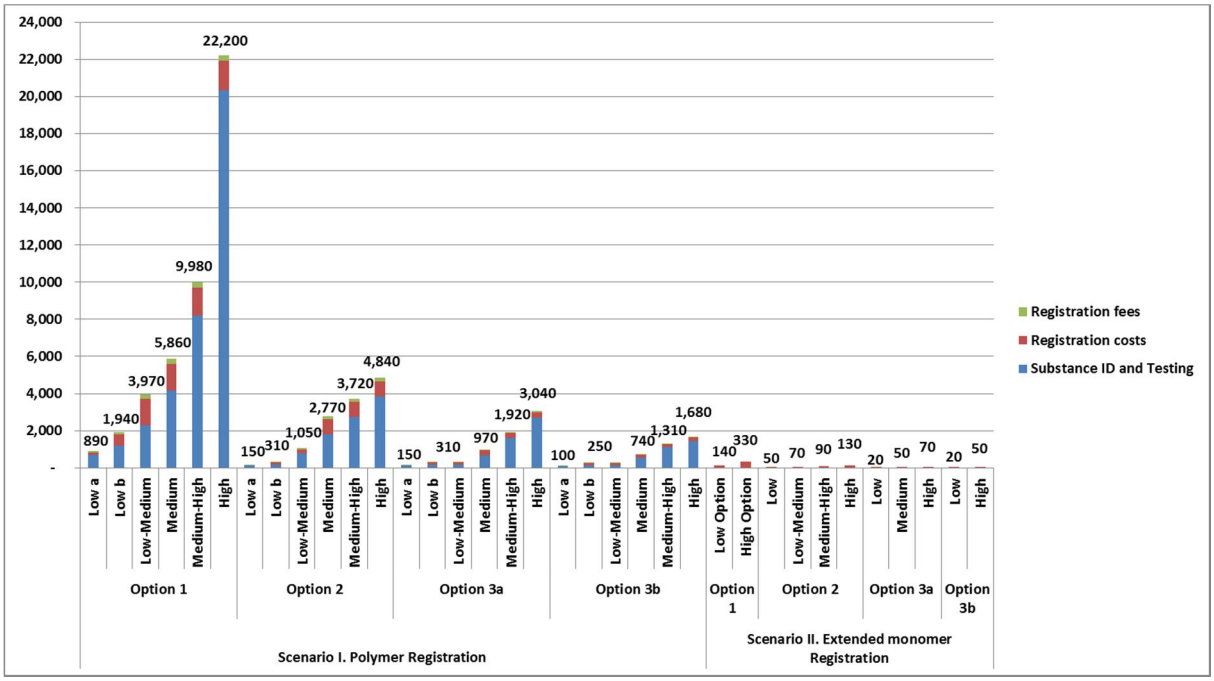


**Figure 1: Total costs for options and by cost type (€ million)**

required (although the costs of substance ID remain constant across the options) which, as expected, constitute the major cost burden.

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.

### *Average Costs per Substance*

In this respect, it is also useful to consider the average cost per polymer registered. This is illustrated in Figure 2.

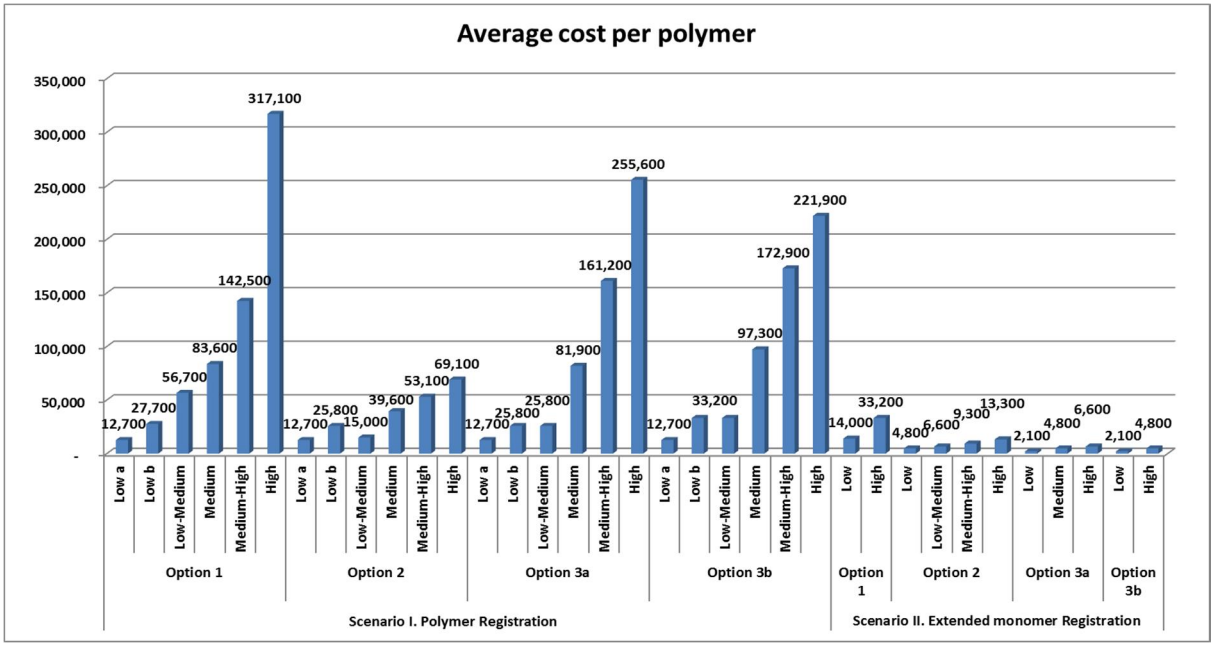


**Figure 11.2: Average cost per polymer registered or per extended monomer Registration dossier ( € )**

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 these can include full REACH information requirements for some groups of polymers (e.g. under the medium high and high registration options), the variations from the averages may be significant for some polymers.

## 2.7 Cost-Effectiveness

As one increases information requirements and the number of polymers required to generate information, 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 7 provides a summary of the cost-effectiveness of the different polymer registration options in newly identifying hazardous properties.

As can be seen from Table 7, 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 thus does not to produce an increase in the cost-effectiveness of the option. If we measure cost-effectiveness only in terms of the 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 cost-effectiveness 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 7: Average Cost per New Classification (€ Million per Substance Identified)**

| Registration Requirements | 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.

## 2.8 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**: 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 polymers 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.

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).

# 3. Part B: Review of Requirements for 1 to 10 Tonne Substances

## 3.1 Overview

The objective of this component of the study, as set out in the Specifications, was:

> *"…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, the aim was to review the registration requirements for 1 to 10 tonne substances, within the framework of the June 2012 report of the Commission required under Article 117(4).

As part of this review, the study collated background information on the EU chemicals industry and set out the current information requirements for 1 to 10 tonne substances. Approaches other than testing, especially testing on vertebrate animals, to fulfil the information requirements for registration were considered, in particular the potential for read across and for the use of SARs/QSARs.

The available data on substance properties was also examined, with this then used to predict the degree to which substances manufactured or imported at less than 10 tonnes per year per manufacturer/importer are likely to have hazardous properties.

A varied set of options were then developed for consideration in the assessment, and a probabilistic model was developed specifically for this study to help assess the costs and associated benefits of the different options. The outputs of the model include the estimated costs of implementing each of the options, together with a qualitative assessment of their potential impacts on innovation and competition.

Benefits are predicted in terms of the number of substances that would be newly identified as having hazardous properties; this is then accompanied by a consideration in quantitative terms of the value of the potential health effects that might be avoided through the availability of better information on the properties of substances registered in this tonnage band.

Finally, information on costs and benefits is brought together to provide a comparative assessment. The key findings of this comparative assessment are summarised below.

It is important to note that while the costs and benefits discussed here relate only to those substances registered in the 1 to 10 tonnage band, the impacts of extending or reducing information requirements would fall on all registrants registering substances in this particular tonnage range.

## 3.2 The Options

This study examined a range of options involving reduced information and extended information requirements for the registration of substances manufactured or imported only at 1 to 10 tonne substances under REACH. In total, eleven different options were considered:

- The Baseline: Current requirements under Article 12 and Annex III of REACH;
- Option 1 - No registration for substances manufactured or imported in quantities between 1 and 10 tonnes;
- Option 2 - Annex VII physicochemical data only;
- Option 3a - data on all Annex VII endpoints for hazardous substances:
- Option 3b - data on all Annex VII endpoints for all the substances:
- Option 4a - data on all Annex VII endpoints plus selected endpoints from Annex VIII for hazardous substances;
- Option 4b - data on all Annex VII endpoints and selected endpoints from Annex VIII for all the substances;
- Option 4c - No registration for non-CMR substances;
- Option 4d - No registration for non-CMR, non-PBT or non vPvB substances;
- Option 5a - data on all Annex VIII endpoints for hazardous substances; and
- Option 5b - data on all Annex VIII endpoints for all the substances.

## 3.3 Cost-Effectiveness of Options

### *Average Total Costs*

The estimated total costs for each option are presented in Table 8. As 1 to 10 tonne substances would not have to be registered under Option 1, this is clearly the lowest cost of all of the options, followed by Options 4c and 4d which make use of screening information to determine the number of substances that would have to go through registration. As can be seen from the above estimates, the total average costs per substances decrease significantly when moving from the current baseline requirements to either of these options; Option 4d is associated with slightly higher costs than Option 4c due to the additional need to screen for PBTs as a trigger to registration (with this also identifying additional substances requiring registration).

**Table 8: Total Costs by 1 to 10 Tonne Substance and Registrant**

| | Total Costs (€ million) | Total average costs per registered substance (€) | Total average costs per registrant (€) |
|---|---|---|---|
| **Baseline** | 168 | 9,590 | 6,830 |
| **Option 1** | 0 | 0 | 0 |
| **Option 2** | 119 | 6,810 | 4,850 |
| **Option 3a** | 210 | 11,990 | 8,530 |
| **Option 3b** | 248 | 14,190 | 10,100 |
| **Option 4a** | 601 | 34,330 | 24,430 |
| **Option 4b** | 26 | 1,510 | 1,080 |
| **Option 4c** | 823 | 47,020 | 33,460 |
| **Option 4d** | 22 | 1,260 | 890 |
| **Option 5a** | 1,877 | 107,280 | 76,340 |
| **Option 5b** | 2,313 | 132,150 | 94,030 |

Interestingly, Option 2 with its reliance on physicochemical information only does not result in as significant reductions in the total average cost of registering a substance as might initially be anticipated due to the heavy reliance on QSARs and read across under the other options. It is also of note that the costs under the Baseline are significantly lower than those under either Options 3a or 3b, although the latter are only between €2,100 and €4,300 more expensive on a per substance basis with the difference in costs per registrant being slightly lower.

As might be expected, Options 4a and 4b followed by Options 5a and 5b are significantly more expensive than the other options. In this case, the costs per registered substance under 4a and 4b range from between €34,000 and €47,000, with the average costs per registrant ranging from between €24,000 and €33,500. These figures rise to between €107,000 and €132,000 as an average per registered substance for Options 5a and 5b respectively, and between €76,000 and €94,000 per registrant.

This increase is due to the cost of the additional tests required, i.e. for option 4a and 4b the increase is driven by the cost of the mutagenicity tests (€28,000) and repeat dose toxicity tests (€50,000), while for option 5a and 5b the increase is driven by the reproductive toxicity test cost (around €110,000).

Table 9 below shows the statistical average costs to register a substance manufactured or imported in quantities of between 1 and 10 tonnes by company size under each option. Note that these figures take into account the fact that there may be multiple registrants of some 1 to 10 tonne substances).

**Table 9: Total Average Costs per Substance by Company Size (€)**

| | Micro enterprise | Small enterprise | Medium enterprise | Large enterprise |
|---|---|---|---|---|
| Baseline | 9,300 | 19,300 | 45,000 | 97,700 |
| Option 1 | 0 | 0 | 0 | 0 |
| Option 2 | 5,400 | 12,300 | 30,900 | 72,600 |
| Option 3a | 11,800 | 23,600 | 54,500 | 119,400 |
| Option 3b | 14,000 | 28,400 | 65,100 | 140,800 |
| Option 4a | 34,100 | 68,800 | 158,800 | 351,500 |
| Option 4b | 45,600 | 96,200 | 219,600 | 478,000 |
| Option 4c | 900 | 2,200 | 5,700 | 13,500 |
| Option 4d | 1,200 | 2,800 | 6,700 | 16,300 |
| Option 5a | 106,000 | 220,700 | 506,300 | 1,083,000 |
| Option 5b | 128,200 | 272,300 | 625,600 | 1,333,300 |

For microenterprises, taking into account their classification criteria of less than 10 employees and a turnover of less than €2 million, these costs are high. It is understood from consultation for other REACH related work, that although not a provision within the Regulation, downstream users have helped some manufacturers support essential chemicals through REACH already. If downstream users were not willing to share such costs under Options 5a and 5b, it may be more difficult for microenterprises to meet the estimated registration costs. They would have to plan the registration some years in advance of the 2018 deadline, with this implying that testing would also have to be carried out over time in order to amortise the costs. As stated in the CSES study, highly innovative exporting SMEs that concentrate on relatively few product lines may unable to spread the costs to non-REACH affected products in their business portfolio, making them vulnerable to competition from non-EU countries in export markets.

This would be true also for the import company described in the case study for small enterprises. In that case, if the manufacturers based abroad would not be willing to share the registration costs, the case study company could choose to stop the imports of some of the substances (in the example, colours for textiles, tanning and paper industry). This could affect their market share but also impact their downstream users, in terms of higher prices to purchase the same products from other manufacturers/importers or in terms of range of products in their portfolio in the case

those substances are not available anymore on the EU market, resulting in a potential loss of innovation and competitiveness against non-EU companies. Indeed, the textile industry is especially concerned about the withdrawal of low production volume substances, believing that possible substitutes and reformulation changes could impede the quality of the overall product.

As found by the consultation conducted for the CSES study, medium and large companies, having a broader range of substances, could consider to rationalise their products portfolio, withdrawing some of the substances in consideration of both financial costs of registering and of the hazardous properties of the substances.

***Cost-Effectiveness***

The increased costs as one moves up the options is accompanied by more extensive and reliable information on the hazard properties of 1 to 10 tonne substances. Table 10 provides summary data on number of substances newly identified as having different properties of concern under each of the options, indicates the costs per newly identified substance and then ranks the options in terms of their cost-effectiveness.

These cost-effectiveness results are interesting for two reasons. Firstly, they highlight an interplay between the Baseline and Options 4c and 4d which both incorporate screening requirements prior to triggering the need for registration; in both cases, registration requirements would then relate to Annex VII and selected Annex VIII data together with the need to prepare a Chemical Safety Assessment. Option 4c is focused on screening for M and R properties (as there is no test endpoint specific to C in Annex VII or VIII) while Option 4d adds screening for PBT and vPvB properties. Note that, under these two Options, there is no screening for other human health or environmental classifications, nor a trigger related to diffuse use, as exists currently in Annex III of REACH.

As a result, Options 4c and 4d perform better than the Baseline option when it comes to their cost-effectiveness in identifying substances with M and R properties, but perform much worse if other human health and environmental classifications are also a key focus. Furthermore, because these options are so targeted, they are much more cost-effective than Options 5a and 5b which would produce more reliable data and identify significantly more M and R substances.

The Baseline option would identify over 8,300 substances as having new environmental or human health classifications and a higher number of M and R substances, but at a higher overall cost and thus lower cost-effectiveness. However, the Baseline would also be associated with a high number of false positive outcomes which would need to be resolved by registrants. It is likely that many registrants would turn to testing in order to resolve the uncertainties over the classification of these substances, with this suggesting that the costs actually incurred under the Baseline would be higher than those predicted here.

| Table 10: Summary Data on Cost-effectiveness and Option Ranking for 1 to 10 Tonne Substances Review | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **Number of already classified substances where new classifications found** | **Number of previously unknown substances with any new health or environmental classification** | **Number of Previously Unknown MRs Identified** | **Number of Previously Unknown PBT/vPvB Identified** | **Total Costs (€ Million)** | **Cost per New substance with classification identified (€ Million)** | **Cost per New Actual PBT/vPvB and CMR identified (€ Million)** | **Rank New substance with classification identified** | **Rank New Actual PBT/vPvB and CMR identified** |
| **Baseline** | 120 | 8,309 | 184 | 19 | € 167.89 | € 0.02 | € 0.8 | 1 | 3 |
| **Option 1** | 0 | 0 | 0 | 0 | € 118.66 | € 0.00 | € 0.0 | 10 | 10 |
| **Option 2** | 0 | 0 | 0 | 0 | € 119.20 | € 0.00 | € 0.0 | 10 | 10 |
| **Option 3a** | 125 | 8,310 | 196 | 21 | € 204.96 | € 0.02 | € 0.9 | 2 | 4 |
| **Option 3b** | 125 | 9,532 | 204 | 22 | € 243.21 | € 0.03 | € 1.1 | 3 | 5 |
| **Option 4a** | 183 | 8,265 | 166 | 11 | € 600.77 | € 0.07 | € 3.4 | 4 | 6 |
| **Option 4b** | 183 | 9,599 | 173 | 11 | € 822.91 | € 0.09 | € 4.5 | 5 | 7 |
| **Option 4c** | 0 | 82 | 166 | 11 | € 21.98 | € 0.27 | € 0.1 | 8 | 1 |
| **Option 4d** | 0 | 92 | 166 | 0 | € 26.49 | € 0.30 | € 0.2 | 9 | 2 |
| **Option 5a** | 1826 | 10,341 | 349 | 17 | € 1,877.44 | € 0.18 | € 5.1 | 6 | 8 |
| **Option 5b** | 1826 | 11,902 | 390 | 17 | € 2,312.68 | € 0.19 | € 5.7 | 7 | 9 |

The potentially high number of false positive outcomes under the Baseline also holds for Options 3a and 3b, which come after the Baseline in the rankings. Again, this suggests that the actual costs may be more than those predicted by the model, which takes into account only those costs specifically associated with fulfilment of each option's requirements.

The question then arises as to whether, even with the additional testing that registrants may need to undertake to resolve such issues, these options would be lower cost in practice than Options 4 or 5. The answer to this is that Option 4a has been designed to include the tests from Annex VIII that would have to be run by registrants in order to correct for the high number of false positive outcomes under the Baseline and Options 3a and 3b (with these being 1,100 for M and R and over 600 for PBT/vPvB based on the use of QSARs, read across and available data). Thus, the actual costs under the Baseline, Option 3a and 3b may be much closer to those for Option 4a, with the key difference being no requirement to also prepare a CSA (as is assumed under Option 4a where Annex VIII endpoints are identified).

Based on data from Cefic and other sources, the estimated costs of carrying out tests so as to clarify whether or not a substance is a M or an R under Annex VIII are around €100,000 to €150,000. Recent reports indicate that the starting point for the price of fine or speciality chemicals is around €10,000 per tonne, with searches for market prices for specific chemicals suggesting a figure of around €20,000 per tonne would be reasonable, then it could clearly take many years to recover the costs of undertaking such tests unless downstream users are willing to contribute to the costs of registration or it is possible to increase the price charged per tonne of substance sold due to an inelastic demand.

Substance withdrawal can have significant implications for downstream users. It can lead to a cessation of some activities where critical inputs are lost or to significant reformulation costs where it is possible to find an alternative. Even when reformulation is possible, increases in costs may lead to some activities (or companies) no longer being competitive and hence the loss of production within the EU. Of course the degree to which such outcomes would be associated with 1 to 10 tonne substances is unknown, although many sectors have raised concerns in the past over the loss of speciality low volume substances for the on-going viability of their activities.

***Costs versus Benefits***

Following on from the above discussion, there is clearly a range of different trade-offs involved in choosing between the eleven options considered here. The main report provides a discussion on the types of human health and environmental benefits that could stem from the information that would be developed under each of the options. This included both qualitative descriptions and quantification of potential benefits related to the new identification of mutagens and reprotoxins, which are also likely to be carcinogens, and skin and respiratory irritants/sensitisers. These estimates are reproduced in Table 11 to provide an indication of the total present value benefits estimated for each option in terms of reduced future health effects. Table 12 follows this by combining estimates of total costs with total benefits to calculate net effects.

| **Table 11: Estimated Total Benefits from Reduction of Human Health Impacts for 1 to 10 Substances Options** | | | | | | |
|---|---|---|---|---|---|---|
| **Option** | **Benefits of fatal cancer avoidance (€ million)** | **Benefits of non-fatal cancer avoidance (€ million)** | **Benefits of avoided dermatitis cases (€ million)** | **Benefits of avoided respiratory cases (€ million)** | **Total benefits – assuming fatal cancers (€ million)** | **Total benefits – assuming non-fatal cancers (€ million)** |
| **Baseline** | 1667 | 375 | 54 | 0 | 1721 | 429 |
| **Option 1** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Option 2** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Option 3a** | 1776 | 400 | 54 | 0 | 1830 | 454 |
| **Option 3b** | 1848 | 416 | 54 | 0 | 1902 | 470 |
| **Option 4a** | 1504 | 338 | 54 | 0 | 1558 | 392 |
| **Option 4b** | 1568 | 353 | 109 | 109 | 1786 | 571 |
| **Option 4c** | 1504 | 338 | 54 | 0 | 1558 | 392 |
| **Option 4d** | 1504 | 338 | 54 | 0 | 1558 | 392 |
| **Option 5a** | 3162 | 712 | 109 | 109 | 3380 | 930 |
| **Option 5b** | 3534 | 795 | 109 | 109 | 3752 | 1013 |
| Notes: Benefits discounted at 4% over 20 years to be consistent with previous assessments. | | | | | | |

| **Table 12: Costs versus Benefits for 1 to 10 Tonne Substances Options** | | | | | |
|---|---|---|---|---|---|
| **Options** | **Total costs (€ million)** | **Total benefits – assuming fatal cancers (€ million)** | **Total benefits – assuming non-fatal cancers (€ million)** | **Benefits Minus Costs – assuming fatal cancers (€ million)** | **Benefits Minus Costs – assuming non-fatal cancers (€ million)** |
| **Baseline** | 168 | 1721 | 429 | 1553 | 261 |
| **Option 1** | 0 | 0 | 0 | 0 | 0 |
| **Option 2** | 119 | 0 | 0 | -119 | -119 |
| **Option 3a** | 205 | 1830 | 454 | 1625 | 249 |
| **Option 3b** | 243 | 1902 | 470 | 1659 | 227 |
| **Option 4a** | 601 | 1558 | 392 | 957 | -208 |
| **Option 4b** | 823 | 1786 | 571 | 963 | -252 |
| **Option 4c** | 22 | 1558 | 392 | 1536 | 370 |
| **Option 4d** | 26 | 1558 | 392 | 1532 | 366 |
| **Option 5a** | 1877 | 3380 | 930 | 1503 | -948 |
| **Option 5b** | 2313 | 3752 | 1013 | 1439 | -1300 |

As can be seen from Table 11, all options other than Option 1 and 2 deliver net benefits in terms of the avoidance of future cancer cases (where these are assumed to be fatal) and occupational skin and respiratory diseases. The highest level of net benefits are delivered by Options 3a and 3b where disease avoidance relates to fatal cancer cases, and Options 4c and 4d where it relates to non-fatal cancers.

Interestingly, on the conservative assumptions made for the analysis, with respect to the avoidance of future cancer cases and future cases of skin and respiratory disease, the increased costs associated with Option 5a and 5b are not outweighed by the estimated benefits.

Table 13 helps make the differences between the Baseline and the various options clearer. There are clear variations in the performance of the options depending on whether one assumes all future cancers avoided would be fatal rather than non-fatal. However, on the basis of the diseases considered here, Option 1 and 2 are non-favoured compared to the Baseline, as would be Options 4a and 4b, and Options 5a and 5b. Otherwise, it is more difficult to draw clear conclusions from these figures. It should be noted though that small incremental differences between options should not necessarily be considered significant given the probabilistic nature of the model and the uncertainties in the underlying data (including the valuation of a fatal and non-fatal cancer and estimates of the number and value of avoiding skin and respiratory diseases). Furthermore, as emphasised above, the fact that costs under the Baseline and Options 3a and 3b are likely to be higher than assumed here due to registrants wishing to resolve false positive QSAR and read across outcomes would have an effect on these incremental net benefit calculations.

What also becomes clear from the above calculations is that other refinements could be carried out on some of the options considered here. For example, Options 4a, 4b, 5a and 5b do not include the "any other human health and environmental classification AND dispersive or diffuse use" hurdle that is included in the Baseline. If the dispersive /diffuse use hurdle was included in these options, then their testing and registration costs would reduce. Similarly, new Options 5c and 5d could be developed which would perform in a similar manner to Options 4c and 4d, albeit at a higher costs but also resulting in the identification of a higher number of new hazardous properties in relation to any human health or environmental classification, as well as mutagens and reprotoxins and PBT/vPvBs.

**Table 13: Incremental Net Benefits over the Baseline for 1 to 10 Tonnes Options**

| Options | Benefits Minus Costs (€ million) | | Incremental Net Benefits over Baseline (€ million) | |
|---|---|---|---|---|
| | Fatal cancers | Non-fatal cancers | Fatal cancers | Non-fatal cancers |
| **Baseline** | 1553 | 261 | 0 | 0 |
| **Option 1** | 0 | 0 | -1553 | -261 |
| **Option 2** | -119 | -119 | -1672 | -380 |
| **Option 3a** | 1625 | 249 | 72 | -13 |
| **Option 3b** | 1659 | 227 | 106 | -35 |
| **Option 4a** | 957 | -208 | -596 | -470 |
| **Option 4b** | 963 | -252 | -591 | -513 |
| **Option 4c** | 1536 | 370 | -17 | 109 |
| **Option 4d** | 1532 | 366 | -22 | 105 |
| **Option 5a** | 1503 | -948 | -50 | -1209 |
| **Option 5b** | 1439 | -1300 | -114 | -1561 |

***Other Factors***

The above discussion has considered the estimated total costs of each option as well as human health benefits in terms of the avoidance of a sub-set of (illustrative) diseases linked to exposures to industrial chemicals. There are 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 industrial chemicals. As a result, there may be indirect impacts on some actors under Option 1 should the requirement for the registration of substances manufactured or imported at between 1 and 10 tonnes be removed from the regulation with national governments responding by establishing their own information requirements on the basis of the need to protect human health and the environment. This may impact upon the competitiveness of smaller chemical manufacturers in particular, as it may make it harder to export chemicals across national boundaries.

- **Wider health and environmental benefits**: The assessment of benefits was only able to consider a sub-set of potential health effects, and these only in terms of occupational health. Given the potential for additional health benefits from the identification of additional concerns under Option 4b and 5 (and 5b in particular), the benefits reported here are likely to be underestimates but serve to illustrate the relative effectiveness of the various options. No attempt has been made to try and quantify potential benefits to consumers or the general public. This is important as there may be benefits from reduced exposures for consumers in particular, where a substance is found to have M and R properties for example, depending on exposure patterns.

  With respect to the environment, the identification of new PBTs (in particular) and vPvBs may help avoid long term damage to the environment. It has not been possible to include any quantified measure of the benefits of avoiding these in this assessment given that, for the production volumes considered here, such damages are most likely to arise at the local level; but the fact that effects may occur on a broader basis should not be entirely dismissed given the P and B characteristics of these chemicals.

- **Innovation**: With regard to innovation, Options 4c and 4d are likely to have the lowest impacts, followed by Option 2 and then the Baseline. However, there is likely to be little difference in effects between the Baseline and Option 3. This conclusion with respect to the Baseline and Option 3 assumes though that registrants do not decide to test rather than rely on QSAR and read across information so as to avoid false positive declarations of M, R, PBT and vPvB properties. Given the significant increases in costs associated with Options 4a and b and 5a and b, these options are assumed to give rise to the most significant impacts on innovation.

The withdrawal of substances from the market, for example, in response to the total costs of registration or due to false positive indications of hazardous properties could have knock-on effects for the level of innovation in downstream user sectors. This is because substance 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.

This is illustrated by the results of the CSES Innovation Survey, to which 63% of respondents said that that the requirements of the REACH regulation had diverted resources from 'truly' innovative research. Indeed, for a fairly stable set of companies (roughly 30% but varying by size and cost item), the registration fees, testing costs, dossier preparation costs and resource costs associated with supply chain communication had resulted in a significant diversion of resources away from innovative activities. Although 46% of respondents to the CSES Innovation Survey indicated that there had been an overall increase in expenditure on R&D and other innovative activities, this was primarily due to factors outside REACH that have a greater impact on innovation than the Regulation itself (e.g. the state of markets and technology). Overall, though, the CSES report concludes that it is still too early to assess the impacts of REACH in relation to innovation.

- **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 1 to 10 tonne substances within the EU. At the second level, the costs of registering 1 to 10 tonne substances 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 chemicals sector (in terms of extra-EU exports) as well as downstream user sectors in placing their products on the global market.

  Substance withdrawal, and the loss of critical inputs, may also impact upon the competitiveness of EU industry vis a vis producers in other countries.