REACH - ONE SUBSTANCE, ONE REGISTRATION

Final Report

prepared for
the Department for the Environment,
Food and Rural Affairs

RPA

December 2004

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Defra

by

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EXECUTIVE SUMMARY

1. INTRODUCTION

On 29 October 2003 the European Commission published proposals for a new regulation on chemicals, known as REACH[i].

The UK and Hungary are proposing that the requirements under REACH for the registration of substances be modified to an approach based on 'One Substance, One Registration'[ii]. Although this bears many similarities to the Commission's proposals published in October, it also differs in some key aspects. These include:

- revised data requirements and dates for the pre-registration of substances with an aim of ensuring greater participation in Substance Information Exchange Fora (SIEF);
- publication of a list of substances pre-registered with the Agency within a short period of time after the close of the pre-registration date;
- flexibility for Small and Medium Size Enterprises (SMEs) to register either with the higher tonnage suppliers or to take advantage of the longer time frames available for lower tonnage bands;
- a requirement on all pre-registered manufacturers/importers to contribute all core data to the SIEF;
- the entitlement of all manufacturers/importers to join a SIEF;
- an expansion to the data that must be shared within the SIEF with this applying to more than just vertebrate animal tests; various mechanisms are put forward for resolution of technical disputes, cost-sharing, etc.;
- the potential for companies within a SIEF to work together on other aspects of a registration remains, although this would not be a requirement;
- additional, new provisions in relation to late registrants and the need for all registrants to update information should new core data become available; and
- the introduction of an Ombudsman for determination of cost-sharing arrangements.

The UK and Hungary believes that its proposals should both reduce the cost burden faced by industry in relation to testing and registration, and also significantly reduce the work and hence resources required by Competent Authorities in evaluating REACH dossiers. Defra commissioned RPA to consider what the impact of the UK and Hungary's proposals could be in terms of costs to industry and to Competent Authorities. Broadly the objectives were:

- to examine the scope for savings from adopting the UK and Hungary's proposed amendments compared with the estimates prepared for the revised BIA; and

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[i] European Commission (2003): **Proposal for a Regulation of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC**, COM (2003) 644 Final, Brussels, 29 October 2003.

[ii] Proposals are available online at http://www.defra.gov.uk/environment/chemicals/eufuture.htm

- to consider the critical assumptions in the BIA, particularly as regards the potential for consortia formation, repeat registration and repeat testing and to examine any resultant sensitivities within the calculated costs to variations in responses by manufacturers, importers and downstream users.

2. APPROACH TO THE STUDY

In the various Business Impact Assessments (BIAs), a number of assumptions are used to model the response of industry to the new regulations and, therein, the associated costs of the proposals. For the original BIA (of the White Paper), a range of variables and low to high assumptions were explored to determine a range of costs for REACH.

In the revised BIA (on the Consultation Document), work was focussed on a subset of these assumptions to model the intended response of industry to the regulations (rather than the range of possible responses). However, there remains the possibility that industry will respond to the regulations in a way that was not intended (and therefore not accounted for in the Extended Impact Assessment).

This study (on behalf of Defra) has examined the influence of different behavioural responses by industry on the magnitude of the total costs of the proposed regulation (as it is currently drafted) and compared these with the costs that might be expected under the One Substance, One Registration proposals. The key variables and variations that have been examined concern:

- the relationship between size of consortia and cost of consortia registrations;
- testing costs and repeat registrations;
- Competent Authourity (CA) reviewing costs; and
- numbers and types of registration.

Relationship between Size of Consortia and Cost of Consortia Registrations

The revised BIA assumed that a consortium of more than two manufacturers/importers (M/Is) would be made up of three to five M/Is and that the break-up of a large consortium (of greater than two M/Is) only results in one individual registration and one consortium registration.

The evidence suggests that, depending on tonnage band, consortia may have considerably more than the three to five members assumed previously. This has required the revision of estimates of the cost of a consortium registration (to account for a larger number of members).

Testing Costs and Repeat Testing

The revised BIA assumes that no repeat testing occurs (Table 2.1, page 7). The implicit assumption was that the creation of Substances Information and Exchange

Fora (SIEFs) and a desire to minimise test costs would lead to complete data sharing between M/Is of all substances and of all test results (animal and non-animal) **even though there is no specific provision in the Commission proposal to ensure that sharing of non-animal tests will actually occur**.

In this study (for Defra), the costs of non-animal tests have been extracted from the Directorate General Joint Research Centre (JRC) estimates and applied to repeat registrations from the 'break-up' of consortia.

Competent Authority Reviewing Costs

The costs to Competent Authorities (CAs) of reviewing dossiers and testing proposals were not modelled in the revised BIA. This study has developed and applied new cost estimates for the following cost components for reviewing of dossiers by CAs:

- completeness check and administration;
- reviewing testing proposals;
- PBT evaluations; and
- substance evaluations.

Numbers and Types of Registration

As noted above, the evidence suggests that, depending on tonnage band, consortia may have considerably more than the three to five members assumed previously. As such, it is no longer valid to assume that the break-up of a large consortium (of greater than two M/Is) would only result in one individual registration and one consortium registration. Rather, the break-up of a consortium (or its failure to form cohesively) could, potentially, involve many more individual registrations or multiple consortia registrations.

Under One Substance, One Registration, the size of consortia and the numbers of registrations is, by definition, fixed. Under the existing REACH proposals, however, there remains considerable uncertainty over the extent to which consortia will form and the number of individual repeat registrations that would result from consortia break-up.

The extent to which the break-up/incomplete formation of a consortium may result in more than one M/I leaving (or never joining) logically depends on the size of a consortium (in terms of the number of M/Is), the number (percentage) of substances where consortia break-up (or fail to form) and the number (percentage) of members leaving (or never joining in the first place). Given the inherent uncertainties, a range of reasonably possible variations in these latter two variables has been examined. The variations are as follows:

- consortia break-up has been assumed to take place for between 10% and 40% of substances that could be registered in a consortium; and

- in each case that a consortium breaks-up, the percentage of members leaving to submit an individual registration has been assumed to be between 5% and 75% (where clearly this variable only applies to consortia of greater than two).

Every possible combination of these two variables has been applied in the new analysis to provide a range of values. 75 scenarios based on all combinations of the percentage consortia breaking-up and percentage of members leaving have been analysed where, in each case, the model calculates:

- **the number of individual registrations** – which is a function of the number of substances where there is only one M/I, the number of consortia of two breaking-up into two separate full registrations, and the number of consortia of greater than two experiencing a break-up with a certain number leaving to submit an individual registration;

- **the number of registrations by Consortia of two** – which is a combined function of the number of substances where there are two M/Is (and there is no break-up) and the number of substances manufactured by more than two M/Is but where the number of members leaving to submit an individual registration results in the remaining consortium being comprised of only two remaining members; and

- **the number of registrations by consortia of more than two and the average size of these consortia** – which is a combination of the number and size of consortia where there is no break-up and the number of consortia where there is a break-up but the average number of remaining members is still more than two.

Partial Registrations

Under both the existing REACH proposals and One Substance, One Registration, there is also the potential for partial registration, where this involves some consortium members 'leaving' the consortium towards the end of the dossier preparation process so that they can include sensitive information that they may not wish to share with the other consortium members.

As with repeat registration, the way in which industry may respond is not known so a similar percentage based approach to that taken for repeat registration has been used and applied to both the existing proposals and the proposals for One Substance, One Registration.

3. TOTAL COSTS OF TESTING AND REGISTRATION

The revised BIA (and the Commission's Extended Impact Assessment) applied a simple single assumption that there would be 20% repeat registration. The closest approximation to this scenario in the 75 scenarios run for this study is one where 20%

of substance consortia experience a break-up, and 15% of the members leave to submit an individual registration.

A full set of results for all 75 scenarios can be found in the main text. Table 1 provides the costs of testing and registration for phase-in substances for the three data points that represent the lowest and highest reasonable scenarios and the scenario that best reflects that used in the Extended Impact Assessment.

Table 1: Summary of Cost Ranges and Savings for Costs of Testing and Registration

		Lowest Possible Scenario	Extended Impact Assessment Equivalent Scenario	Highest Reasonable Scenario
Percentage of Substance Consortia Breaking-up		10%	20%	40%
Percentage of Members Leaving		5%	15%	75%
Cost of REACH Proposals	€ Million	1,802	1,869	2,493
Cost of One Sub., One Reg.	€ Million	1,785	1,794	1,884
Savings One Sub.,One Reg.	€ Million	17	74	609
	%	0.9%	4%	24.4%

As can be seen from Table 1, under a worst (reasonable) case scenario that 40% of consortia would break-up and 75% of members would leave to submit an individual registration, the testing and registration costs for phase-in substances alone would be €2.5 billion.

This suggests that the testing and registration costs of the current REACH proposals could be 33% higher than previous estimates if industry does not behave as intended. Under a very best case scenario, the costs would only reduce to €1.8 billion, or about 3.6% lower than previous estimates.

The savings achievable under One Substance, One Registration are potentially as high a €609 million (24.4%). The level of saving in comparison with equivalent assumptions in the Commission's Extended Impact Assessment is some €74.4 million.

4. TOTAL COSTS OF THE REGULATION

The total costs of the proposed regulation for phase-in substances under the existing REACH proposals and under One Substance, One Registration are provided in Table 2. These costs are the total of registration and testing costs, and costs of review of dossiers by CAs.

From the table, it can be seen that the total costs under the existing REACH proposals range between €1.8 and €2.6 billion depending on the scenario. The savings achievable under One Substance, One Registration are potentially as high as €631 million (24% - comprised of €16.4 million savings in CA costs and €609 million

savings in industry testing and registration costs). The level of saving in comparison with equivalent assumptions in the Commission's Extended Impact Assessment is some €77 million (4% - €3.6 million savings in CA costs).

Table 2: Summary of Cost Ranges and Savings for Total Costs of Regulation				
		Lowest Possible Scenario	**Extended Impact Assessment Equivalent Scenario**	**Highest Reasonable Scenario**
Percentage of Substance Consortia Breaking-up		10%	20%	40%
Percentage of Members Leaving		5%	15%	75%
Cost of REACH Proposals	€ Million	1,883	1,955	2,632
Cost of One Sub., One Reg.	€ Million	1,865	1,878	2,000
Savings One Sub.,One Reg.	€ Million	17.7	77.5	631.5
	%	0.9	4.0	24.0

5. CONCLUSIONS

There remains considerable uncertainty concerning industry's response to the proposed REACH regulation as regards the level of cooperation, data sharing and cost sharing within consortia. Under the 75 different scenarios analysed in this study, the One Substance, One Registration proposals always provide savings on the existing proposals. The actual level of these savings will depend on the level of mutual industry cooperation that occurs in practice.

The total savings achievable under One Substance, One Registration are potentially as high as €631 million (24%). When calculated using equivalent assumptions to those in the Commission's Extended Impact, savings are estimated at around €77 million (4%).

However, the study has also highlighted that costs and associated savings are also dependent on other key uncertainties (and accompanying assumptions), most notably the number of substances manufactured by one, two and more than two M/Is and the average number of M/Is per substance. Altering these assumptions very slightly increases the cost estimate from the €2.6 billion (above) to €3.1 billion; with savings from One Substance, One Registration being as high as nearly €900 million.

This suggests that actual costs of the existing REACH proposals are very dependent on what the actual structure of the industry is, and how individual M/Is respond to it in practice (particularly regarding consortia formation). The One Substance, One Registration proposals would appear to provide a means of managing these uncertainties. As such, they provide a means of ensuring that the costs of the regulation are maintained within acceptable bounds and within the anticipated cost range calculated by the revised BIA and the Commission's Extended Impact Assessment.

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1. INTRODUCTION

1.1 Background to the Study

On 29 October 2003 the European Commission published proposals for a new regulation on chemicals, known as REACH[1]. The aim of REACH is to:

- require enterprises that manufacture and import chemical substances to generate information about their properties and the potential risks that they pose for health and the environment, and to develop strategies to manage these risks;
- ensure that the resulting information is made available to downstream industries and the public;
- encourage industry to develop and use substances less dangerous to health and the environment; and
- enable the authorities to take more speedy action where measures are needed to reduce risks.

An Extended Impact Assessment of the proposed Regulation, based partly on a revised Business Impact Assessment (BIA) prepared by RPA[2], estimated that the direct costs of registration and testing would be €2.3 billion over an 11 year period. These costs would initially be borne by manufacturers and importers of substances, but would largely be passed on to their customers (downstream users). The Commission estimated that downstream users would face additional costs of €0.5 billion to €2.9 billion for substitution of substances withdrawn from the market by manufacturers and importers because of the costs of registration and testing. Total costs to downstream users would thus range from €2.9 billion (normal expectation, lower estimate) to €5.2 billion (higher substitution cost, upper estimate).

The UK and Hungary are proposing that the requirements under REACH for the registration of substances be modified to an approach based on 'One Substance, One Registration'[3]. Although this bears many similarities to the Commission's proposals published in October, it also differs in some key aspects. These include:

- revised data requirements and dates for the pre-registration of substances with an aim of ensuring greater participation in Substance Information Exchange Fora (SIEF);
- publication of a list of substances pre-registered with the Agency within a short period of time after the close of the pre-registration date;

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1 European Commission (2003): **Proposal for a Regulation of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC**, COM (2003) 644 Final, Brussels, 29 October 2003.

2 The revised BIA was based on an earlier draft of the Regulation and estimated the most likely value of testing and registration costs at €12.6 billion. The Commission subsequently amended its proposal to remove certain high-cost requirements and estimated that this would reduce testing and registration costs by €10.6 billion.

3 Available online at http://www.defra.gov.uk/environment/chemicals/eufuture.htm

- flexibility for Small and Medium Size Enterprises (SMEs) to register either with the higher tonnage suppliers or to take advantage of the longer time frames available for lower tonnage bands;
- a requirement on all pre-registered manufacturers/importers to contribute all core data to the SIEF;
- the entitlement of all manufacturers/importers to join a SIEF;
- an expansion to the data that must be shared within the SIEF with this applying to more than just vertebrate animal tests; various mechanisms are put forward for resolution of technical disputes, cost-sharing, etc.;
- the potential for companies within a SIEF to work together on other aspects of a registration remains, although this would not be a requirement;
- additional, new provisions in relation to late registrants and the need for all registrants to update information should new core data become available; and
- the introduction of an Ombudsman for determination of cost-sharing arrangements.

The UK and Hungary believes that its proposals should both reduce the cost burden faced by industry in relation to testing and registration, with this being of particular benefits to SMEs, and also significantly reduce the work and hence resources required by Competent Authorities in evaluating REACH dossiers.

1.2. Scope and Objectives of the Study

Defra commissioned RPA to consider what the impact of the UK and Hungary's proposals could be in terms of costs to industry and to Competent Authorities.

The study has taken into account new information that has become available since submission of the revised BIA. Broadly the objectives were:

- to examine the scope for savings from adopting the UK and Hungary's proposed amendments compared with the estimates prepared for the revised BIA; and

- to consider the critical assumptions in the BIA, particularly as regards the potential for consortia formation, repeat registration and repeat testing and to examine any resultant sensitivities within the calculated costs to variations in responses by manufacturers, importers and downstream users.

In terms of the latter, intrinsic in the various BIAs is a series of assumptions to model an anticipated response of industry to the REACH proposals. Within the existing proposals, however, there remains the potential for industry to act in a manner different from that anticipated in the revised BIA[4]. In a number of respects, then, it is this potential for deviations from the anticipated response that the UK and Hungary's proposed amendments would control.

[4] Where this variation was examined using a series of assumptions in the Initial BIA on the White Paper, the revised BIA draws on a subset of these assumptions. The revised BIA essentially assumes that industry will respond to REACH in a manner which would minimise costs.

1.3 Structure of the Report

Section 2 of this Report provides a brief description of the approach taken to re-model costs of the regulation in a way that allows comparison to be made between the existing proposals and the proposed amendments for One Substance, One Registration.

Section 3 provides a description of the assumptions used in the revised BIA, revisions and improvements to these calculations and, the assumptions used to calculate the costs of testing, registration and Competent Authority (CA) review costs. Section 4 provides the results of the analysis and Section 5 the conclusions.

2. APPROACH TO THE STUDY

2.1 Rationale

As noted in Section 1, there is the potential for industry to act in a manner different from that anticipated in the revised BIA and, hence, assumed in the model underlying the Commission's Extended Impact Assessment.

In the various BIAs, there are two core assumptions that are used to model the response of industry to the new regulations and, therein, the associated costs of the proposals. These core assumptions concern:

- the potential for consortia break-up and repeat registrations; and
- the potential for, and costs of, repeat testing (for non-animal tests).

In the original BIA (of the White Paper), these variables were explored using a series of low to high assumptions to determine the range of costs for REACH. However, the revised BIA (on the Consultation Document) was focussed on a subset of these assumptions to model the intended response of industry to the regulations (rather than the range of possible responses). The objective of this was to identify a single cost estimate for the regulation based on this intended industry response.

However, the potential for industry to respond to the regulations (as they are currently drafted) in a way that was not intended (and therefore not accounted for) remains and, indeed, a number of responses to the consultation document published since the revised BIA indicate that some companies may resist both sharing test data and active participation in a consortium when completing the remainder of a dossier.

Accordingly, the focus of this work has been to examine the influence of different behavioural responses by industry on the magnitude of the total costs of the proposed regulation (as it is currently drafted) and compare these with the costs that might be expected under the One Substance, One Registration scenario.

2.2 Approach to the Analysis

Examining the issue of variations in industry response has required the consideration of a number of elements in the BIA model. In addition, new information has become available since the original analysis that sheds greater light on the facts (or what the facts may be).

The most significant aspect of this work concerns the interaction between the following two sets of assumptions applied in the BIA:

- the number of manufacturers/importers (M/Is) in consortia of greater than two; and
- the number of consortia breaking-up into repeat (individual) registrations.

The revised BIA assumed that a consortium of more than two M/Is would be made up of three to five M/Is. The evidence suggests that there may be many more than this and, hence, it may no longer be valid to assume that the break-up of a large consortium (of greater than two M/Is) only results in one individual registration and one consortium registration. Instead, it could, potentially, involve many more individual registrations or multiple consortia registrations.

However, the costs of a consortium registration in the revised BIA were also based on a consortium size of three to five companies. As such, the potential increase in the number of individual M/Is registering outside a consortium (and associated costs) must be balanced by the need to increase the estimate of the costs of registering inside a consortium, where there is a high probability that more than five companies may be involved.

This study has therefore demanded a new analysis to better account for these variables. This has required us to develop the BIA model further so that it enables one to examine:

- the costs of a consortium registration for a given (but variable) consortium size;
- the number (percentage) of substance consortia that experience a break-up or fail from the start;
- the number (percentage) of consortium members that may leave the consortium at this point (or never join); and
- the number of consortium members who work within the consortium on non-sensitive elements but, for reasons of commercial confidentiality, choose to submit a separate (termed 'partial') registration duplicating much of the shared information but adding in their own commercially sensitive information.

This work has then enabled us to model reasonable combinations of consortia formation, break-up and associated costs.

3. ASSUMPTIONS AND NUMBERS FOR THE ANALYSIS

3.1 Introduction

This Section describes the assumptions used in the revised BIA and the adjustments that have been made to model a range of eventualities.

As with the BIA, the discussion takes a stepwise approach and discusses the following elements and assumptions:

- numbers of phase-in substances;
- costs of registration dossiers;
- testing costs;
- Competent Authority (CA) reviewing costs (these were not part of the remit of the BIA and this is a new element); and
- numbers and types of registration.

3.2 Numbers of Phase-in Substances

For reference, Table 3.1 provides the starting numbers of phase-in substances used in the revised BIA, where these are adjusted on the basis of substances covered by other regulations and the percentage assumed to cease production as per the revised BIA.

The new analysis concentrates on phase-in substances and, for consistency, uses exactly the same numbers as were used in all of the BIAs on behalf of the Commission.

Table 3.1: Starting Numbers of Phase-in Substances

	Existing Substances	Petrol/ biocides etc.	Adjusted Number	Rationalisation		
				% Ceasing Production	Number Ceased	Final Number for REACH
>1000 tpa	2,465	275	2,190	0%	0	2,190
>100 tpa	2,500	275	2,225	5%	111	2,114
>10 tpa	5,300	0	5,300	10%	530	4,770
>1 tpa	20,000	0	20,000	15%	3,000	17,000
Totals	**30,265**	**550**	**29,715**		**3,641**	**26,074**

3.3 Costs of Registration

3.3.1 The Revised BIA and Extended Impact Assessment

The costs of registration in the revised BIA were divided on the basis of:

- dangerous versus non-dangerous substances;
- the tonnage band; and
- whether or not the registration was from a consortium.

These costs were based on a per person rate of €1,000 per day and are provided in Tables 3.2 and 3.3 for individual and consortium registrations. **In its Extended Impact Assessment the Commission reduced the daily rate to €875. Other changes include the fact that a Chemical Safety Report (CSR) is no longer required for the 1-10t substances**.

In the revised BIA, it was assumed that the formation of consortia should save companies money through expenditure sharing, when there are several producers of the same substance. Table 3.3 presents the estimates of the costs per consortium of submitting a registration dossier used in the revised BIA. In contrast to the figures presented in Table 3.2, the additional administrative costs relevant to consortia participation and management have been included based on experience of the OECD HPV initiative. The costs in Table 3.3 are per consortium, and, therefore, would be shared between the members of the consortium.

Table 3.2: Costs of Individual Full Registration for Phase-in Substances (€/registration)

Cost Item	**>1 t/y**	**>10 t/y**	**>100 t/y**	**>1,000 t/y**
Registration Costs for Dangerous Substances				
Physicochem Hazard Assess.	€ 240	€ 240	€ 600	€ 600
Human health Hazard Assess.	€ 600	€ 600	€ 4,500	€ 4,500
Environmental Hazards Assess.	€ 530	€ 530	€ 3,300	€ 3,300
PBT Assessment	€ 100	€ 100	€ 250	€ 250
Exposure Assessment	€ 1,150	€ 2,650	€ 7,200	€ 19,500
Robust Study Summary	€ 0	€ 0	€ 500	€ 1,000
Risk Characterisation	€ 800	€ 800	€ 3,500	€ 3,500
Chemical Safety Report	€ 500	€ 1,000	€ 2,000	€ 2,000
Testing Proposals	€ 0	€ 0	€ 500	€ 500
Liaison with Downstream Users	€ 2,000	€ 3,500	€ 12,000	€ 15,000
Administration	€ 5,000	€ 5,000	€ 10,000	€ 10,000
Total per Dossier	**€ 10,920**	**€ 14,420**	**€ 44,350**	**€ 60,150**
Registration Costs for Non-Dangerous Substances				
Physicochem Hazard Assess.	€ 240	€ 240	€ 600	€ 600
Human health Hazard Assess.	€ 600	€ 600	€ 4,500	€ 4,500
Environmental Hazards Assess.	€ 530	€ 530	€ 3,300	€ 3,300
PBT Assessment	€ 100	€ 100	€ 250	€ 250
Exposure Assessment	€ 0	€ 0	€ 0	€ 0
Robust Study Summary	€ 0	€ 0	€ 0	€ 0
Risk Characterisation	€ 0	€ 0	€ 0	€ 0
Chemical Safety Report	€ 500	€ 1,000	€ 2,000	€ 2,000
Testing Proposals	€ 0	€ 0	€ 0	€ 0
Liaison with Downstream Users	€ 0	€ 0	€ 0	€ 0
Administration	€ 5,000	€ 5,000	€ 10,000	€ 10,000
Total per Dossier	**€ 6,970**	**€ 7,470**	**€ 20,650**	**€ 20,650**

Table 3.3: Costs of a Consortium Registration per Phase-in Substance (€/registration)				
Cost Item	**>1 t/y**	**>10 t/y**	**>100 t/y**	**>1,000 t/y**
Total Members' Costs for Dangerous Substances				
Physicochem Hazard Assess.	€ 240	€ 240	€ 600	€ 600
Human Health Hazard Assess.	€ 600	€ 600	€ 4,500	€ 4,500
Environmental Hazard Assess.	€ 530	€ 530	€ 3,300	€ 3,300
PBT Assessment	€ 100	€ 100	€ 250	€ 250
Exposure Assessment	€ 1,150	€ 2,650	€ 7,200	€ 19,500
Robust Study Summary	€ 0	€ 0	€ 500	€ 1,000
Risk Characterisation	€ 800	€ 800	€ 3,500	€ 3,500
Chemical Safety Report	€ 500	€ 1,000	€ 2,000	€ 2,000
Testing Proposals	€ 0	€ 0	€ 500	€ 500
Liaison with Downstream Users	€ 2,000	€ 3,500	€ 12,000	€ 15,000
Administration	€ 15,000	€ 15,000	€ 30,000	€ 30,000
Consortium Administration	€ 9,000	€ 9,000	€ 9,000	€ 30,000
Total per Dossier	**€ 29,920**	**€ 33,420**	**€ 73,350**	**€ 110,150**
Total Members' Costs for Non-Dangerous Substances				
Physicochem Hazard Assess.	€ 240	€ 240	€ 600	€ 600
Human Health Hazard Assess.	€ 600	€ 600	€ 4,500	€ 4,500
Environmental Hazard Assess.	€ 530	€ 530	€ 3,300	€ 3,300
PBT Assessment	€ 100	€ 100	€ 250	€ 250
Exposure Assessment	€ 0	€ 0	€ 0	€ 0
Robust Study Summary	€ 0	€ 0	€ 0	€ 0
Risk Characterisation	€ 0	€ 0	€ 0	€ 0
Chemical Safety Report	€ 500	€ 1,000	€ 2,000	€ 2,000
Testing Proposals	€ 0	€ 0	€ 0	€ 0
Liaison with Downstream Users	€ 0	€ 0	€ 0	€ 0
Administration	€ 15,000	€ 15,000	€ 30,000	€ 30,000
Consortium Administration	€ 9,000	€ 9,000	€ 9,000	€ 30,000
Total per Dossier	**€ 25,970**	**€ 26,470**	**€ 49,650**	**€ 70,650**

3.3.2 Revisions for this Work

At the time of the assessment for the revised BIA, it was assumed that, on average, a consortium would involve the participation of three to five companies[4]. Thus, the costs presented in Table 3.3 represent the costs that are assumed to be spread across all of the companies (so that the costs incurred by any one company are the figures presented in the Table divided by three, four, five, etc. depending on the number of companies in the consortium; in other words, the administration costs indicated for a <10t/y substance of €15,000 are spread across three to five companies, or are assumed to be €5,000 to €3,000 per company).

However, as discussed later in this report (Section 3.6), the actual size of consortia may be much greater. As such, we have revised the costs of providing dossiers to provide greater sensitivity to the number companies in a consortium.

[4] With this being an assumed average figure, as for some chemicals there may be many more companies acting within a consortium, all incurring administrative costs.

In this new analysis, the costs of registration are divided as follows:

- dangerous versus non-dangerous substances (as before);
- the tonnage band (as before);
- costs of an individual (full) registration (i.e. by one company – as before);
- costs of a registration by a consortium of two;
- costs of a registration by a consortium of greater than two (where this varies depending on the size of the consortium);
- costs of an individual partial registration, where a partial registration is one where an M/I participates in and shares the bulk of the costs but, because of sensitive information, wishes to complete a separate CSR and liaison with its downstream users, submitting a separate (but nearly duplicate) registration.

Table 3.4 sets out these costs. As can be seen from this, the costs of a consortium registration of two are less than twice the costs of two separate individual registrations. This has actually been derived by considering the costs set out in the revised BIA (reported above) and the spread of the additional administrative costs in the consortium registration estimates described above.

The costs of a partial registration are calculated on the basis of the costs of a CSR (where required) plus 50% of the administrative and downstream user liaison costs in an individual full registration.

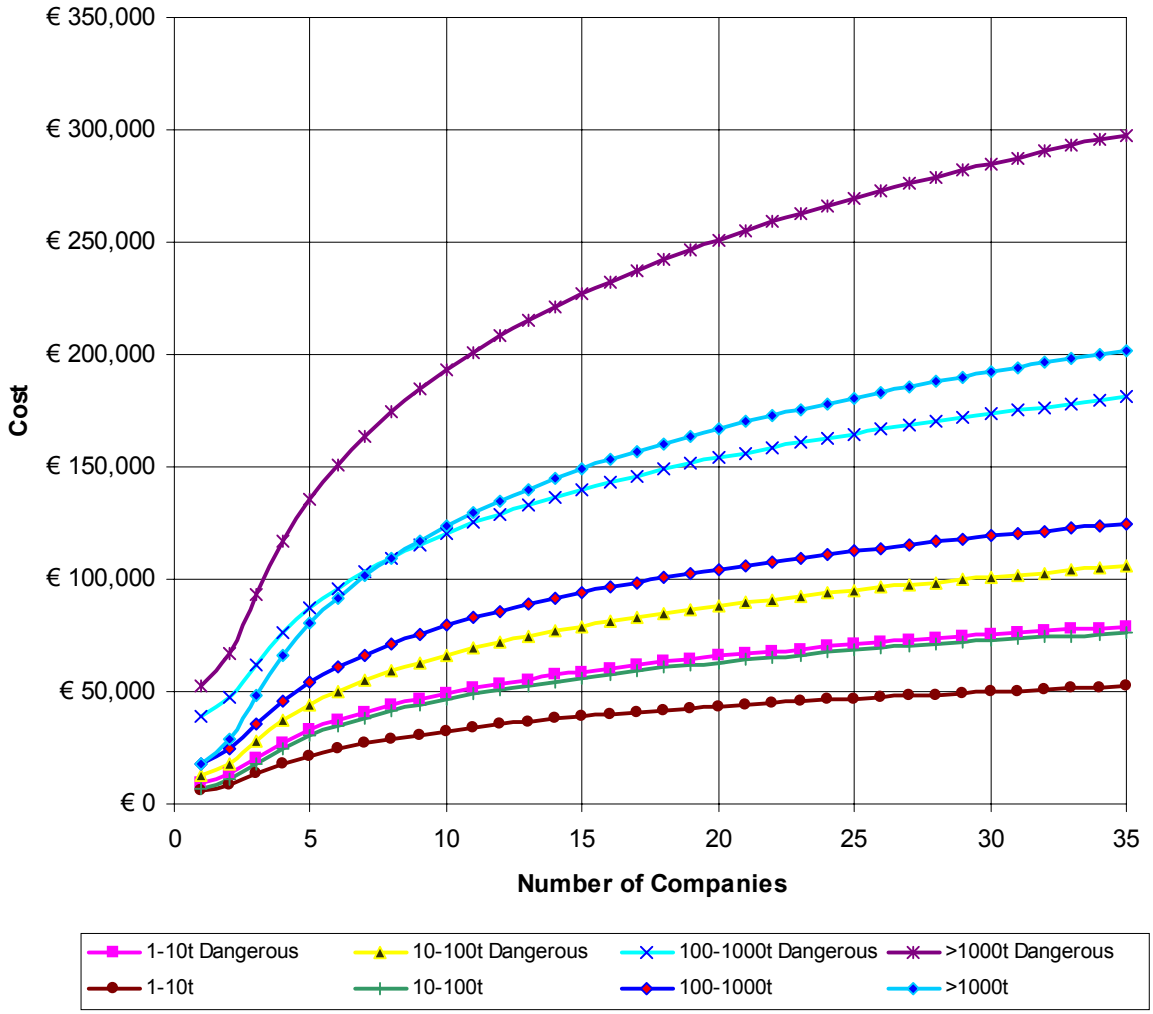
Table 3.4: Estimated Total Costs per Dossier

	<10 t/y	**<100 t/y**	**<1000 t/y**	**>1000 t/y**
Phase-in Full Reg dangerous	€ 9,118	€ 12,618	€ 38,806	€ 52,631
Phase-in Full Reg not dangerous	€ 5,661	€ 6,536	€ 18,069	€ 18,069
Full Reg Phase-in Consortia 2-danger	€ 13,274	€ 18,159	€ 47,265	€ 67,215
Full Reg Phase-in Consortia 2-no danger	€ 8,432	€ 10,693	€ 24,413	€ 29,006
Full Reg Phase-in Consortia>2-danger	**Variable and Proportionate to the Average Number of Companies in Consortia**			
Full Reg Phase-in Consortia>2-no danger				
Phase-in Partial dangerous	€ 3,063	€ 4,594	€ 11,375	€ 12,688
Phase-in partial non dangerous	€ 2,188	€ 3,063	€ 6,125	€ 6,125

In terms of the costs of a consortium registration for a consortium of more than two, these are dependant on the number of companies in the consortium. To calculate these, we have developed a series of functions to reflect the increase in total cost with increase in the size of a consortium. The costs of these consortium registrations are provided in Figure 3.1, which includes the costs of individual and consortia registrations of two as well. As can be seen from the Figure, there is a slight increase in gradient in moving from a consortium of two to three. This reflects the greater difficulty associated with agreeing issues between three parties compared to two.

Thereafter, the total costs increase with increasing size of consortia. The level of incremental increase in costs decays slowly with the addition of further M/Is to the consortium.

Figure 3.1: Registration Costs with Increasing Consortium Size



3.4 Testing Costs and Repeat Testing

3.4.1 BIA Assumptions

The revised BIA assumes that no repeat testing occurs (Table 2.1, page 7). The implicit assumption was that the creation of SIEFs and a desire to minimise test costs would lead to complete data sharing between M/Is of all substances and of all test results (animal and non-animal) even though there is no specific provision in the Commission proposal to ensure that sharing of non-animal tests will actually occur.

Accordingly, with the introduction of SIEFs in the REACH proposals, no repeat testing was assumed to occur in the revised BIA[5] (because none was intended). The actual potential for repeat testing to occur under the existing REACH proposals (and thus the

[5] As such, compared to the estimates in the revised BIA, the potential benefits of the UK and Hungary's proposed amendments to avoid repeat testing for non-vertebrate test endpoints are not readily estimated.

cost savings under the proposed amendments) is related to the issue of consortia formation, break-up and repeat registration.

In the revised BIA, the potential for repeat registration was modelled on the basis of data on the textiles industry concerning the percentage of substances manufactured by one or more companies. No estimate was made of the size of consortia and it was assumed that the break-up of a consortium of greater than two M/Is would only result in one additional individual repeat registration (with no repeat testing).

3.4.2 Revisions for this Work

The current REACH proposals stipulate that there will be no repeat testing for endpoints involving tests on vertebrates. However, there could be repeats of the non-vertebrate tests.

Table 3.5 provides the costs of the non-vertebrate animal tests per statistical substance in the Directorate General Joint Research Centre's (JRC's) spreadsheets for the average scenario (accounting for changes in the testing regime since the consultation document). When considering repeat testing, then, these are the costs that could be repeated.

Table 3.5: Costs of Repeatable (Non-vertebrate) Tests in JRC Average Scenarios (€ thousands per statistical substance)

>1000 t/y	<1000 t/y	<100 t/y	<10 t/y
€ 29.16	€ 22.17	€ 15.65	€ 8.99

3.5 Competent Authority Reviewing Costs

3.5.1 Overview

The costs to Competent Authorities (CAs) of reviewing dossiers and testing proposals were not modelled in the revised BIA.

This new analysis has considered the following cost components for reviewing dossiers:

- completeness check and administration;
- reviewing testing proposals;
- PBT evaluations; and
- substance evaluations.

3.5.2 Completeness Check and Administration

Completeness checking and administration applies to all dossiers submitted whether they are full or partial, repeated or not repeated.

We have assumed this would take 0.75 days each at a cost of €875 per day on average, resulting in €656 per dossier under REACH and One Substance, One Registration.

3.5.3 Reviewing Testing Proposals (Dossier Evaluation)

The cost of reviewing testing proposals is based on the following sub-components and person days:

Exposure assessment	=	1 day per proposal
Test review	=	0.5 days per test
Follow-up before and after completion	=	2 days per proposal

The **absolute minimum** number of proposals has been derived from the JRC estimates of vertebrate tests that would be required under REACH for the 100-1000t and >1000t bands. For each tonnage band, this figure is equal to the maximum number of substances requiring an individual vertebrate test in the JRC 'average testing' spreadsheets.

Consideration of other vertebrate tests in the spreadsheet (and the number of substances requiring these tests) provides information on the average number of tests per testing proposal. These calculations suggest that at least:

- 57% of substances in the 100-1000t band will require an average of 3.2 vertebrate tests; and
- 47% of substances in the >1000t band will require an average of 2.4 vertebrate tests.

As such, 57% of 100-1000t substance dossiers will require an average of 4.6 days of reviewing [1+(0.5x3.2)+2] and 47% of > 1000t substance dossiers will require an average of 4.2 days [1+(0.5x2.4)+2]. At €875 per day, this is equivalent to €4,029 and €3,674 respectively.

3.5.4 PBT Evaluations

PBT evaluations are expected for 2% of all substances. Costs are based on 5 days per evaluation, with an additional 0.5 days for every repeat dossier for administration and cross-checking of information. Total costs are charged at €875 per day and are, in part, dependent on the number of repeat registrations.

3.5.5 Substance Evaluations

On the basis of the numbers used in the various BIAs, 1,470 evaluations are expected to be required. Costs are based on 50 days per evaluation, with an additional 2 days for every dossier repetition covering administration and cross-checking. Total costs are charged at €875 per day and are, in part, dependent on repeat registrations.

3.6 Numbers and Types of Registration

3.6.1 BIA Assumptions

In the original BIA (for the White Paper), assumptions concerning the level of consortia formation that would occur were tied in with assumptions concerning grouping, and 20%

was assumed in both cases. The net result was that, under the average scenario in the original BIA, there were no net repeat registrations.

In the revised BIA, information on the number of substances produced by more than one company was examined to identify the potential for consortia formation and repeat registrations. The basis for this was that, clearly, in cases where there is only one manufacturer of a substance, there is no potential to form a consortium. Further to this, in situations where there are only two M/Is, there is the potential for consortia formation; there is also the potential for these to break-up into two individual registrations. The same potential for consortia formation and individual registrations is also present for chemicals manufactured by more than two companies.

In the revised BIA, data provided for the textile sector on the number of substances produced by more than one company were examined. These data indicated that roughly 45% of substances produced for this sector at over 10 t/y are manufactured/imported by only one company, with a further 18% of the total produced by only two companies (meaning that 63% of substances for this sector are produced by only one or two companies).

Table 3.6 summarises the percentages of substances manufactured by one, two and more than two companies that were applied in the revised BIA. To these was applied the assumption that there would be 20% repeat registration. In other words, 20% of consortia would break-up or would fail to capture all M/Is.

Thus, using the <10 t/y tonnage band as an example, where only 20% of substances are manufactured by more than one M/I, consortia can only be formed for 20% of substances, and if 20% of these break-up, this equates to a total of 4% of substances having additional individual registrations (in this case 2% for consortia of 2 M/Is and 2% for consortia >2 M/Is).

Table 3.6: Consortia Formation, Repeat Registrations and Resultant Consortia/Individual Registrations Assumed in the Revised BIA

	>1 t/y	**>10 t/y**	**>100 t/y**	**>1000 t/y**
Substances manufactured by only 1 company	80%	60%	60%	60%
Substances manufactured by 2 companies	10%	20%	20%	20%
Substances manufactured by 3 or more companies	10%	20%	20%	20%
Repeat registration	20%	20%	20%	20%
Consortia of 2 breaking into 2 individual registrations	2%	4%	4%	4%
Consortia of >2 breaking-up into 1 individual and 1 consortia registration	2%	4%	4%	4%
Total individual registrations (as a percentage of all substances)	**86%**	**72%**	**72%**	**72%**
Total consortia registrations (as a percentage of all substances)	**20%**	**40%**	**40%**	**40%**
Total registrations (as a percentage of all substances)	**106%**	**112%**	**112%**	**112%**
Repeat registrations (as a percentage of all substances)	**6%**	**12%**	**12%**	**12%**

In terms of the percentage of substances having dangerous properties, the BIA (and this new analysis) used a figure of 40% with dangerous properties. This was based on estimates of the percentage of substances that are likely to be found to have no dangerous properties for notification under Directive 67/548/EEC (as amended by Directive 92/32/EEC). The second three yearly report on implementation of this Directive (CEC, 2001) indicates that 71% of notified substances required classification as dangerous. Of these classified substances, over 34% were notified for use in chemical synthesis (i.e. intermediates) and over 9% for use as polymers. The remaining 56%+ of the classified substances are effectively used in the same types of sectors/applications as phase-in substances. This indicates that 40% of notified substances that are equivalent to phase-in substances are classified as dangerous. Based on this information, it was assumed that 40% of registrations for phase-in substances will be of substances with properties of concern and 60% of registrations will be of phase-in substances with no properties of concern (i.e. not requiring classification).

3.6.2 Revisions for this Work

Assumptions concerning the percentage of substances manufactured by a single M/I will have a significant effect on the potential for repeat registration. The reason for this is simply that, the larger the percentage of substances manufactured by one M/I, the less the number of potential consortia registrations and, in turn, the fewer the opportunities for M/Is to submit individual repeat registrations.

A further factor in the revised BIA analysis that may affect the potential for repeat registrations is the assumption that the break-up or incomplete formation of a consortium would result in at least one consortium registration and one individual registration (see page 24 of the revised BIA). In practice, it is possible that the break-up of a consortium may result in more than one M/I leaving (or never joining) and (potentially) submitting an individual repeat registration.
The extent to which the break-up/an incomplete formation of a consortium may result in more than one M/I leaving (or never joining) logically depends on the size of a consortium (in terms of the number of M/Is) and the number of members leaving (or never joining in the first place).

In their work on the impacts of REACH on the UK, ERM assumed that there was an average of three manufacturers per chemical substance (this number is referenced to a personal communication with the ECB in October 2003).

The implication of this figure is that if, on average, 60-80% of chemicals are manufactured by only one manufacturer and a further 10-20% are manufactured by only two, then, for substances manufactured by more than two M/Is (constituting 10-20% of substances), the average number of M/Is involved (and assumed to be forming a consortium) must be larger than the three to five assumed in the revised BIA (and probably much higher).

Table 3.7 provides a calculation of the average size of consortia (of greater than two M/Is) implied by a combination of the data used in the revised BIA and the assumption that there are three manufacturers per chemical on average.

Table 3.7: Implied Size of Larger Consortia						
	No. Phase-in Substances	**Fraction of Statistical Substance**	**% of Substances Manufact. by 1 M/I**	**% of Substances Manufact. by 2 M/Is**	**% of Substances Manufact. by X M/Is**	**Where X=**
>1000 t/y	2,191	0.08	60%	20%	20%	***30***
>100 t/y	2,115	0.08	60%	20%	20%	***47***
>10 t/y	4,770	0.18	60%	20%	20%	***15***
>1 t/y	17,000	0.65	80%	10%	10%	***4***
Resultant Average Number M/Is per statistical substance = 3.08						

The calculation is based on the number of phase-in substances assumed in the BIA and data for the textiles sector on the percentages of substances having different numbers of M/Is (also assumed in the BIA). The number of M/Is in consortia at each tonnage level is then adjusted until the overall weighted average is equal to three[6]. This provides the maximum size of consortia ('X') for each tonnage band for a statistical substance used the analysis.

3.6.3 Consortium Formation and Break-up

As has been described in Section 2, consideration of the level of consortia formation and break-up is crucial to the examination of the relative costs of existing proposals compared with One Substance, One Registration.

For the analysis of One Substance, One Registration, the size of consortia and the numbers of registrations is fixed. However, the equivalent numbers for the existing REACH proposals are variable because it is not certain how industry will respond or behave and this is unregulated in the Commission's existing proposals.

As such, because no one knows the extent to which consortia will form and stay together under the existing proposals, assumptions have to be made concerning the percentage of consortia that may break-up (or never completely form) and the percentage of members that leave when a consortium does break-up.

In this new analysis, a range of reasonably possible variations in these two variables has been examined. The variations are as follows:

- consortia break-up has been assumed to take place for between 10% and 40% of substances that could be registered in a consortium; and
- in each case that a consortium breaks-up, the percentage of members leaving to submit an individual registration has been assumed to be between 5% and 75% (where clearly this variable only applies to consortia of greater than two).

[6] In this calculation, there are different combinations of numbers of M/Is that can be chosen to achieve the average of three and these numbers represent only one of these combinations.

Application to the Existing REACH Proposals

Every possible combination of these two variables has been applied in the new analysis to provide a range of values. In this way, for all combinations of the percentage consortia breaking-up and percentage of members leaving, the model calculates:

- **the number of individual registrations** – which is a function of the number of substances where there is only one M/I, the number of consortia of two breaking-up into two separate full registrations, and the number of consortia of greater than two experiencing a break-up with a certain number leaving to submit an individual registration;

- **the number of registrations by consortia of two** – which is a combined function of the number of substances where there are two M/Is (and there is no break-up) and the number of substances manufactured by more than two M/Is but where the number of members leaving to submit an individual registration results in the remaining consortium being comprised of only two remaining members; and

- **the number of registrations by consortia of more than two and the average size of these consortia** – which is a combination of the number and size of consortia where there is no break-up and the number of consortia where there is a break-up but the average number of remaining members is still more than two.

Partial Registrations

Under both the existing REACH proposals and One Substance, One Registration, there is also the potential for partial registration, where this involves some consortium members 'leaving' the consortium towards the end of the dossier preparation process so that they can include sensitive information that they may not wish to share with the other consortium members.

As with repeat registration, the way in which industry may respond is not known, so a similar percentage based approach to that taken for repeat registration has been used. For both REACH and One Substance, One Registration, the following ranges have been used:

- partial registration has been assumed to take place for between 10% and 40% **of substances registered in a consortium**; and

- for each substance where partial registration occurs, the percentage of members submitting a partial registration has been assumed to be between 5% and 75% (where clearly this variable only applies to consortia of greater than two).

In calculations for One Substance, One Registration, the size of consortia and number of substances is fixed, so these percentages are simply applied to these consortia and sizes of consortia.

For the existing REACH proposals, as described above, the size of consortia and number of substances is variable depending on the extent of repeat registration. As such, these percentages are applied to the remaining numbers of consortium registrations and associated members in the scenario. As a result, in the scenarios considered here there are always more partial registrations under One Substance, One Registration than under the existing proposals.

3.7 Application of Unit Costs to Numbers of Registrations

As described above, the analysis has used a range of values for percentages of repeat and partial registrations and percentages of members undertaking these. Every possible combination of these percentages has been analysed.

In each case, the model calculates the number of registrations by type (described in Section 3.6) and applies the appropriate cost of testing and registration (described in Sections 3.3 to 3.5).

Table 3.8 provides a summary of which cost is attributed to which type of registration in the analysis for the key cost elements of repeat testing and registration.

Table 3.8: Application of Unit Costs to Numbers of Substances in Each Category

Repeat Testing

	REACH	**One Substance, One Registration**
Number of substances manufactured by 1 M/I	No repeat testing	No repeat testing
Number of consortia of 2 breaking into 2 individual registrations	Cost of 1 repeat of non-vertebrate tests in each case	N/A
Number of consortia of 2 staying intact	No repeat testing	No repeat testing
Number of consortia of >2 breaking into x individual (full) registrations and 1 consortium registration	Cost of 1 repeat of non-vertebrate tests for each member leaving or never joining in each case	N/A
Number of consortia of >2 staying intact	No repeat testing	No repeat testing

Full Registration Costs

	REACH	**One Substance, One Registration**
Number of substances manufactured by 1 M/I	Cost of Individual Registration	Cost of Individual Registration
Number of consortia of 2 breaking into 2 individual registrations	Cost of two Individual Registrations	N/A
Number of consortia of 2 staying intact	Cost of Consortia Registration for two members	Cost of Consortia Registration for two members
Number of consortia of >2 breaking into x individual (full) registrations and 1 consortium registration	Cost of X Individual Registrations **PLUS** Cost of one consortia registration for remainder (based on size of remaining consortium)	N/A
Number of consortia of >2 staying intact	Cost of single consortium registration for maximum number of members	Cost of single consortium registration for maximum number of members

4. RESULTS OF THE ANALYSIS

4.1 Introduction

As has been described in Section 3, because there is uncertainty over the way in which industry will respond, the analysis has covered a wide range of scenarios concerning repeat (and partial) registrations and associated costs under the existing proposals and One Substance, One Registration.

This Section provides the data on the total costs to industry of registering phase-in substances (including testing and registration), the total costs to Competent Authorities (CAs) and the total costs of these combined. A separate breakdown of testing costs and registration costs is provided in Annex 1.

In terms of interpretation of the data, as was discussed in Sections 2 and 3, the revised BIA (and the Commission's Extended Impact Assessment) applied a simple single assumption that there would be 20% repeat registration. The closest approximation to this in the new analysis is the situation where 20% of substance consortia experience a break-up, and 15% of the members leave to submit an individual registration.

4.2 Total (Industry) Costs of Testing and Registration Combined

The total costs of testing and registration for phase-in substances under the existing REACH proposals and under One Substance, One Registration are provided in Figures 4.1 and 4.2 respectively. The figures are based on data points for 75 different scenarios for repeat testing and registration, with estimates given in the accompanying data table.

From these figures, the testing and registration costs under the existing REACH proposals can be derived for a number of different consortium break-up scenarios.

As noted above, the closest approximation to the repeat testing assumptions used in the revised BIA is the situation where 20% of substance consortia experience a break-up and 15% of the members leave to submit an individual registration. The cost for this scenario (shaded in yellow in the data tables) is €1.87 billion.

Under a worst (reasonable) case scenario that 40% of consortia would break-up and 75% of members would leave to submit an individual registration, the costs would be €2.5 billion. This suggests that the testing and registration costs of the current REACH proposals could be 33% higher than previous estimates if industry does not behave as intended. Under a very best case scenario, the costs would only reduce to €1.8 billion, or about 3.6% lower than previous estimates.

The savings under One Substance, One Registration have been provided in € millions and as a percentage of REACH costs in Figures 4.4 and 4.5.

From these data it can be seen that the savings achievable under One Substance, One Registration are potentially as high a €609 million (24.4%). The level of saving in

comparison with equivalent assumptions in the Commission's Extended Impact Assessment is some €74.4 million. Table 4.1 provides a summary of the data ranges for testing and registration costs.

Table 4.1: Summary of Cost Ranges and Savings for Costs of Testing and Registration				
		Lowest Possible Scenario	**Extended Impact Assessment Equivalent Scenario**	**Highest Reasonable Scenario**
Percentage of Substance Consortia Breaking-up		10%	20%	40%
Percentage of Members Leaving		5%	15%	75%
Cost of REACH Proposals	€ Million	1,802	1,869	2,493
Cost of One Sub., One Reg.	€ Million	1,785	1,794	1,884
Savings One Sub.,One Reg.	€ Million	17	74	609
	%	0.9%	4%	24.4%

Figure 4.1: Total Testing and Registration Costs under REACH (€ Millions)

Costs Under Existing REACH Proposals (€ Millions)
Total Industry Costs (Testing and Registration)

% Members leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	€ 1,801.8	€ 1,811.8	€ 1,821.6	€ 1,841.2	€ 1,860.4
10%	€ 1,813.6	€ 1,829.4	€ 1,845.1	€ 1,876.2	€ 1,907.0
15%	€ 1,825.4	€ 1,847.0	**€ 1,868.6**	€ 1,911.3	€ 1,953.7
20%	€ 1,837.1	€ 1,864.6	€ 1,892.0	€ 1,946.3	€ 2,000.0
25%	€ 1,847.3	€ 1,879.9	€ 1,912.3	€ 1,976.7	€ 2,040.6
30%	€ 1,859.9	€ 1,898.6	€ 1,937.1	€ 2,013.5	€ 2,088.9
35%	€ 1,871.8	€ 1,916.4	€ 1,960.8	€ 2,048.6	€ 2,135.2
40%	€ 1,883.7	€ 1,934.2	€ 1,984.3	€ 2,083.5	€ 2,181.2
45%	€ 1,895.6	€ 1,952.0	€ 2,007.8	€ 2,118.3	€ 2,226.9
50%	€ 1,907.5	€ 1,969.7	€ 2,031.3	€ 2,152.9	€ 2,272.4
55%	€ 1,921.0	€ 1,989.7	€ 2,057.7	€ 2,192.0	€ 2,323.7
60%	€ 1,932.3	€ 2,006.5	€ 2,080.0	€ 2,224.7	€ 2,366.5
65%	€ 1,943.6	€ 2,023.3	€ 2,102.2	€ 2,257.3	€ 2,409.0
70%	€ 1,954.9	€ 2,040.1	€ 2,124.3	€ 2,289.7	€ 2,451.2
75%	€ 1,966.2	€ 2,056.8	€ 2,146.3	€ 2,322.0	€ 2,493.1

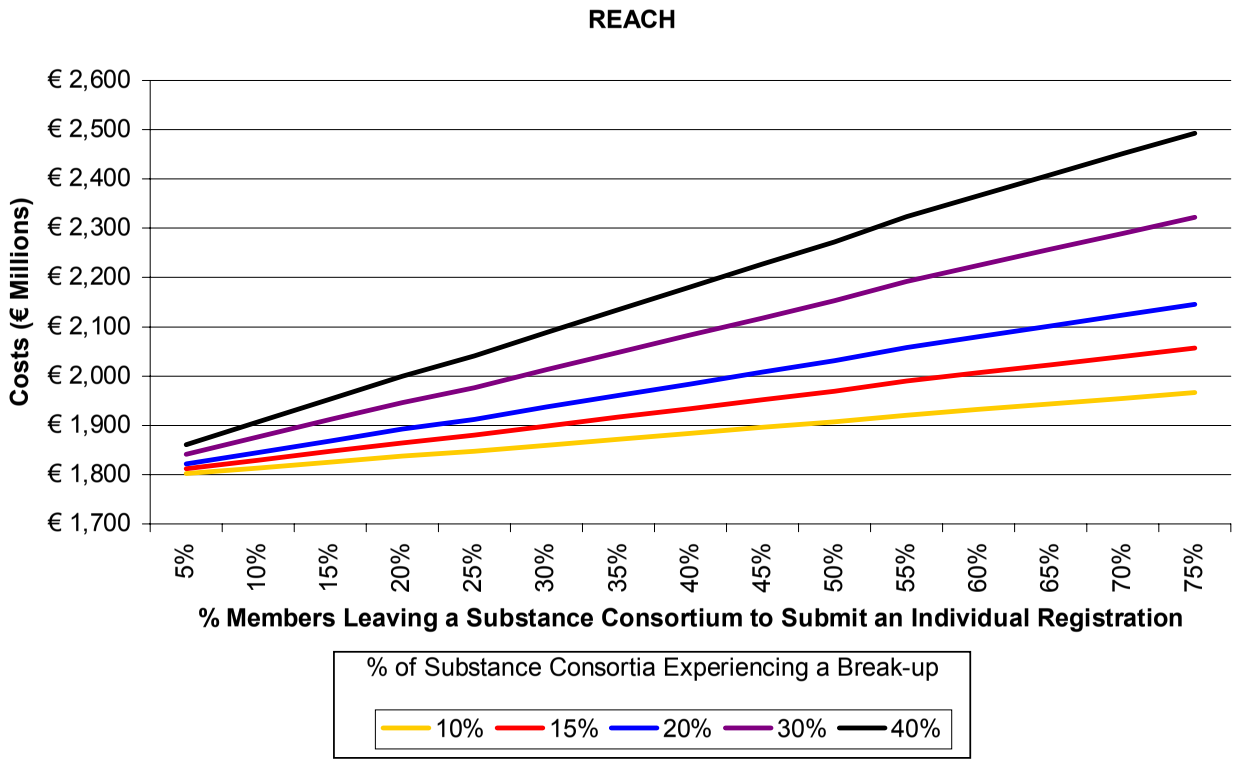


Figure 4.2: Total Testing and Registration Costs under One Substance, One Registration (€ Millions)

Costs Under One Substance, One Registration (€ Millions)
Total Industry Costs (Testing and Registration)

% Members leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	€ 1,784.7	€ 1,786.2	€ 1,787.7	€ 1,790.7	€ 1,793.7
10%	€ 1,786.3	€ 1,788.6	€ 1,790.9	€ 1,795.6	€ 1,800.2
15%	€ 1,788.0	€ 1,791.1	**€ 1,794.2**	€ 1,800.4	€ 1,806.7
20%	€ 1,789.6	€ 1,793.5	€ 1,797.4	€ 1,805.3	€ 1,813.1
25%	€ 1,791.2	€ 1,795.9	€ 1,800.7	€ 1,810.2	€ 1,819.6
30%	€ 1,792.8	€ 1,798.4	€ 1,803.9	€ 1,815.0	€ 1,826.1
35%	€ 1,794.4	€ 1,800.8	€ 1,807.2	€ 1,819.9	€ 1,832.6
40%	€ 1,796.1	€ 1,803.2	€ 1,810.4	€ 1,824.7	€ 1,839.1
45%	€ 1,797.7	€ 1,805.7	€ 1,813.6	€ 1,829.6	€ 1,845.6
50%	€ 1,799.3	€ 1,808.1	€ 1,816.9	€ 1,834.5	€ 1,852.0
55%	€ 1,800.9	€ 1,810.5	€ 1,820.1	€ 1,839.3	€ 1,858.5
60%	€ 1,802.5	€ 1,813.0	€ 1,823.4	€ 1,844.2	€ 1,865.0
65%	€ 1,804.2	€ 1,815.4	€ 1,826.6	€ 1,849.0	€ 1,871.5
70%	€ 1,805.8	€ 1,817.8	€ 1,829.8	€ 1,853.9	€ 1,878.0
75%	€ 1,807.4	€ 1,820.2	€ 1,833.1	€ 1,858.8	€ 1,884.5

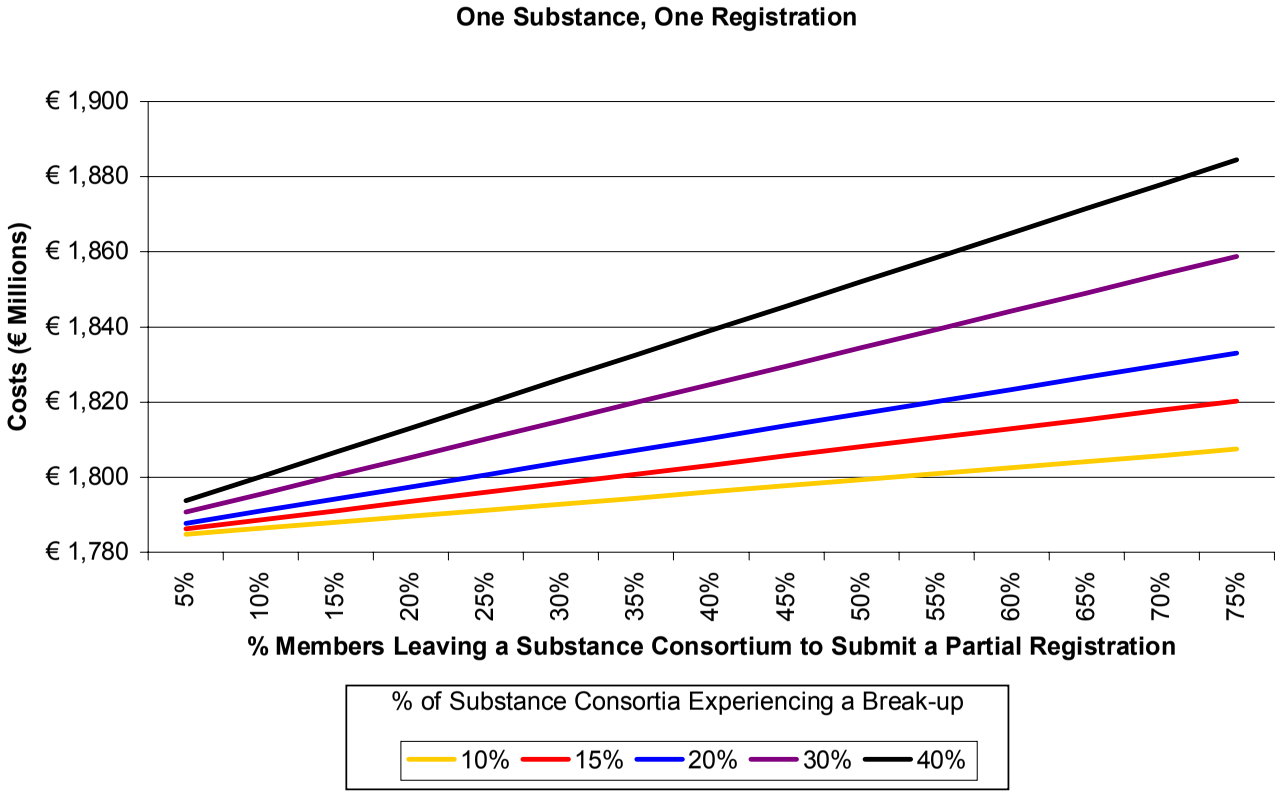


Figure 4.3: Total Testing and Registration Cost Savings (€ Millions) under One Substance, One Registration

Savings Under One Substance, One Registration (€ Millions)
Total Industry Costs (Testing and Registration)

% Members Leaving	% of Consortia Experiencing a Break-up				
	10%	15%	20%	30%	40%
5%	€ 17.1	€ 25.6	€ 33.9	€ 50.5	€ 66.7
10%	€ 27.2	€ 40.7	€ 54.1	€ 80.7	€ 106.8
15%	€ 37.4	€ 55.9	**€ 74.4**	€ 110.9	€ 147.0
20%	€ 47.6	€ 71.1	€ 94.6	€ 141.0	€ 186.9
25%	€ 56.1	€ 83.9	€ 111.6	€ 166.6	€ 220.9
30%	€ 67.1	€ 100.3	€ 133.2	€ 198.5	€ 262.8
35%	€ 77.4	€ 115.7	€ 153.6	€ 228.7	€ 302.6
40%	€ 87.7	€ 131.0	€ 173.9	€ 258.8	€ 342.1
45%	€ 98.0	€ 146.3	€ 194.2	€ 288.7	€ 381.4
50%	€ 108.2	€ 161.6	€ 214.4	€ 318.4	€ 420.3
55%	€ 120.0	€ 179.1	€ 237.6	€ 352.7	€ 465.2
60%	€ 129.8	€ 193.5	€ 256.6	€ 380.6	€ 501.5
65%	€ 139.4	€ 207.9	€ 275.6	€ 408.3	€ 537.5
70%	€ 149.1	€ 222.3	€ 294.4	€ 435.8	€ 573.3
75%	€ 158.8	€ 236.6	€ 313.2	€ 463.2	€ 608.7

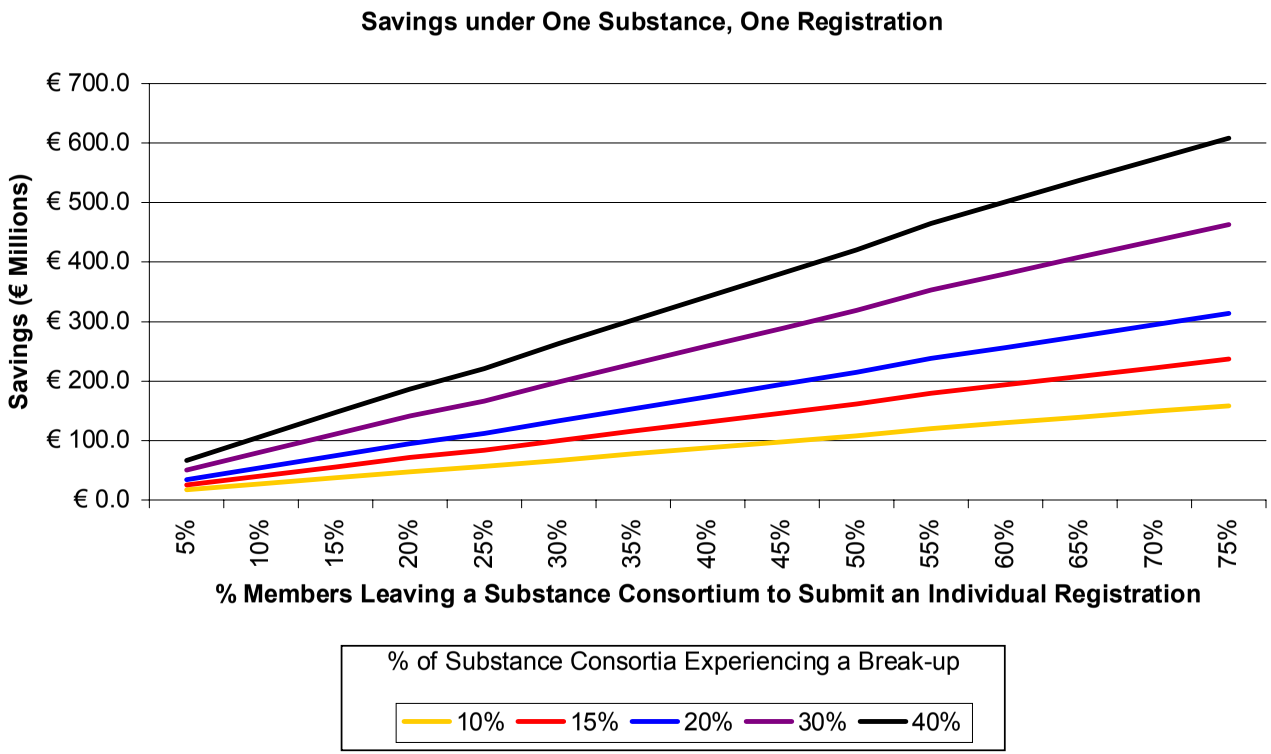
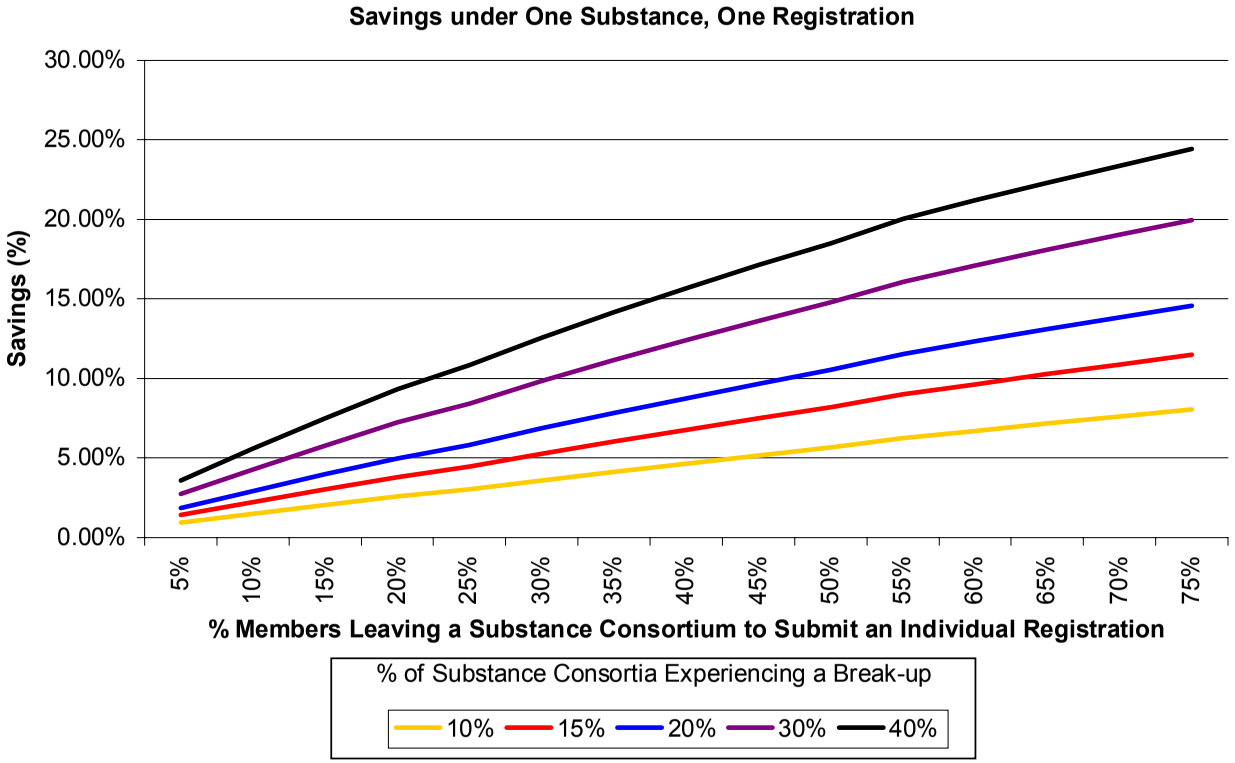


Figure 4.4: Total Testing and Registration Cost Savings (%) under One Substance, One Registration

Savings Under One Substance, One Registration (%)
Total Industry Costs (Testing and Registration)

% Members Leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	0.9%	1.4%	1.9%	2.7%	3.6%
10%	1.5%	2.2%	2.9%	4.3%	5.6%
15%	2.0%	3.0%	**4.0%**	5.8%	7.5%
20%	2.6%	3.8%	5.0%	7.2%	9.3%
25%	3.0%	4.5%	5.8%	8.4%	10.8%
30%	3.6%	5.3%	6.9%	9.9%	12.6%
35%	4.1%	6.0%	7.8%	11.2%	14.2%
40%	4.7%	6.8%	8.8%	12.4%	15.7%
45%	5.2%	7.5%	9.7%	13.6%	17.1%
50%	5.7%	8.2%	10.6%	14.8%	18.5%
55%	6.2%	9.0%	11.5%	16.1%	20.0%
60%	6.7%	9.6%	12.3%	17.1%	21.2%
65%	7.2%	10.3%	13.1%	18.1%	22.3%
70%	7.6%	10.9%	13.9%	19.0%	23.4%
75%	8.1%	11.5%	14.6%	19.9%	24.4%



4.3 Competent Authority Reviewing Costs

The CA costs of reviewing dossiers for phase-in substances under the existing REACH proposals and under One Substance, One Registration are provided in Figures 4.5 and 4.6 respectively. Savings under One Substance, One Registration are provided in Figures 4.7 and 4.8 as € Millions and as a % of REACH costs.

For convenience, data points reflecting the minimum, maximum and the Extended Impact Assessment equivalent assumption are summarised in Table 4.2.

Table 4.2: Summary of Cost Ranges and Savings for CA Costs of Reviewing Dossiers

		Lowest Possible Scenario	Extended Impact Assessment Equivalent Scenario	Highest Reasonable Scenario
Percentage of Substance Consortia Breaking-up		10%	20%	40%
Percentage of Members Leaving		5%	15%	75%
Cost of REACH Proposals	€ Million	80.9	86.8	139.0
Cost of One Sub., One Reg.	€ Million	80.3	83.7	116.2
Savings One Sub.,One Reg.	€ Million	0.6	3.1	22.9
	%	0.8	3.6	16.4

From these figures, it can be seen that the CA costs of reviewing dossiers under the existing REACH proposals range between €81 and €139 million depending on the scenario. The savings achievable under One Substance, One Registration are potentially as high as €22.9 million (16.4%) with the level of saving in comparison with equivalent assumptions in the Commission's Extended Impact Assessment estimated at some €3.1million (3.6%).

Figure 4.5: Competent Authority Reviewing Costs under REACH (€ Millions)

Costs Under Existing REACH Proposals (€ Millions)
Competent Authority Costs

% Members leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	€ 80.9	€ 81.7	€ 82.5	€ 84.0	€ 85.4
10%	€ 82.0	€ 83.3	€ 84.6	€ 87.2	€ 89.6
15%	€ 83.1	€ 84.9	**€ 86.8**	€ 90.4	€ 93.8
20%	€ 84.2	€ 86.6	€ 88.9	€ 93.5	€ 98.0
25%	€ 85.2	€ 88.2	€ 91.0	€ 96.6	€ 102.0
30%	€ 86.3	€ 89.8	€ 93.2	€ 99.7	€ 106.1
35%	€ 87.4	€ 91.4	€ 95.3	€ 102.8	€ 110.0
40%	€ 88.5	€ 93.0	€ 97.3	€ 105.8	€ 113.9
45%	€ 89.6	€ 94.6	€ 99.4	€ 108.8	€ 117.7
50%	€ 90.6	€ 96.1	€ 101.5	€ 111.7	€ 121.5
55%	€ 91.8	€ 97.8	€ 103.7	€ 114.9	€ 125.5
60%	€ 92.8	€ 99.3	€ 105.7	€ 117.7	€ 129.0
65%	€ 93.9	€ 100.9	€ 107.6	€ 120.5	€ 132.4
70%	€ 94.9	€ 102.4	€ 109.5	€ 123.2	€ 135.8
75%	€ 95.9	€ 103.8	€ 111.5	€ 125.8	€ 139.0

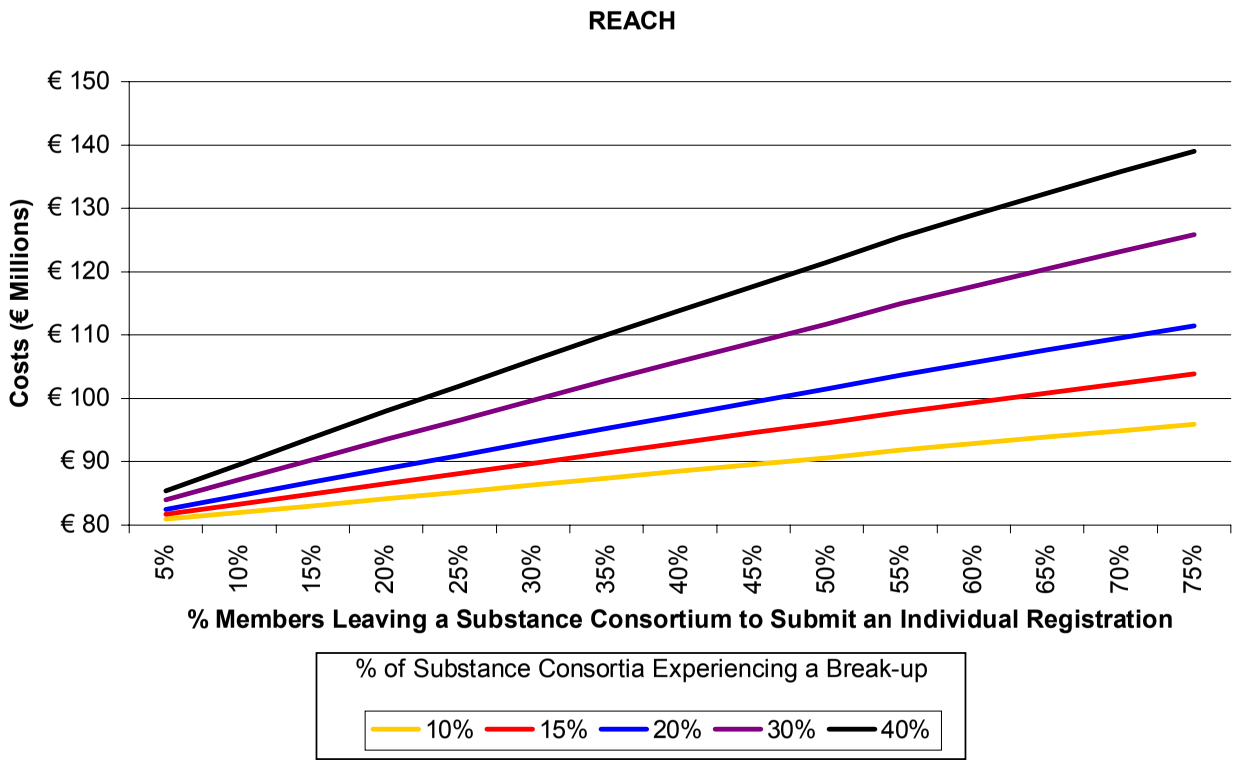


Figure 4.6: Competent Authority Reviewing Costs under One Substance, One Registration (€ Millions)

Costs Under One Substance, One Registration (€ Millions)
Competent Authority Costs

% Members leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	€ 80.3	€ 80.8	€ 81.3	€ 82.4	€ 83.4
10%	€ 80.9	€ 81.7	€ 82.5	€ 84.1	€ 85.7
15%	€ 81.5	€ 82.6	**€ 83.7**	€ 85.9	€ 88.1
20%	€ 82.0	€ 83.4	€ 84.8	€ 87.6	€ 90.4
25%	€ 82.6	€ 84.3	€ 86.0	€ 89.4	€ 92.8
30%	€ 83.2	€ 85.2	€ 87.2	€ 91.1	€ 95.1
35%	€ 83.8	€ 86.1	€ 88.3	€ 92.9	€ 97.4
40%	€ 84.4	€ 87.0	€ 89.5	€ 94.7	€ 99.8
45%	€ 85.0	€ 87.8	€ 90.7	€ 96.4	€ 102.1
50%	€ 85.6	€ 88.7	€ 91.9	€ 98.2	€ 104.5
55%	€ 86.1	€ 89.6	€ 93.0	€ 99.9	€ 106.8
60%	€ 86.7	€ 90.5	€ 94.2	€ 101.7	€ 109.1
65%	€ 87.3	€ 91.3	€ 95.4	€ 103.4	€ 111.5
70%	€ 87.9	€ 92.2	€ 96.5	€ 105.2	€ 113.8
75%	€ 88.5	€ 93.1	€ 97.7	€ 106.9	€ 116.2

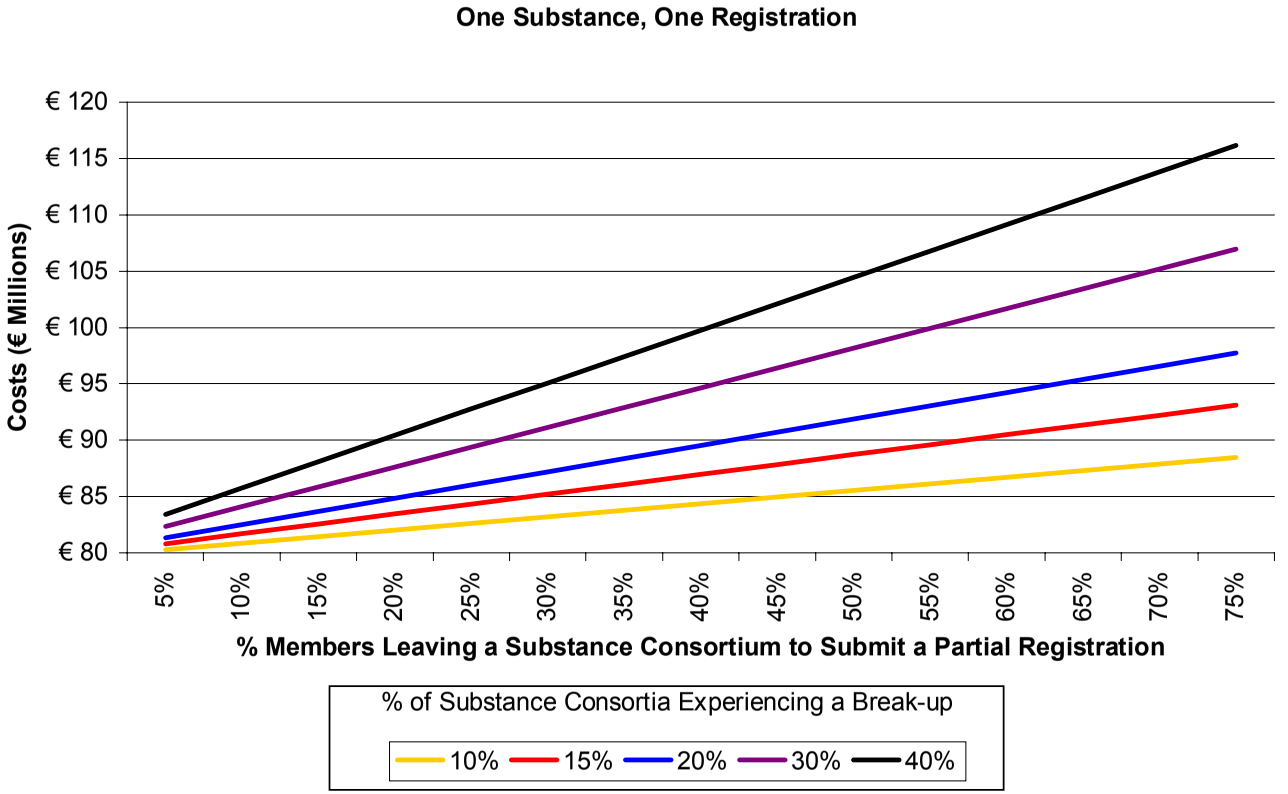


Figure 4.7: Competent Authority Reviewing Cost Savings (€ Millions) under One Substance, One Registration

Savings Under One Substance, One Registration (€ Millions)
Competent Authority Costs

% Members Leaving	% of Consortia Experiencing a Break-up				
	10%	15%	20%	30%	40%
5%	€ 0.6	€ 0.9	€ 1.2	€ 1.6	€ 2.0
10%	€ 1.1	€ 1.6	€ 2.1	€ 3.0	€ 3.9
15%	€ 1.6	€ 2.4	**€ 3.1**	€ 4.5	€ 5.7
20%	€ 2.1	€ 3.1	€ 4.1	€ 5.9	€ 7.5
25%	€ 2.6	€ 3.8	€ 5.0	€ 7.2	€ 9.3
30%	€ 3.1	€ 4.6	€ 6.0	€ 8.6	€ 11.0
35%	€ 3.6	€ 5.3	€ 6.9	€ 9.9	€ 12.6
40%	€ 4.1	€ 6.0	€ 7.8	€ 11.2	€ 14.1
45%	€ 4.6	€ 6.7	€ 8.7	€ 12.4	€ 15.6
50%	€ 5.1	€ 7.4	€ 9.6	€ 13.6	€ 17.0
55%	€ 5.7	€ 8.2	€ 10.7	€ 15.0	€ 18.7
60%	€ 6.1	€ 8.9	€ 11.5	€ 16.0	€ 19.8
65%	€ 6.6	€ 9.5	€ 12.2	€ 17.0	€ 20.9
70%	€ 7.0	€ 10.1	€ 13.0	€ 18.0	€ 21.9
75%	€ 7.5	€ 10.7	€ 13.7	€ 18.9	€ 22.9

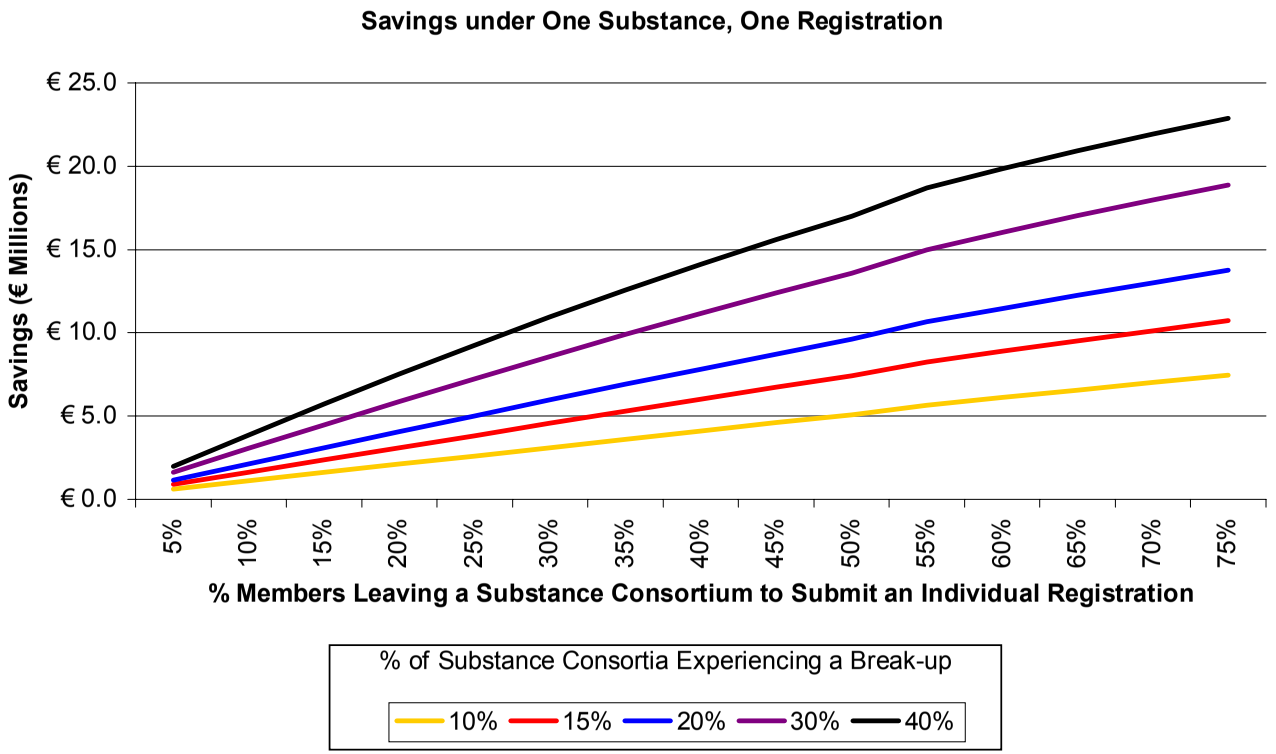
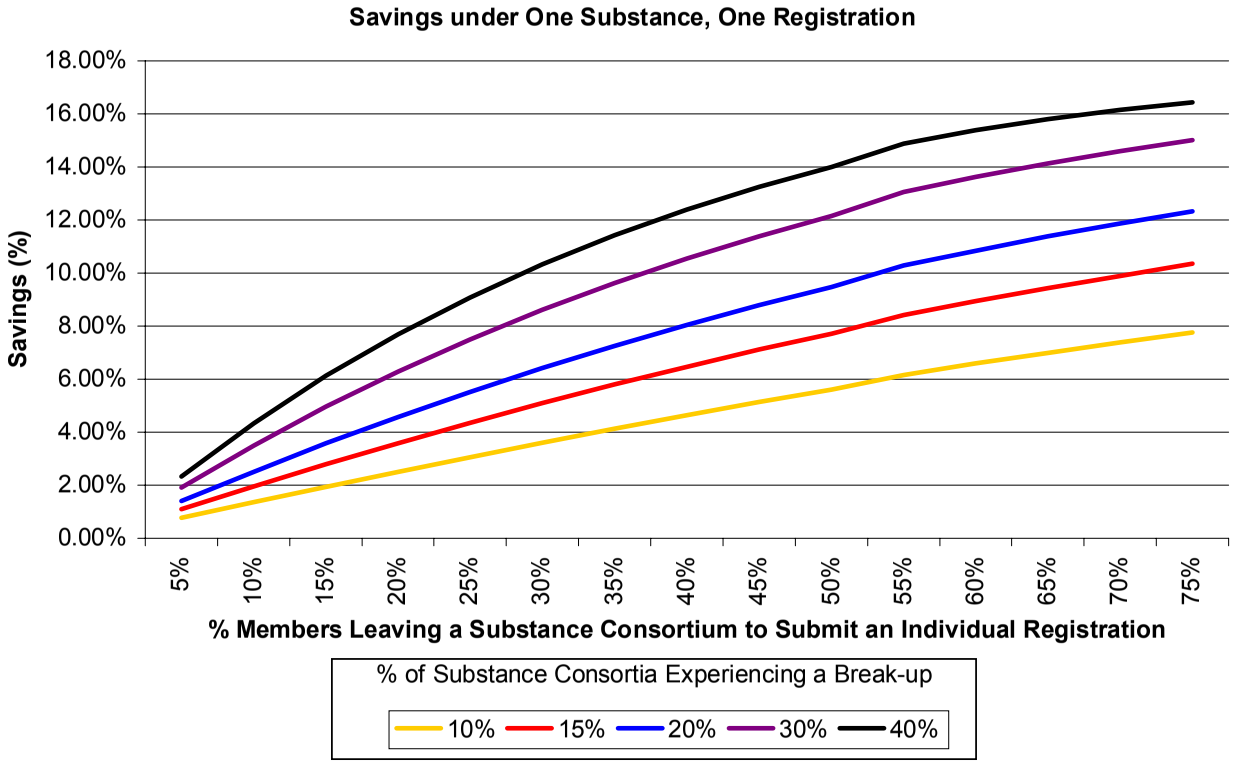


Figure 4.8: Competent Authority Reviewing Cost Savings (%) under One Substance, One Registration

Savings Under One Substance, One Registration (%)
Competent Authority Costs

% Members Leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	0.8%	1.1%	1.4%	1.9%	2.3%
10%	1.4%	2.0%	2.5%	3.5%	4.3%
15%	1.9%	2.8%	3.6%	5.0%	6.1%
20%	2.5%	3.6%	4.6%	6.3%	7.7%
25%	3.1%	4.3%	5.5%	7.5%	9.1%
30%	3.6%	5.1%	6.4%	8.6%	10.3%
35%	4.1%	5.8%	7.3%	9.6%	11.4%
40%	4.6%	6.5%	8.0%	10.6%	12.4%
45%	5.1%	7.1%	8.8%	11.4%	13.3%
50%	5.6%	7.7%	9.5%	12.2%	14.0%
55%	6.2%	8.4%	10.3%	13.1%	14.9%
60%	6.6%	8.9%	10.8%	13.6%	15.4%
65%	7.0%	9.4%	11.4%	14.1%	15.8%
70%	7.4%	9.9%	11.9%	14.6%	16.2%
75%	7.8%	10.3%	12.3%	15.0%	16.4%



4.4 Total Costs of the Regulation

The total costs of the proposed regulation for phase-in substances (i.e. including testing, registration and review of dossiers by CAs) under the existing REACH proposals and under One Substance, One Registration are provided in Figures 4.9 and 4.10 respectively. Savings under One Substance, One Registration are provided in Figures 4.11 and 4.12 as € Millions and as a % of REACH costs.

Data points reflecting the minimum, maximum and the Extended Impact Assessment equivalent assumption are summarised in Table 4.3.

Table 4.3: Summary of Cost Ranges and Savings for Total Costs of Regulation

		Lowest Possible Scenario	Extended Impact Assessment Equivalent Scenario	Highest Reasonable Scenario
Percentage of Substance Consortia Breaking-up		10%	20%	40%
Percentage of Members Leaving		5%	15%	75%
Cost of REACH Proposals	€ Million	1,883	1,955	2,632
Cost of One Sub., One Reg.	€ Million	1,865	1,878	2,000
Savings One Sub.,One Reg.	€ Million	17.7	77.5	631.5
	%	0.9	4.0	24.0

From these figures, it can be seen that the total costs under the existing REACH proposals range between €1.8 and €2.6 billion depending on the scenario. The savings achievable under One Substance, One Registration are potentially as high as €631 million (24%) with the level of saving in comparison with equivalent assumptions in the Commission's Extended Impact Assessment being some €77 million (4%).

Costs Under Existing REACH Proposals (€ Millions)
Total Costs of the Regulation

% Members leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	€ 1,882.7	€ 1,893.5	€ 1,904.1	€ 1,925.1	€ 1,945.8
10%	€ 1,895.6	€ 1,912.7	€ 1,929.7	€ 1,963.4	€ 1,996.6
15%	€ 1,908.4	€ 1,932.0	**€ 1,955.3**	€ 2,001.7	€ 2,047.5
20%	€ 1,921.3	€ 1,951.2	€ 1,980.9	€ 2,039.8	€ 2,098.0
25%	€ 1,932.5	€ 1,968.0	€ 2,003.3	€ 2,073.3	€ 2,142.6
30%	€ 1,946.2	€ 1,988.4	€ 2,030.3	€ 2,113.2	€ 2,195.0
35%	€ 1,959.2	€ 2,007.8	€ 2,056.0	€ 2,151.4	€ 2,245.2
40%	€ 1,972.2	€ 2,027.2	€ 2,081.7	€ 2,189.3	€ 2,295.1
45%	€ 1,985.2	€ 2,046.5	€ 2,107.3	€ 2,227.1	€ 2,344.6
50%	€ 1,998.2	€ 2,065.8	€ 2,132.7	€ 2,264.6	€ 2,393.8
55%	€ 2,012.8	€ 2,087.5	€ 2,161.4	€ 2,306.9	€ 2,449.2
60%	€ 2,025.1	€ 2,105.8	€ 2,185.6	€ 2,342.5	€ 2,495.5
65%	€ 2,037.5	€ 2,124.2	€ 2,209.8	€ 2,377.8	€ 2,541.4
70%	€ 2,049.8	€ 2,142.4	€ 2,233.8	€ 2,412.9	€ 2,587.0
75%	€ 2,062.1	€ 2,160.6	€ 2,257.8	€ 2,447.8	€ 2,632.2

Figure 4.9: Total Costs under REACH (€ Millions)

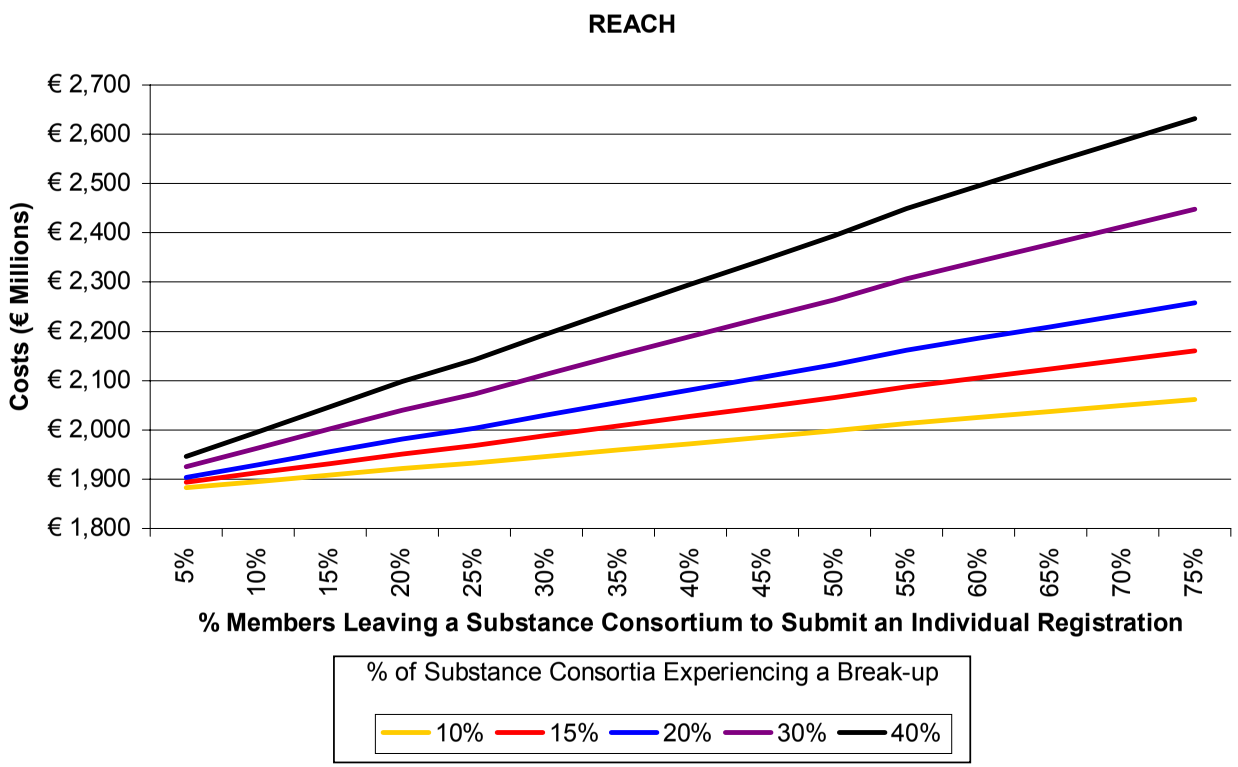


Figure 4.10: Total Costs under One Substance, One Registration (€ Millions)

Costs Under One Substance, One Registration (€ Millions)
Total Costs of the Regulation

% Members leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	€ 1,865.0	€ 1,867.0	€ 1,869.0	€ 1,873.1	€ 1,877.1
10%	€ 1,867.2	€ 1,870.3	€ 1,873.4	€ 1,879.7	€ 1,885.9
15%	€ 1,869.4	€ 1,873.6	**€ 1,877.9**	€ 1,886.3	€ 1,894.7
20%	€ 1,871.6	€ 1,876.9	€ 1,882.3	€ 1,892.9	€ 1,903.6
25%	€ 1,873.8	€ 1,880.3	€ 1,886.7	€ 1,899.5	€ 1,912.4
30%	€ 1,876.0	€ 1,883.6	€ 1,891.1	€ 1,906.2	€ 1,921.2
35%	€ 1,878.2	€ 1,886.9	€ 1,895.5	€ 1,912.8	€ 1,930.0
40%	€ 1,880.4	€ 1,890.2	€ 1,899.9	€ 1,919.4	€ 1,938.9
45%	€ 1,882.7	€ 1,893.5	€ 1,904.3	€ 1,926.0	€ 1,947.7
50%	€ 1,884.9	€ 1,896.8	€ 1,908.7	€ 1,932.6	€ 1,956.5
55%	€ 1,887.1	€ 1,900.1	€ 1,913.2	€ 1,939.2	€ 1,965.3
60%	€ 1,889.3	€ 1,903.4	€ 1,917.6	€ 1,945.9	€ 1,974.2
65%	€ 1,891.5	€ 1,906.7	€ 1,922.0	€ 1,952.5	€ 1,983.0
70%	€ 1,893.7	€ 1,910.0	€ 1,926.4	€ 1,959.1	€ 1,991.8
75%	€ 1,895.9	€ 1,913.3	€ 1,930.8	€ 1,965.7	€ 2,000.6

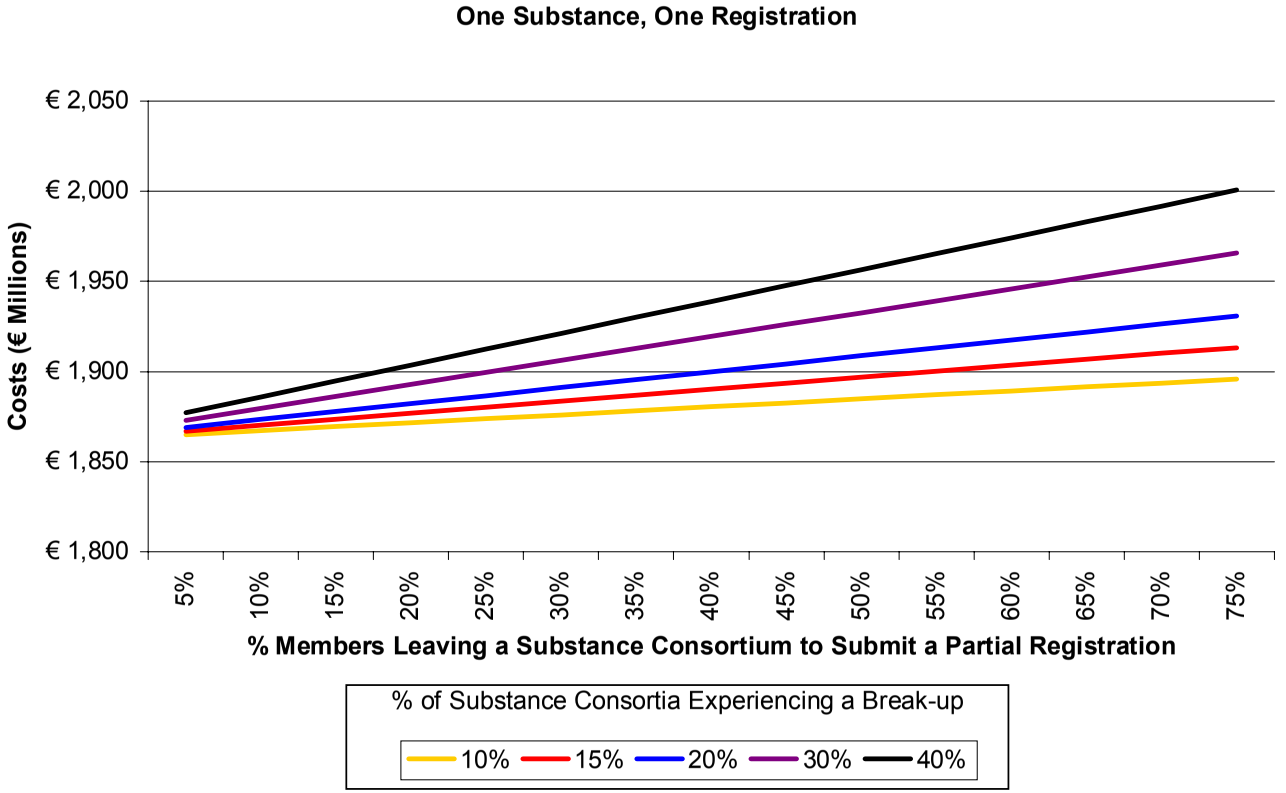


Figure 4.11: Total Cost Savings (€ Millions) under One Substance, One Registration

Savings Under One Substance, One Registration (€ Millions)
Total Costs of the Regulation

% Members Leaving	% of Consortia Experiencing a Break-up				
	10%	15%	20%	30%	40%
5%	€ 17.7	€ 26.5	€ 35.1	€ 52.1	€ 68.7
10%	€ 28.3	€ 42.3	€ 56.2	€ 83.7	€ 110.7
15%	€ 39.0	€ 58.3	**€ 77.5**	€ 115.4	€ 152.7
20%	€ 49.7	€ 74.2	€ 98.6	€ 146.9	€ 194.4
25%	€ 58.7	€ 87.8	€ 116.6	€ 173.8	€ 230.2
30%	€ 70.2	€ 104.8	€ 139.2	€ 207.1	€ 273.8
35%	€ 81.0	€ 120.9	€ 160.5	€ 238.6	€ 315.2
40%	€ 91.8	€ 137.0	€ 181.8	€ 269.9	€ 356.3
45%	€ 102.6	€ 153.0	€ 202.9	€ 301.1	€ 397.0
50%	€ 113.3	€ 169.0	€ 224.0	€ 332.0	€ 437.3
55%	€ 125.7	€ 187.4	€ 248.3	€ 367.7	€ 483.9
60%	€ 135.9	€ 202.4	€ 268.1	€ 396.6	€ 521.4
65%	€ 146.0	€ 217.4	€ 287.8	€ 425.3	€ 558.5
70%	€ 156.1	€ 232.4	€ 307.4	€ 453.8	€ 595.2
75%	€ 166.2	€ 247.3	€ 327.0	€ 482.1	€ 631.5

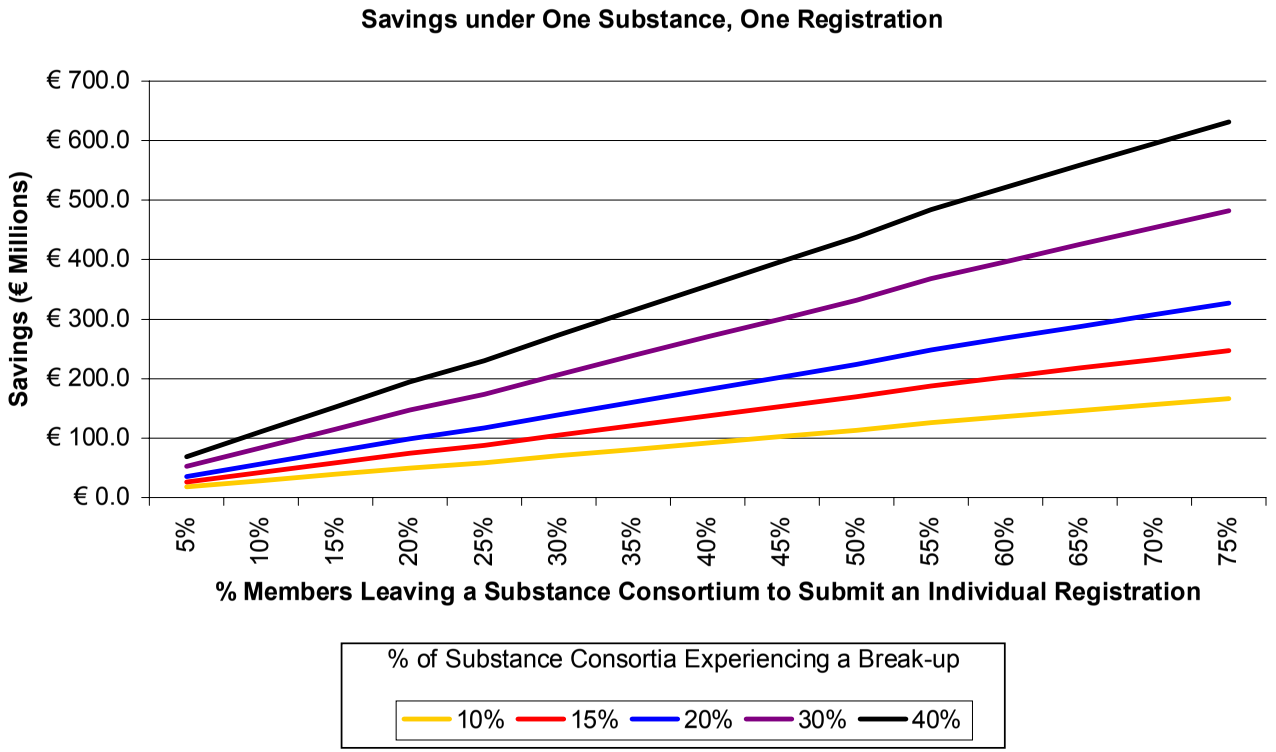
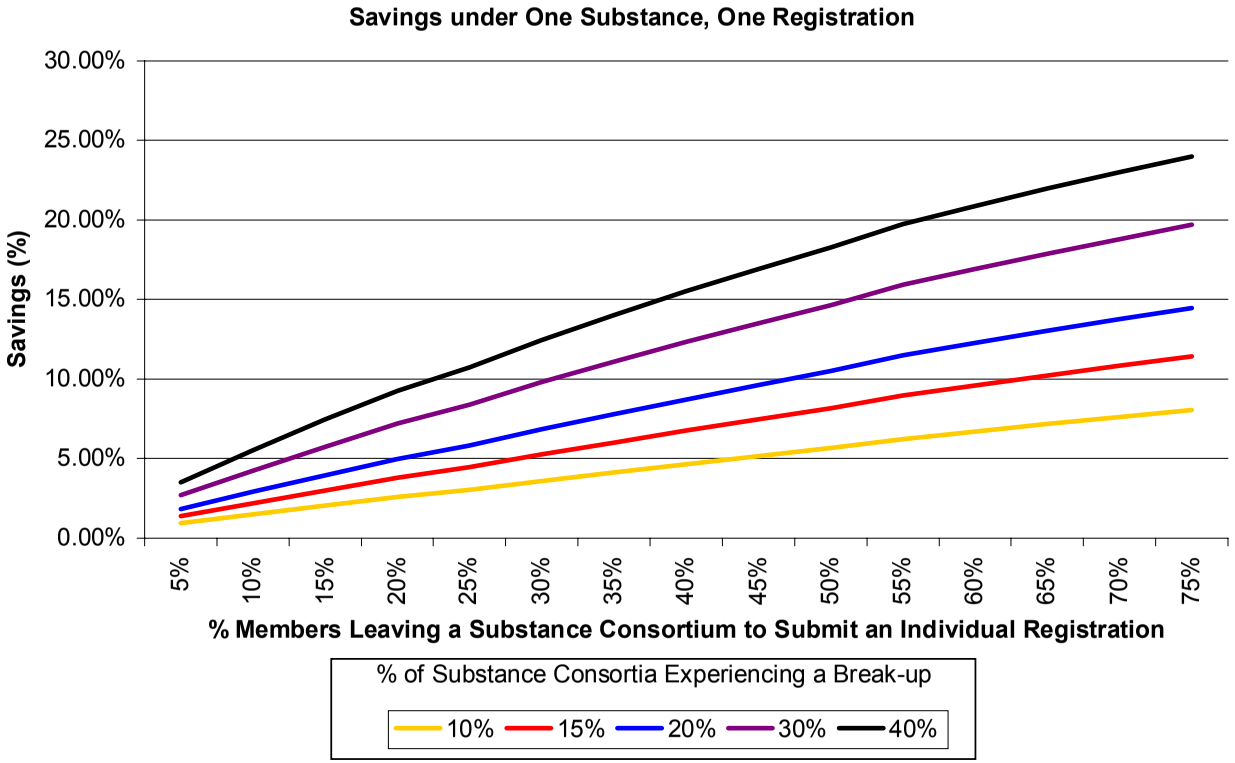


Figure 4.12: Total Cost Savings (%) under One Substance, One Registration

Savings Under One Substance, One Registration (%)
Total Costs of the Regulation

% Members Leaving	% of Consortia Experiencing a breakup				
	10%	**15%**	**20%**	**30%**	**40%**
5%	0.9%	1.4%	1.8%	2.7%	3.5%
10%	1.5%	2.2%	2.9%	4.3%	5.5%
15%	2.0%	3.0%	**4.0%**	5.8%	7.5%
20%	2.6%	3.8%	5.0%	7.2%	9.3%
25%	3.0%	4.5%	5.8%	8.4%	10.7%
30%	3.6%	5.3%	6.9%	9.8%	12.5%
35%	4.1%	6.0%	7.8%	11.1%	14.0%
40%	4.7%	6.8%	8.7%	12.3%	15.5%
45%	5.2%	7.5%	9.6%	13.5%	16.9%
50%	5.7%	8.2%	10.5%	14.7%	18.3%
55%	6.2%	9.0%	11.5%	15.9%	19.8%
60%	6.7%	9.6%	12.3%	16.9%	20.9%
65%	7.2%	10.2%	13.0%	17.9%	22.0%
70%	7.6%	10.8%	13.8%	18.8%	23.0%
75%	8.1%	11.4%	14.5%	19.7%	24.0%



5. SUMMARY AND CONCLUSIONS

As has been described throughout, there is considerable uncertainty concerning industry's response to the proposed REACH regulation as regards the level of cooperation, data sharing and cost sharing within consortia.

In many respects, the UK and Hungary's proposals for One Substance, One Registration can be viewed as a means to control these variables and uncertainties.

The analysis has sought to examine the potential influence of these behavioural factors on the potential costs of the regulation using a multi-scenario analysis to cover all reasonable eventualities regarding consortia formation, break-up and repeat registrations.

Under the 75 different scenarios analysed in this study, the One Substance, One Registration proposals always provide savings on the existing proposals. The actual level of these savings will depend on the level of mutual industry cooperation that occurs in practice.

Using the assumptions set out in Sections 3 and 4, the total savings achievable under One Substance, One Registration are potentially as high as €631 million (24%). When calculated using equivalent assumptions to those in the Commission's Extended Impact, savings are estimated at around €77 million (4%).

Savings are, however, also dependent on other key uncertainties (and accompanying assumptions) that affect the level of cost of the regulation in its current form and under One Substance, One Registration. One of the most significant assumptions in the analysis is that the average number of M/Is per substance is, on average, only three. Also important are the assumptions concerning the percentage of substances manufactured by one, two and more than two M/Is where, for this analysis and the revised BIA, data from the textile sector was used. These assumptions were summarised in Section 3, Table 3.7.

To test sensitivity to these assumptions and the effect on costs, we have run a further scenario with different percentages and an average number of M/Is per substance equal to four. The assumptions are outlined in Table 5.1. The results of this analysis are provided in Annex 2; Table 5.2 provides a summary of the key data points.

Table 5.1: Size of Larger Consortia under a Different Scenario

	No. Phase-in Substances	Fraction of Statistical Substance	% of Substances Manufact. by 1 M/I	% of Substances Manufact. by 2 M/Is	% of Substances Manufact.. by X M/Is	Where X=
>1000 t/y	2191	0.08	40%	30%	30%	***30***
>100 t/y	2115	0.08	40%	30%	30%	***40***
>10 t/y	4770	0.18	40%	30%	30%	***15***
>1 t/y	17000	0.65	60%	20%	20%	***4***
Resultant Average Number M/Is per statistical substance = 4.1						

Table 5.2: Summary of Cost Ranges and Savings for Total Costs of Regulation for Sensitivity				
		Lowest Possible Scenario	**Extended Impact Assessment Equivalent Scenario**	**Highest Reasonable Scenario**
Percentage of Substance Consortia Breaking-up		10%	20%	40%
Percentage of Members Leaving		5%	15%	75%
Cost of REACH Proposals	€ Million	2,013	2,117	3,079
Cost of One Sub., One Reg.	€ Million	1,986	2,004	2,179
Savings One Sub.,One Reg.	€ Million	26.7	112.7	899.8
	%	1	5	29

As can be seen from a comparison of Tables 4.3 and 5.2, changing these assumptions has a dramatic effect on the predicted costs of the proposed regulation. The data suggest that if, in fact, there are four manufacturers of each substance on average instead of three (and a slightly different distribution of M/Is) the costs of REACH could be as high as €3.1 billion instead of €2.6 billion and the savings from One Substance, One Registration could be as high as nearly €900 million.

The conclusion of all of the analyses presented in this Report is that the uncertainties concerning both the structure of the industry and the behaviour of individual M/Is has a very large impact on the level of cost that may be experienced under the regulations in their current form.

Actual costs of the existing REACH proposals are very dependent on what the actual structure of the industry is, and how individual M/Is respond to it in practice (particularly regarding consortia formation). The One Substance, One Registration proposals would appear to provide a means of managing these uncertainties. As such, they provide a means of ensuring that the costs of the regulation are maintained within acceptable bounds and within the anticipated cost range calculated by the revised BIA and the Commission's Extended Impact Assessment.

A1. ANNEX 1: TESTING AND REGISTRATION COST BREAK-DOWN

Figures A1.1 to A1.8 provide a break-down of the data for the costs of testing and of registration under REACH, One Substance, One Registration and associated savings.

Tables A1.1 and A1.2 provide a summary of key data points.

Table A1.1: Summary of Cost Ranges and Savings for Costs of Testing

		Lowest Possible Scenario	Extended Impact Assessment Equivalent Scenario	Highest Reasonable Scenario
Percentage of Substance Consortia Breaking-up		10%	20%	40%
Percentage of Members Leaving		5%	15%	75%
Cost of REACH Proposals	€ Million	1,313.2	1,346.1	1,655.9
Cost of One Sub., One Reg.	€ Million	1,302.4	1,302.4	1,302.4
Savings One Sub.,One Reg.	€ Million	10.8	43.7	353.5
	%	1	3	21

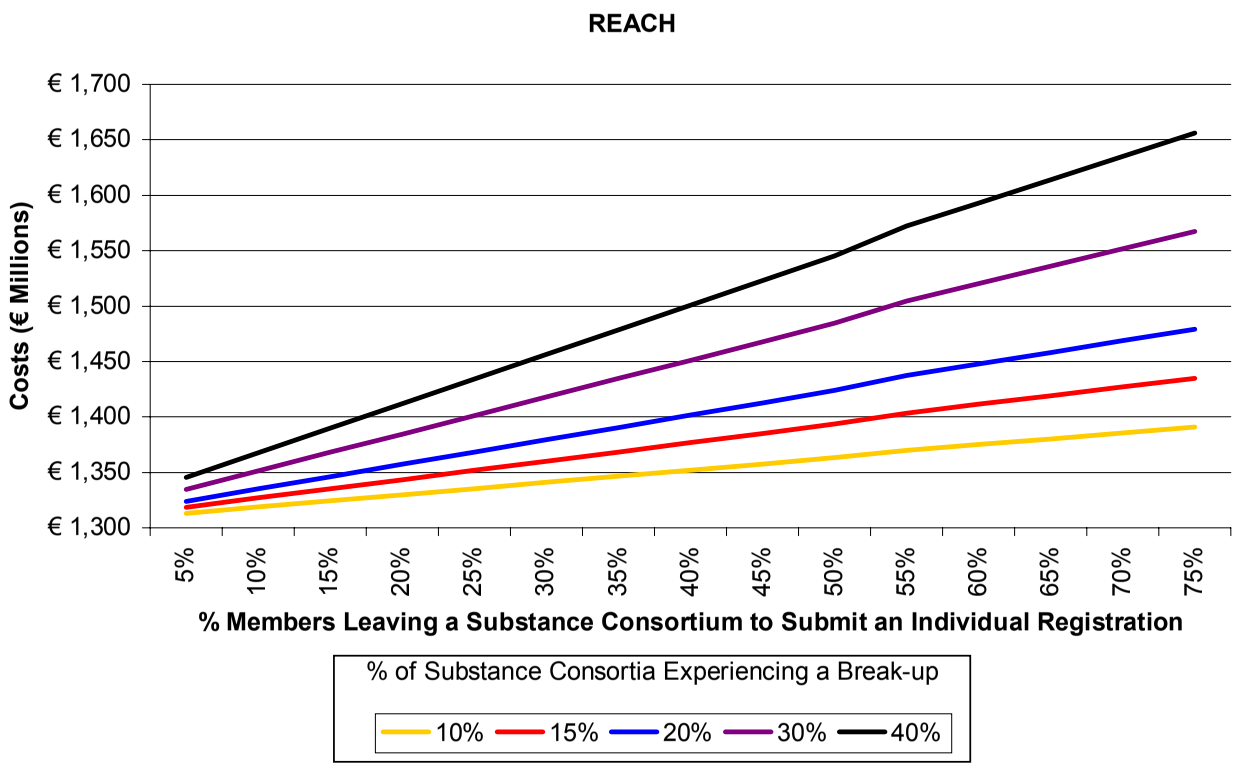
Table A1.2: Summary of Cost Ranges and Savings for Costs of Registration

		Lowest Possible Scenario	Extended Impact Assessment Equivalent Scenario	Highest Reasonable Scenario
Percentage of Substance Consortia Breaking-up		10%	20%	40%
Percentage of Members Leaving		5%	15%	75%
Cost of REACH Proposals	€ Million	488.6	522.4	837.2
Cost of One Sub., One Reg.	€ Million	482.3	491.8	582.0
Savings One Sub.,One Reg.	€ Million	6.3	30.6	255.2
	%	1	6	30

Costs Under Existing REACH Proposals (€ Millions)
Testing Costs

% Members leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	€ 1,313.2	€ 1,318.6	€ 1,324.0	€ 1,334.7	€ 1,345.5
10%	€ 1,318.7	€ 1,326.9	€ 1,335.1	€ 1,351.4	€ 1,367.7
15%	€ 1,324.3	€ 1,335.2	**€ 1,346.1**	€ 1,368.0	€ 1,389.9
20%	€ 1,329.8	€ 1,343.5	€ 1,357.2	€ 1,384.6	€ 1,412.0
25%	€ 1,335.4	€ 1,351.8	€ 1,368.3	€ 1,401.3	€ 1,434.2
30%	€ 1,340.9	€ 1,360.1	€ 1,379.4	€ 1,417.9	€ 1,456.4
35%	€ 1,346.4	€ 1,368.5	€ 1,390.5	€ 1,434.5	€ 1,478.6
40%	€ 1,352.0	€ 1,376.8	€ 1,401.6	€ 1,451.1	€ 1,500.7
45%	€ 1,357.5	€ 1,385.1	€ 1,412.7	€ 1,467.8	€ 1,522.9
50%	€ 1,363.1	€ 1,393.4	€ 1,423.7	€ 1,484.4	€ 1,545.1
55%	€ 1,369.8	€ 1,403.6	€ 1,437.3	€ 1,504.7	€ 1,572.1
60%	€ 1,375.1	€ 1,411.4	€ 1,447.7	€ 1,520.4	€ 1,593.1
65%	€ 1,380.3	€ 1,419.3	€ 1,458.2	€ 1,536.1	€ 1,614.0
70%	€ 1,385.6	€ 1,427.1	€ 1,468.7	€ 1,551.8	€ 1,635.0
75%	€ 1,390.8	€ 1,435.0	€ 1,479.2	€ 1,567.5	€ 1,655.9

Figure A1.1: Testing Costs under REACH (€ Millions)



Costs Under Existing REACH Proposals (€ Millions)
Registration Costs

% Members leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	€ 488.6	€ 493.2	€ 497.7	€ 506.4	€ 514.9
10%	€ 494.8	€ 502.5	€ 510.0	€ 524.8	€ 539.3
15%	€ 501.1	€ 511.8	**€ 522.4**	€ 543.3	€ 563.8
20%	€ 507.3	€ 521.1	€ 534.8	€ 561.7	€ 588.0
25%	€ 511.9	€ 528.0	€ 544.0	€ 575.5	€ 606.4
30%	€ 519.0	€ 538.5	€ 557.8	€ 595.6	€ 632.5
35%	€ 525.4	€ 548.0	€ 570.3	€ 614.1	€ 656.7
40%	€ 531.8	€ 557.4	€ 582.8	€ 632.4	€ 680.5
45%	€ 538.1	€ 566.9	€ 595.2	€ 650.5	€ 704.0
50%	€ 544.5	€ 576.2	€ 607.5	€ 668.5	€ 727.3
55%	€ 551.1	€ 586.1	€ 620.5	€ 687.3	€ 751.6
60%	€ 557.2	€ 595.1	€ 632.2	€ 704.3	€ 773.5
65%	€ 563.3	€ 604.0	€ 643.9	€ 721.2	€ 795.0
70%	€ 569.4	€ 613.0	€ 655.6	€ 737.9	€ 816.3
75%	€ 575.4	€ 621.8	€ 667.1	€ 754.5	€ 837.2

Figure A1.2: Registration Costs under REACH (€ Millions)

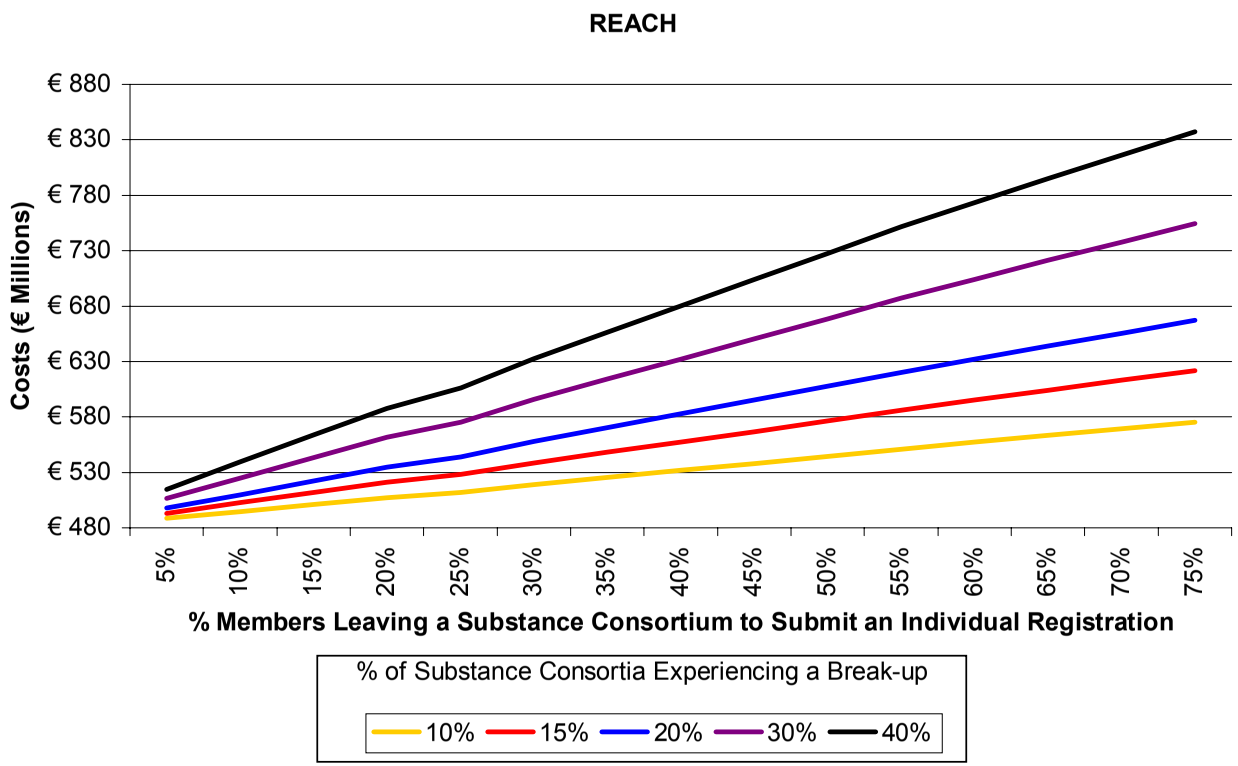


Figure A1.3: Testing Costs under One Substance, One Registration (€ Millions)

Costs Under One Substance, One Registration (€ Millions)
Testing Costs

% Members leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4
10%	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4
15%	€ 1,302.4	€ 1,302.4	**€ 1,302.4**	€ 1,302.4	€ 1,302.4
20%	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4
25%	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4
30%	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4
35%	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4
40%	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4
45%	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4
50%	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4
55%	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4
60%	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4
65%	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4
70%	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4
75%	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4	€ 1,302.4

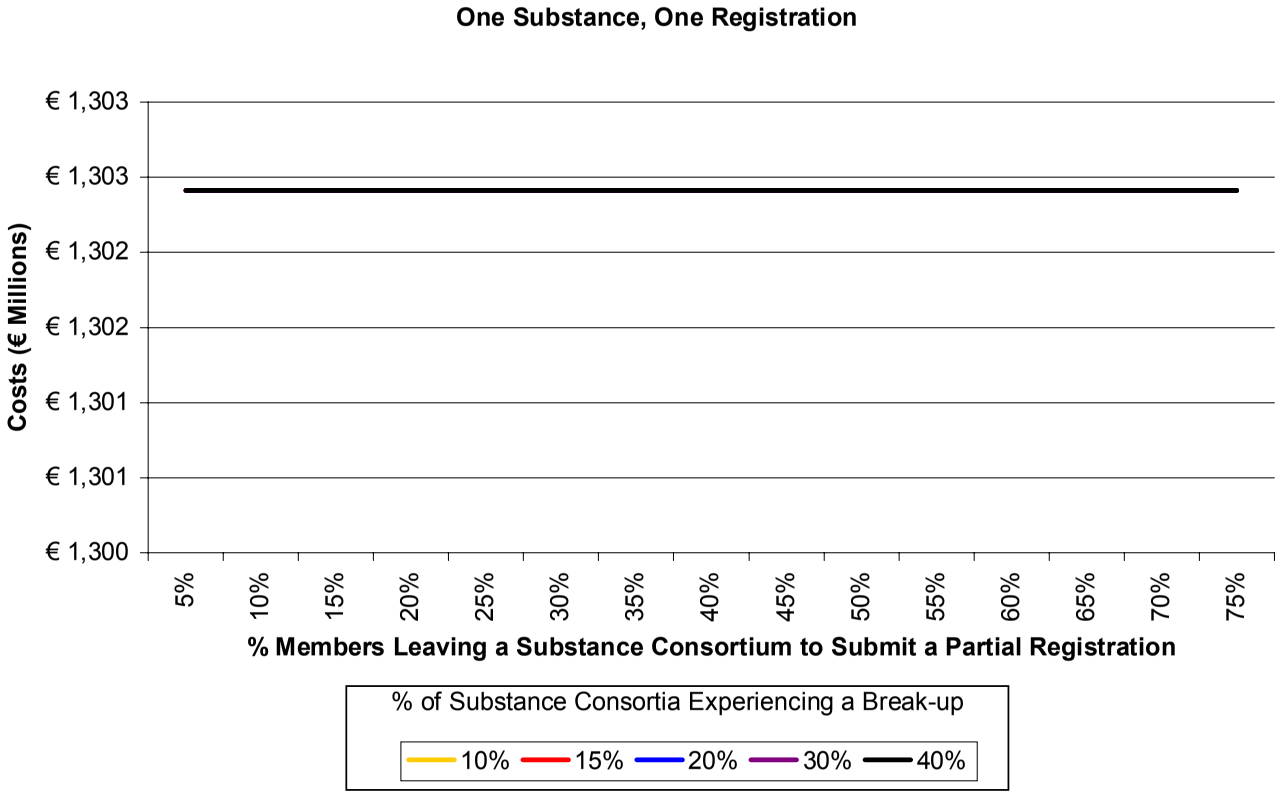


Figure A1.4: Registration Costs under One Substance, One Registration (€ Millions)

Costs Under One Substance, One Registration (€ Millions)
Registration Costs

% Members leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	€ 482.3	€ 483.8	€ 485.3	€ 488.3	€ 491.3
10%	€ 483.9	€ 486.2	€ 488.5	€ 493.2	€ 497.8
15%	€ 485.5	€ 488.7	**€ 491.8**	€ 498.0	€ 504.2
20%	€ 487.2	€ 491.1	€ 495.0	€ 502.9	€ 510.7
25%	€ 488.8	€ 493.5	€ 498.3	€ 507.7	€ 517.2
30%	€ 490.4	€ 496.0	€ 501.5	€ 512.6	€ 523.7
35%	€ 492.0	€ 498.4	€ 504.7	€ 517.5	€ 530.2
40%	€ 493.6	€ 500.8	€ 508.0	€ 522.3	€ 536.7
45%	€ 495.3	€ 503.2	€ 511.2	€ 527.2	€ 543.1
50%	€ 496.9	€ 505.7	€ 514.5	€ 532.1	€ 549.6
55%	€ 498.5	€ 508.1	€ 517.7	€ 536.9	€ 556.1
60%	€ 500.1	€ 510.5	€ 521.0	€ 541.8	€ 562.6
65%	€ 501.8	€ 513.0	€ 524.2	€ 546.6	€ 569.1
70%	€ 503.4	€ 515.4	€ 527.4	€ 551.5	€ 575.6
75%	€ 505.0	€ 517.8	€ 530.7	€ 556.4	€ 582.0

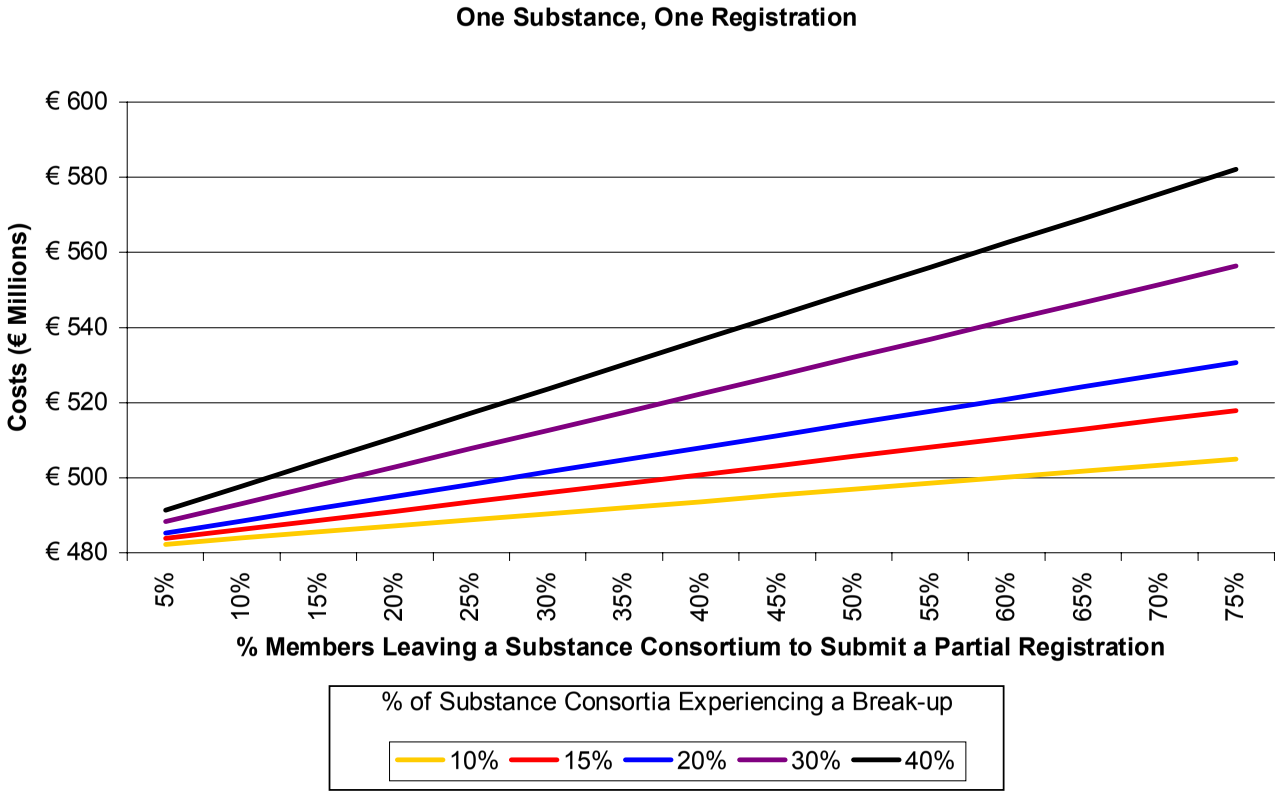


Figure A1.5: Testing Cost Savings (€ Millions) under One Substance, One Registration

Savings Under One Substance, One Registration (€ Millions)
Testing Costs

% Members Leaving	% of Consortia Experiencing a Break-up				
	10%	15%	20%	30%	40%
5%	€ 10.8	€ 16.2	€ 21.6	€ 32.3	€ 43.1
10%	€ 16.3	€ 24.5	€ 32.6	€ 49.0	€ 65.3
15%	€ 21.9	€ 32.8	**€ 43.7**	€ 65.6	€ 87.5
20%	€ 27.4	€ 41.1	€ 54.8	€ 82.2	€ 109.6
25%	€ 32.9	€ 49.4	€ 65.9	€ 98.8	€ 131.8
30%	€ 38.5	€ 57.7	€ 77.0	€ 115.5	€ 154.0
35%	€ 44.0	€ 66.1	€ 88.1	€ 132.1	€ 176.1
40%	€ 49.6	€ 74.4	€ 99.2	€ 148.7	€ 198.3
45%	€ 55.1	€ 82.7	€ 110.2	€ 165.4	€ 220.5
50%	€ 60.7	€ 91.0	€ 121.3	€ 182.0	€ 242.7
55%	€ 67.4	€ 101.1	€ 134.9	€ 202.3	€ 269.7
60%	€ 72.7	€ 109.0	€ 145.3	€ 218.0	€ 290.7
65%	€ 77.9	€ 116.9	€ 155.8	€ 233.7	€ 311.6
70%	€ 83.1	€ 124.7	€ 166.3	€ 249.4	€ 332.6
75%	€ 88.4	€ 132.6	€ 176.8	€ 265.1	€ 353.5

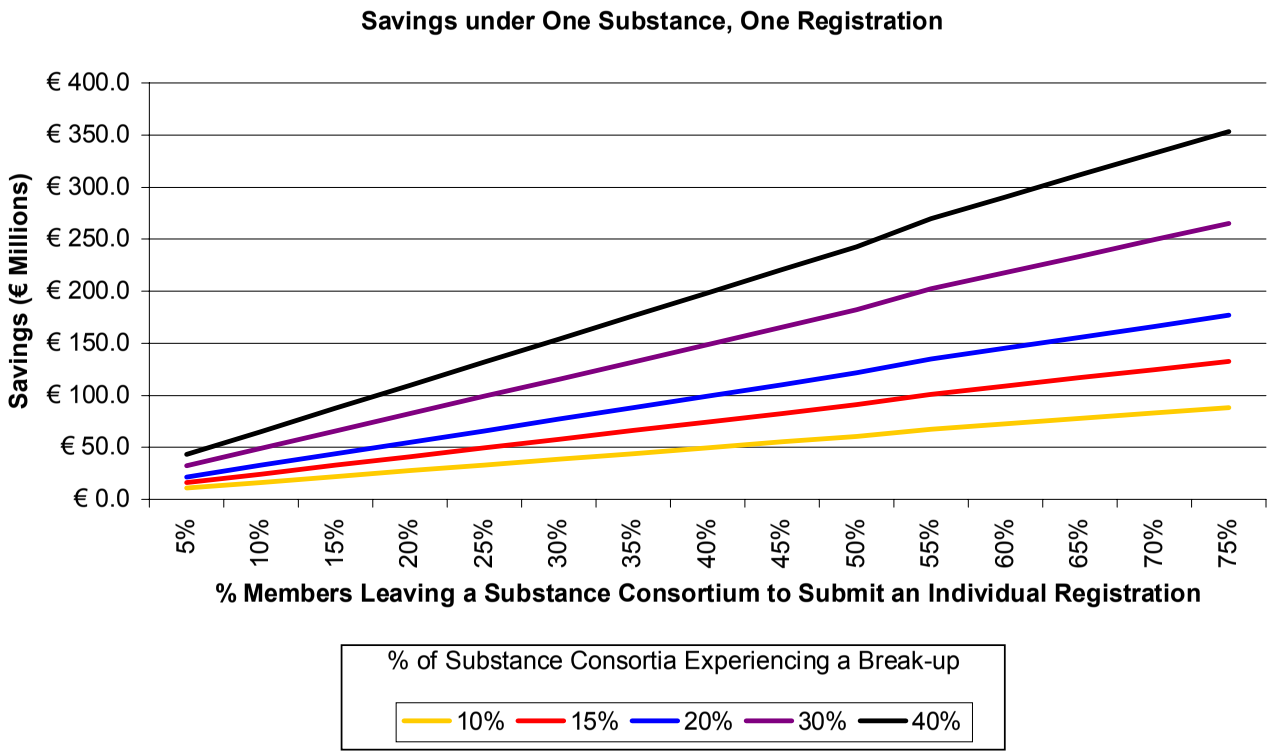


Figure A1.6: Registration Cost Savings (€ Millions) under One Substance, One Registration

Savings Under One Substance, One Registration (€ Millions)
Registration Costs

% Members Leaving	% of Consortia Experiencing a Break-up				
	10%	15%	20%	30%	40%
5%	€ 6.3	€ 9.4	€ 12.4	€ 18.1	€ 23.6
10%	€ 10.9	€ 16.2	€ 21.5	€ 31.7	€ 41.6
15%	€ 15.5	€ 23.1	**€ 30.6**	€ 45.3	€ 59.5
20%	€ 20.2	€ 30.0	€ 39.7	€ 58.8	€ 77.2
25%	€ 23.2	€ 34.5	€ 45.7	€ 67.7	€ 89.2
30%	€ 28.6	€ 42.5	€ 56.3	€ 83.0	€ 108.8
35%	€ 33.4	€ 49.6	€ 65.6	€ 96.6	€ 126.5
40%	€ 38.1	€ 56.6	€ 74.8	€ 110.0	€ 143.8
45%	€ 42.8	€ 63.6	€ 84.0	€ 123.3	€ 160.9
50%	€ 47.6	€ 70.6	€ 93.0	€ 136.4	€ 177.7
55%	€ 52.6	€ 78.0	€ 102.7	€ 150.4	€ 195.5
60%	€ 57.1	€ 84.5	€ 111.3	€ 162.6	€ 210.9
65%	€ 61.5	€ 91.1	€ 119.8	€ 174.6	€ 225.9
70%	€ 66.0	€ 97.5	€ 128.1	€ 186.4	€ 240.7
75%	€ 70.4	€ 104.0	€ 136.5	€ 198.1	€ 255.2

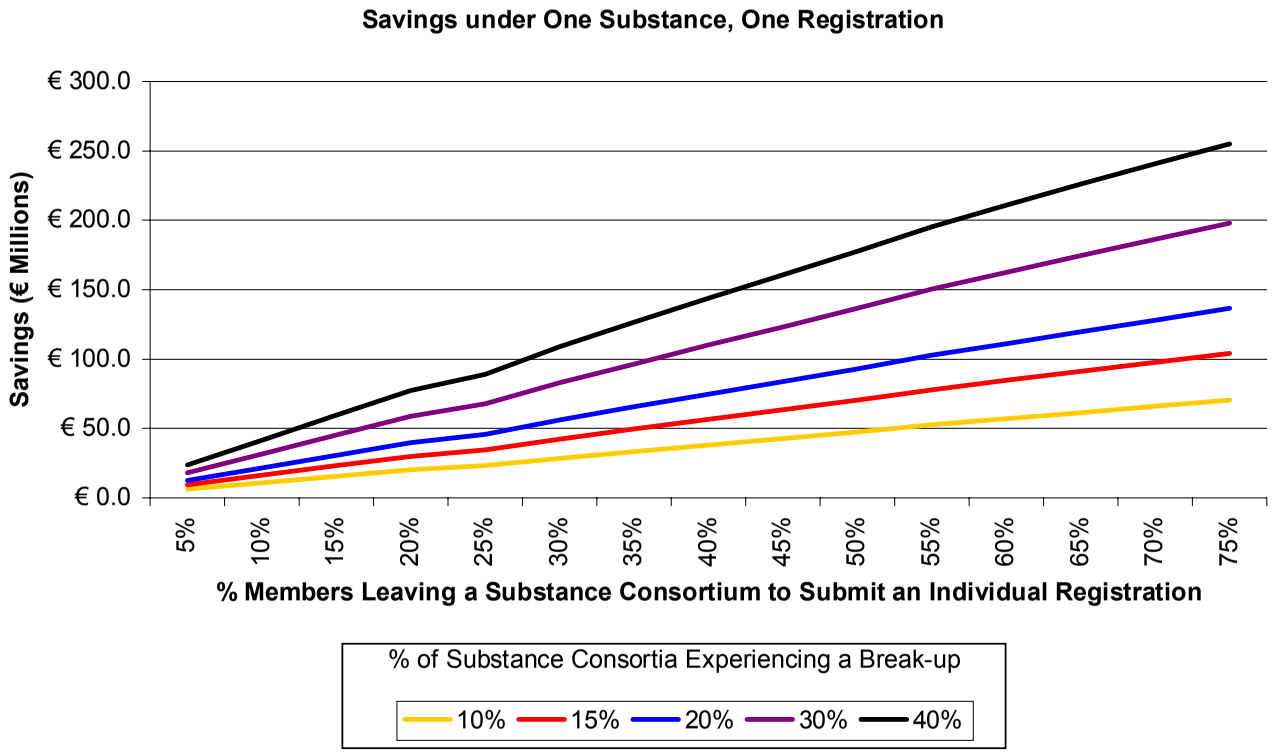


Figure A1.7: Testing Cost Savings (%) under One Substance, One Registration

Savings Under One Substance, One Registration (%)
Testing Costs

% Members Leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	0.8%	1.2%	1.6%	2.4%	3.2%
10%	1.2%	1.8%	2.4%	3.6%	4.8%
15%	1.7%	2.5%	3.2%	4.8%	6.3%
20%	2.1%	3.1%	4.0%	5.9%	7.8%
25%	2.5%	3.7%	4.8%	7.1%	9.2%
30%	2.9%	4.2%	5.6%	8.1%	10.6%
35%	3.3%	4.8%	6.3%	9.2%	11.9%
40%	3.7%	5.4%	7.1%	10.2%	13.2%
45%	4.1%	6.0%	7.8%	11.3%	14.5%
50%	4.5%	6.5%	8.5%	12.3%	15.7%
55%	4.9%	7.2%	9.4%	13.4%	17.2%
60%	5.3%	7.7%	10.0%	14.3%	18.2%
65%	5.6%	8.2%	10.7%	15.2%	19.3%
70%	6.0%	8.7%	11.3%	16.1%	20.3%
75%	6.4%	9.2%	11.9%	16.9%	21.3%

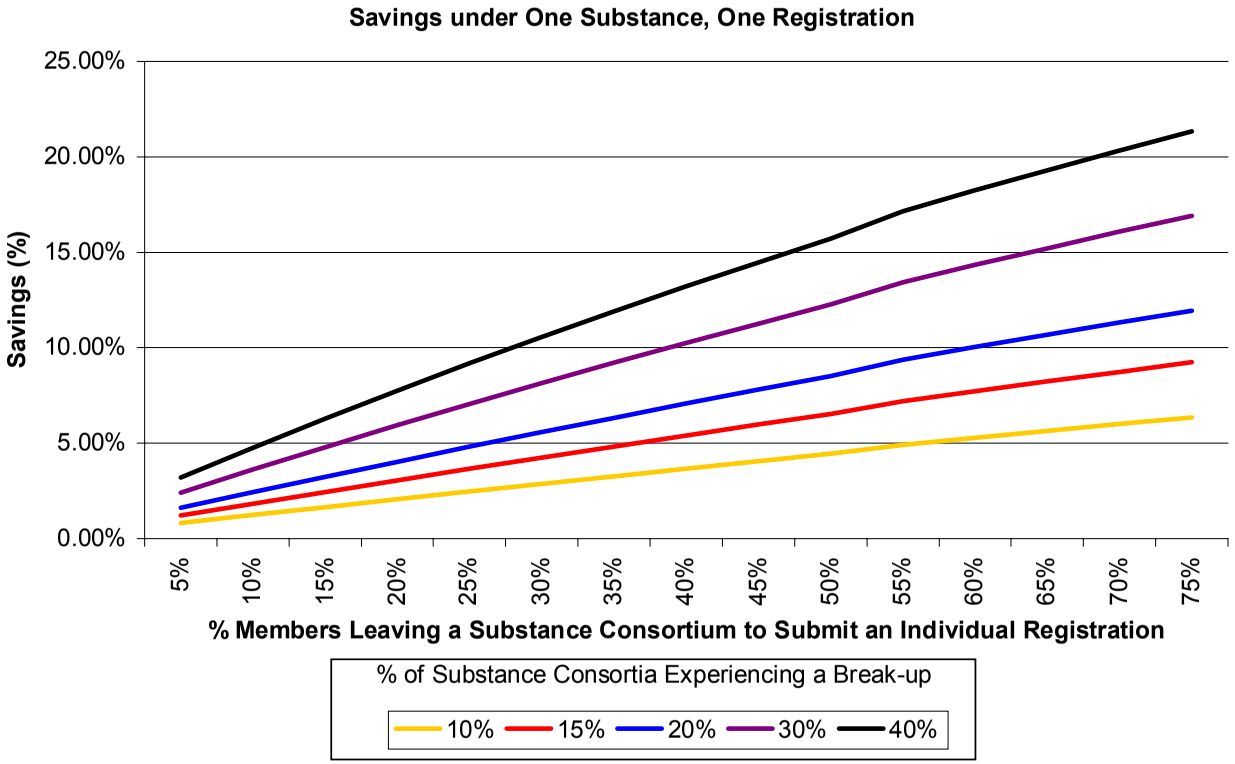
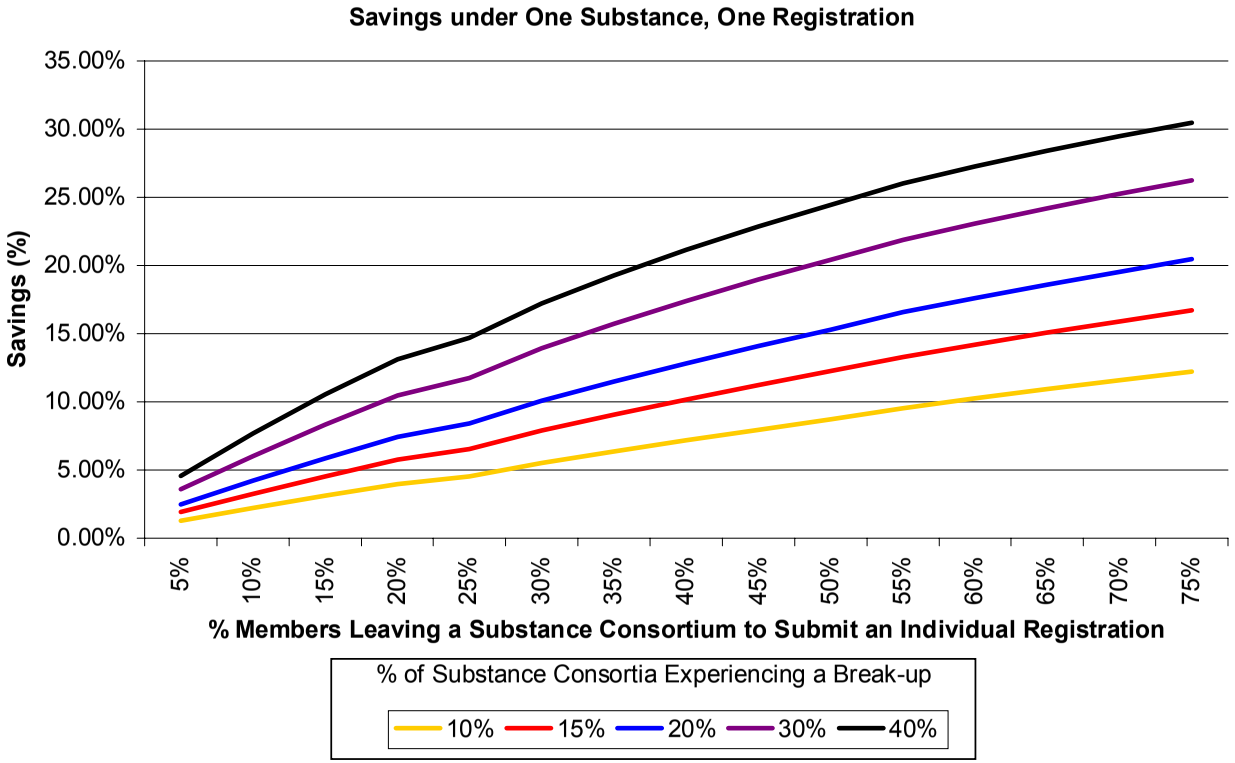


Figure A1.8: Registration Cost Savings (%) under One Substance, One Registration

Savings Under One Substance, One Registration (%)
Registration Costs

% Members Leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	1.3%	1.9%	2.5%	3.6%	4.6%
10%	2.2%	3.2%	4.2%	6.0%	7.7%
15%	3.1%	4.5%	**5.9%**	8.3%	10.6%
20%	4.0%	5.8%	7.4%	10.5%	13.1%
25%	4.5%	6.5%	8.4%	11.8%	14.7%
30%	5.5%	7.9%	10.1%	13.9%	17.2%
35%	6.3%	9.1%	11.5%	15.7%	19.3%
40%	7.2%	10.2%	12.8%	17.4%	21.1%
45%	8.0%	11.2%	14.1%	19.0%	22.9%
50%	8.7%	12.2%	15.3%	20.4%	24.4%
55%	9.5%	13.3%	16.6%	21.9%	26.0%
60%	10.2%	14.2%	17.6%	23.1%	27.3%
65%	10.9%	15.1%	18.6%	24.2%	28.4%
70%	11.6%	15.9%	19.5%	25.3%	29.5%
75%	12.2%	16.7%	20.5%	26.3%	30.5%



A2. ANNEX 2: SENSITIVITY TESTING

This Annex presents the results of running a further scenario with different assumptions concerning percentages of substances manufactured on one, two and more than two M/Is and with an average number of M/Is per substance equal to four.

Table A2.1 duplicates Table 3.7 in the main report and provides the assumptions used throughout the rest of the report while Table A2.2 duplicates Table 5.1 of the main report, showing changes for this 'sensitivity' scenario.

Table 3.7: Size Consortia under MAIN Scenario						
	No. Phase-in Substances	**Fraction of Statistical Substance**	**% of Substances Manufact. by 1 M/I**	**% of Substances Manufact. by 2 M/Is**	**% of Substances Manufact. by X M/Is**	**Where X=**
>1000 t/y	2,191	0.08	60%	20%	20%	***30***
>100 t/y	2,115	0.08	60%	20%	20%	***47***
>10 t/y	4,770	0.18	60%	20%	20%	***15***
>1 t/y	17,000	0.65	80%	10%	10%	***4***
Resultant Average Number M/Is per statistical substance = 3.1						

Table A2.2: Size Consortia under SENSITIVITY Scenario						
	No. Phase-in Substances	**Fraction of Statistical Substance**	**% of Substances Manufact. by 1 M/I**	**% of Substances Manufact. by 2 M/Is**	**% of Substances Manufact.. by X M/Is**	**Where X=**
>1000 t/y	2191	0.08	40%	30%	30%	***30***
>100 t/y	2115	0.08	40%	30%	30%	***40***
>10 t/y	4770	0.18	40%	30%	30%	***15***
>1 t/y	17000	0.65	60%	20%	20%	***4***
Resultant Average Number M/Is per statistical substance = 4.1						

Results of running this sensitivity scenario for the **total costs of the regulation** are provided in Figures A2.1 to A2.4, covering the costs of REACH, One Substance, One Registration, and associated cost savings. Table A2.3 provides a summary of the key data points.

Table A2.3: Summary of Cost Ranges and Savings for Total Costs of Regulation UNDER SENSITIVITY SCENARIO				
		Lowest Possible Scenario	**Extended Impact Assessment Equivalent Scenario**	**Highest Reasonable Scenario**
Percentage of Substance Consortia Breaking-up		10%	20%	40%
Percentage of Members Leaving		5%	15%	75%
Cost of REACH Proposals	€ Million	2,012.6	2,117.1	3,078.9
Cost of One Sub., One Reg.	€ Million	1,985.8	2,004.4	2,179.1
Savings One Sub.,One Reg.	€ Million	26.7	112.7	899.8
	%	1	5	29

Figure A2.1: Total Costs of the Regulation under REACH (€ Millions)

Costs Under Existing REACH Proposals (€ Millions)
Total Costs of the Regulation

% Members leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	€ 2,012.6	€ 2,028.7	€ 2,044.8	€ 2,076.4	€ 2,107.4
10%	€ 2,030.6	€ 2,055.8	€ 2,080.9	€ 2,130.4	€ 2,179.2
15%	€ 2,048.8	€ 2,083.1	**€ 2,117.1**	€ 2,184.5	€ 2,251.0
20%	€ 2,067.0	€ 2,110.2	€ 2,153.2	€ 2,238.3	€ 2,322.3
25%	€ 2,081.9	€ 2,132.6	€ 2,183.1	€ 2,283.1	€ 2,382.2
30%	€ 2,101.8	€ 2,162.2	€ 2,222.1	€ 2,340.8	€ 2,457.7
35%	€ 2,120.3	€ 2,189.8	€ 2,258.7	€ 2,395.0	€ 2,529.2
40%	€ 2,138.8	€ 2,217.4	€ 2,295.2	€ 2,449.0	€ 2,600.2
45%	€ 2,157.3	€ 2,244.9	€ 2,331.6	€ 2,502.8	€ 2,670.6
50%	€ 2,175.7	€ 2,272.3	€ 2,367.9	€ 2,556.2	€ 2,740.6
55%	€ 2,197.4	€ 2,304.6	€ 2,410.6	€ 2,619.3	€ 2,823.3
60%	€ 2,214.7	€ 2,330.3	€ 2,444.5	€ 2,668.9	€ 2,888.0
65%	€ 2,232.0	€ 2,355.9	€ 2,478.2	€ 2,718.3	€ 2,952.2
70%	€ 2,249.2	€ 2,381.4	€ 2,511.8	€ 2,767.4	€ 3,015.8
75%	€ 2,266.5	€ 2,406.9	€ 2,545.3	€ 2,816.2	€ 3,078.9

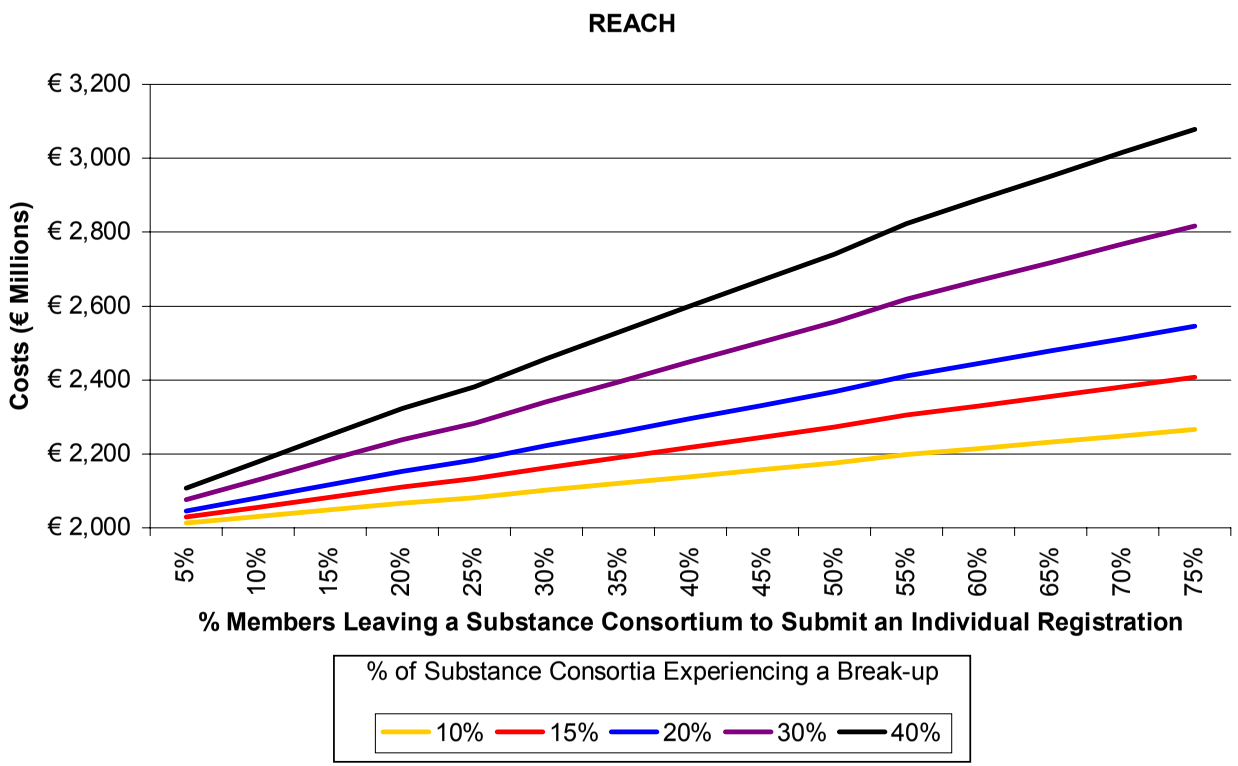


Figure A2.2: Total Costs of the Regulation under One Substance, One Registration (€ Millions)

Costs Under One Substance, One Registration (€ Millions)
Total Costs of the Regulation

% Members leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	€ 1,985.8	€ 1,988.9	€ 1,991.9	€ 1,998.0	€ 2,004.1
10%	€ 1,989.0	€ 1,993.6	€ 1,998.2	€ 2,007.4	€ 2,016.6
15%	€ 1,992.1	€ 1,998.3	**€ 2,004.4**	€ 2,016.8	€ 2,029.1
20%	€ 1,995.2	€ 2,002.9	€ 2,010.7	€ 2,026.2	€ 2,041.6
25%	€ 1,998.3	€ 2,007.6	€ 2,016.9	€ 2,035.5	€ 2,054.1
30%	€ 2,001.5	€ 2,012.3	€ 2,023.2	€ 2,044.9	€ 2,066.6
35%	€ 2,004.6	€ 2,017.0	€ 2,029.4	€ 2,054.3	€ 2,079.1
40%	€ 2,007.7	€ 2,021.7	€ 2,035.7	€ 2,063.7	€ 2,091.6
45%	€ 2,010.8	€ 2,026.4	€ 2,041.9	€ 2,073.0	€ 2,104.1
50%	€ 2,014.0	€ 2,031.1	€ 2,048.2	€ 2,082.4	€ 2,116.6
55%	€ 2,017.1	€ 2,035.8	€ 2,054.4	€ 2,091.8	€ 2,129.1
60%	€ 2,020.2	€ 2,040.4	€ 2,060.7	€ 2,101.2	€ 2,141.6
65%	€ 2,023.3	€ 2,045.1	€ 2,066.9	€ 2,110.5	€ 2,154.1
70%	€ 2,026.5	€ 2,049.8	€ 2,073.2	€ 2,119.9	€ 2,166.6
75%	€ 2,029.6	€ 2,054.5	€ 2,079.4	€ 2,129.3	€ 2,179.1

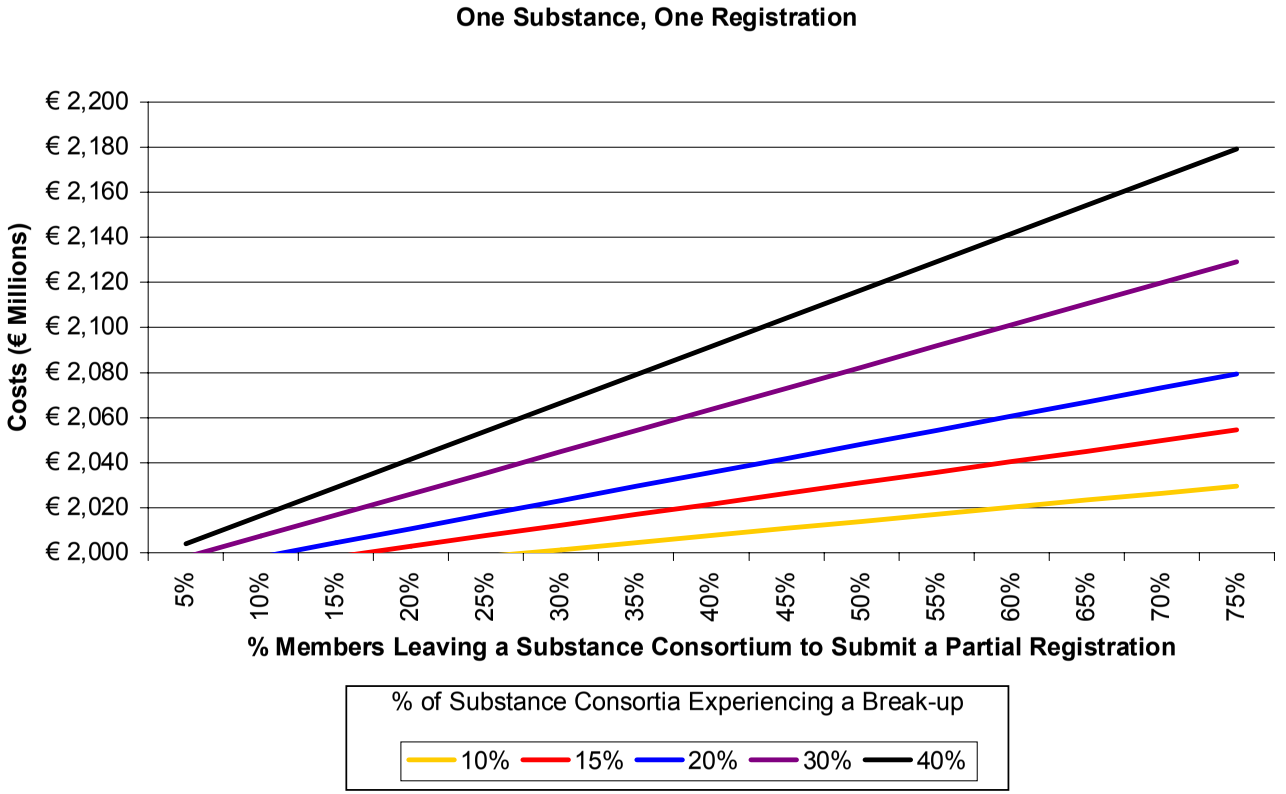


Figure A2.3: Total Costs Savings (€ Millions) under One Substance, One Registration

Savings Under One Substance, One Registration (€ Millions)
Total Costs of the Regulation

% Members Leaving	% of Consortia Experiencing a Break-up				
	10%	15%	20%	30%	40%
5%	€ 26.7	€ 39.9	€ 52.8	€ 78.4	€ 103.3
10%	€ 41.7	€ 62.3	€ 82.7	€ 123.0	€ 162.6
15%	€ 56.8	€ 84.8	**€ 112.7**	€ 167.7	€ 221.9
20%	€ 71.8	€ 107.3	€ 142.5	€ 212.2	€ 280.7
25%	€ 83.6	€ 125.0	€ 166.2	€ 247.6	€ 328.0
30%	€ 100.3	€ 149.8	€ 198.9	€ 295.9	€ 391.1
35%	€ 115.7	€ 172.8	€ 229.3	€ 340.8	€ 450.0
40%	€ 131.1	€ 195.7	€ 259.6	€ 385.4	€ 508.5
45%	€ 146.4	€ 218.5	€ 289.7	€ 429.7	€ 566.5
50%	€ 161.8	€ 241.2	€ 319.7	€ 473.8	€ 624.0
55%	€ 180.3	€ 268.8	€ 356.2	€ 527.5	€ 694.2
60%	€ 194.5	€ 289.8	€ 383.8	€ 567.8	€ 746.4
65%	€ 208.7	€ 310.7	€ 411.3	€ 607.8	€ 798.1
70%	€ 222.8	€ 331.6	€ 438.7	€ 647.5	€ 849.2
75%	€ 236.9	€ 352.4	€ 465.9	€ 686.9	€ 899.8

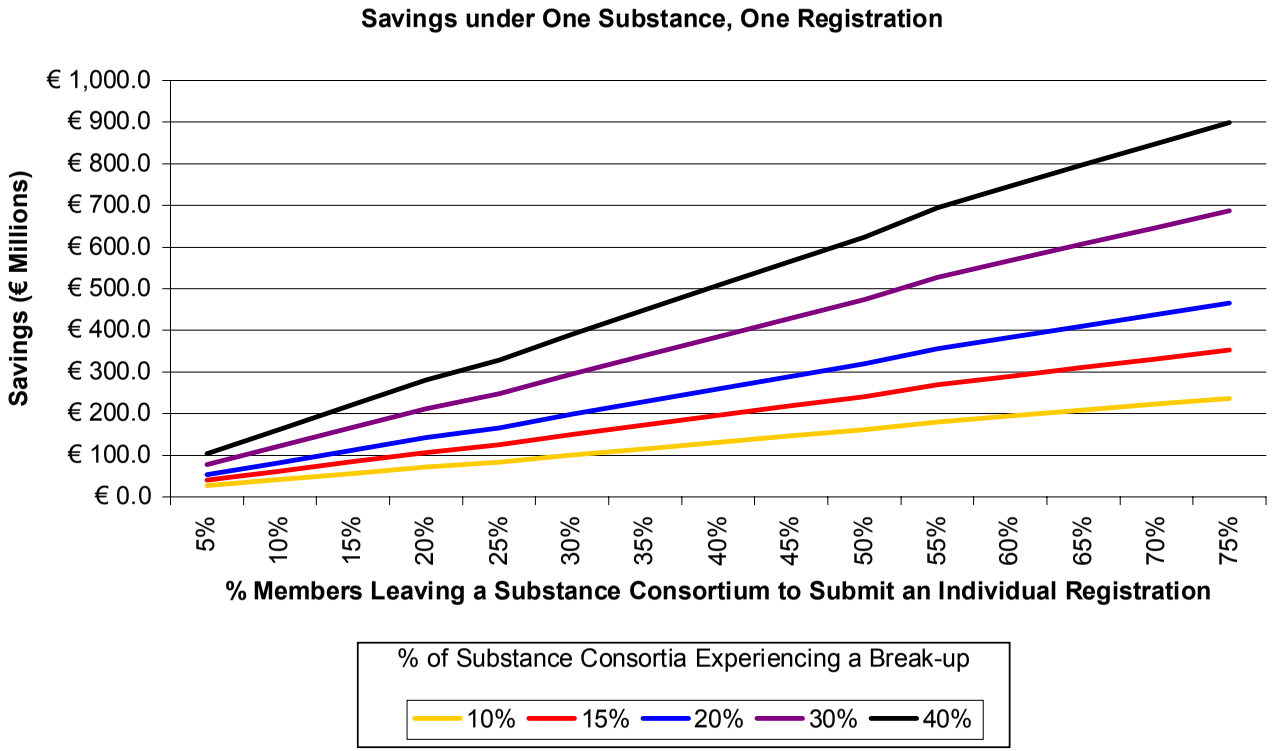


Figure A1.8: Total Cost Savings (%) under One Substance, One Registration

Savings Under One Substance, One Registration (%)
Total Costs of the Regulation

% Members Leaving	% of Consortia Experiencing a breakup				
	10%	15%	20%	30%	40%
5%	1.3%	2.0%	2.6%	3.8%	4.9%
10%	2.1%	3.0%	4.0%	5.8%	7.5%
15%	2.8%	4.1%	5.3%	7.7%	9.9%
20%	3.5%	5.1%	6.6%	9.5%	12.1%
25%	4.0%	5.9%	7.6%	10.8%	13.8%
30%	4.8%	6.9%	9.0%	12.6%	15.9%
35%	5.5%	7.9%	10.2%	14.2%	17.8%
40%	6.1%	8.8%	11.3%	15.7%	19.6%
45%	6.8%	9.7%	12.4%	17.2%	21.2%
50%	7.4%	10.6%	13.5%	18.5%	22.8%
55%	8.2%	11.7%	14.8%	20.1%	24.6%
60%	8.8%	12.4%	15.7%	21.3%	25.8%
65%	9.3%	13.2%	16.6%	22.4%	27.0%
70%	9.9%	13.9%	17.5%	23.4%	28.2%
75%	10.5%	14.6%	18.3%	24.4%	29.2%