Study to gather further information to be used in support of an Impact Assessment of potential options, in particular possible Amendments of REACH Annexes, to modify requirements for registration of low tonnage substances (1-10t/year) and the CSA/CSR Requirement for CMR substances in the framework of REACH

Main Report

Written by Anthony Footitt (Project Manager)

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Executive Summary

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1. Study Objectives

1.1 Overview

Prior to the adoption of REACH, information on the inherent hazardous properties of chemicals needed to manage them safely was not available or was incomplete for a significant percentage of the substances on European market. More than half of these substances (around 20,000) were estimated to be on the market at quantities of 1-10t per manufacturer or importer (MI) per year.

The REACH regulation sought to address these information deficits by requiring MIs to generate toxicological and ecotoxicological information on substances placed on the market in quantities of >1t per MI per year. In so doing, REACH aims to provide a high level of protection of human health and the environment, while at the same time enhancing the competitiveness and innovative capability of the EU industry.

In the light of the latter aim and the need to keep the economic and business impacts of the regulation proportional to the likely risks of chemicals, requirements under REACH were tailored according to tonnage band. To further reduce the burden on (particularly SME) MIs of lower volume (1-10t) substances Article 12 and Annex III of REACH sought to exclude a proportion of the 1-10t substances from requirements to provide toxicological and ecotoxicological information. This was achieved by defining '*priority substances*' on the basis of (Q)SARs or other evidence[1]. In addition, all 1-10t substances were excluded from the requirement to undertake Chemical Safety Assessment (CSA), provide a Chemical Safety Report (CSR) and supply extended Safety Data Sheets (eSDS) to downstream users.

Article 138 of REACH requires the Commission to undertake reviews of the requirements for 1-10t substances. On the basis of these reviews, it may present legislative proposals to modify the requirements for these substances. Here, Article 138 requires reviews of:

- the information that must be submitted in registration dossiers (Article 138(3)); and
- the extension of the obligation to perform a chemical safety assessment (CSA) and to document it in a chemical safety report (CSR) to 1-10 substances (Article 138(1).

Regarding the latter, Article 138(1) distinguishes between substances which meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A or 1B (where the review should be carried out by 1 June 2014) and all other substances (where the review should be carried out by 1 June 2019). This latter review (the extension of CSA/CSR to all substances due by June 2019) is yet to be started and all work to date (including this study) has focussed only on extending the CSA/CSR obligation to CMRs 1A/1B alone.

[1] '*Priority substances*' are "*substances for which it is predicted (i.e. by the application of (Q)SARs or other evidence) that they are likely to meet the criteria for"* classification as C, M or R 1A/1B or PBT/vPvB or any health or environmental hazard classes or differentiations under CLP and also have a dispersive or diffuse use.

Following on from an initial (2012) Phase 1 study it had completed for the Commission on these issues, RPA was commissioned (in December 2013) to provide technical assistance to the review of information requirements and the review of CSA/CSR requirements for CMRs 1A/1B as a Phase 2 study.

On the basis of the outputs from that Phase 2 study and internal discussions, the Commission selected five options for extending information requirements for further evaluation (hereafter referred to as information options). In addition to these five information options, the Commission wished to further examine the option to extend REACH CSA/CSR obligations (Article 14(1)) to all 1-10t substances known or expected to meet criteria for CMR 1A or 1B criteria for further evaluation alongside the information options.

Assessment of these options is the subject of this Phase 3 study and this report. Ultimately the information from this study may be used as part of the preparation of a Commission Impact Assessment (IA) and Public Consultation.

2. Overview of the options

2.1 Information options

2.1.1 Current information requirements for 1-10t substances

The aim of REACH as a whole is to achieve:

- a high level of protection of human health and environment;
- free movement of substances on their own, in mixtures, and in articles; while
- enhancing competitiveness and innovation.

A chief driver for the adoption of REACH was the situation that, prior to its adoption, information on the inherent properties needed to manage chemicals safely was not available for a significant percentage of the substances that have historically been placed on the European market (of which more than half – around 20,000 - are expected to be registered by June 2018 in the 1-10t band only).

One of the main ways by which REACH addresses these issues and achieves its aims is by requiring manufacturers and importers to generate data on the substances they manufacture or import and, on the basis of that information, making the appropriate classifications for and hazardous properties under Regulation (EC) No 1272/2008 (CLP).

Where hazardous properties are identified this is communicated to downstream users (DUs) by means of Safety data Sheets (SDS) and risk management requirements are triggered under parallel community regulation including:

- Worker health and safety regulation;
- Product safety requirements;
- Waste regulation; and
- Regulation that sets limit values and exposure limits.

For substances produced in quantities greater than 10 tonnes per year, environmental and human health exposure assessment, risk characterisation and identification of risk control measures for identified uses is carried out by manufacturers and importers (MIs) under a process of Chemical

Safety Assessment (CSA) under REACH, reported on in a Chemical Safety Report (CSR) and communicated to downstream users via an extended Safety Data Sheet (eSDS). The resulting exposure scenarios and eSDS facilitate/provide documentation necessary for compliance with the parallel regulatory instruments (identified above) triggered by classifications under CLP.

As the requirement to conduct a CSA does not currently apply to the 1-10t substances, risk management is achieved only via classification under CLP and the parallel regulation that is triggered by any classifications for hazardous properties (as in the first bullet above).

The obligation to undertake CSA/CSR is not the only requirement that differs by volume of production. The requirements for generation of information on substances under REACH are also tiered according to the volumes of manufacture or importation of a substance as follows:

- **For substances produced in quantities exceeding 10t per year:** the full physico-chemical, toxicological and ecotoxicological information set out in the appropriate Annexes (VII to X) must be provided (as defined in Article 12 of the Regulation); and
- **For substances produced at 1-10t per year**: all substances must provide the physicochemical information in Annex VII and for "priority substances" the toxicological and ecotoxicological information in Annex VII must be provided.

'*Priority substances*' are 1-10t substances that meet the criteria in Annex III of the Regulation. This identifies them as "*substances for which it is **predicted** (i.e. by the application of (Q)SARs or other evidence) that they are likely to meet the criteria for":*

- classification as C, M or R 1A/1B or PBT/vPvB; or
- any health or environmental hazard classes or differentiations under CLP **and also** have a dispersive or diffuse use.

2.1.2 Options for extending the number of substances required to provide information

The requirements of Article 12 and Annex III mean that, in practice, only a subset of the 1-10t substances are to be tested for toxicological and ecotoxicological endpoints under REACH. Accordingly, it will only be possible to identify the appropriate classifications under CLP for this sub-set of substances. The successfulness (or otherwise) of this strategy is highly dependent on the extent to which hazardous properties will/can be correctly "*predicted by the application of (Q)SARs or other evidence*". Here, substances with as yet unknown hazardous properties that are not correctly identified as priority 1-10t substances will not have to provide the Annex VII toxicological and ecotoxicological information (and hence their hazardous properties will not be identified, classified and associated risks will not be managed).

As no prediction by QSARs or other evidence is 100% accurate in its predictions, the Phase 2 study identified that an obvious option for extending/improving the information requirements is to extend the number of substances required to provide this information by making adjustments to the Annex III criteria. This led to the development of the following three 'Annex III' options:

- **Do nothing**- the baseline;
- **Remove the diffuse/dispersive use criterion in Annex III ('ND')** – which would result in all 1-10t substances identified by QSARs or other information to have any human health or environmental classification to provide toxicological and ecotoxicological information (as opposed to only those identified **and** having dispersive/diffuse uses); and
- **Remove all criteria in Annex III** – i.e. require all 1-10t substances to provide toxicological and ecotoxicological information.

2.1.3 Options for extending and refining the information required

Besides the option of extending the number of substances required to provide toxicological and ecotoxicological information there is also the option to refine the information that is required to be generated. The Phase 2 study provided a detailed examination of options for refining the toxicological and ecotoxicological information and focussed on the merits of including different human health and environmental endpoints from Annex VIII of REACH (which applies to >10t substances).

When selecting endpoints from Annex VIII, the overarching consideration was the opportunities that the additional information might provide for enhanced risk management given that, as described above, a CSA is currently not required for 1-10t substances and a number of the information requirements in Annex VIII are present specifically to provide the enhanced information required to perform a CSA.

As well as considering the merits of additional information from inclusion of Annex VIII endpoints, alterations to the use of information that already forms a part of Annex VII was considered. This applied only to information that must already be gathered and could, in principle, be used to screen for PBT/vPvB properties. As screening for PBT/vPvB properties is currently exclusively part of the CSA process (that, as noted, does not apply to 1-10t substances at present), there is the option to require screening as part of Annex VII.

The following options for extending information requirements based on the inclusion of selected Annex VIII endpoints were developed in Phase 2:

- **Annex VII (the baseline):** Current Annex VII toxicological and ecotoxicological information;
- **Annex VII+:** Current Annex VII toxicological and ecotoxicological information plus endpoints and requirements selected from Annex VIII to deliver additional classifications and information with the smallest possible likely increase in cost;
- **Annex VII++**: As Annex VII+ above but with the addition of certain key elements/changes from Annex VIII that may deliver further benefits in terms of identification of hazardous properties and substances with hazardous properties but would represent a more significant increase in costs.

2.1.4 Final information options

With three options for Annex III requirements and three options for information options, the total number of possible combinations is nine. One of these nine combinations (current Annex III requirements combined with current Annex VII requirements) comprises the baseline for the study and so is not an option in itself.

The Phase 2 study analysed five of the available eight options and, on the basis of the outputs of that study and internal discussions, the Commission has selected five information options for further evaluation in this Phase 3 study. Table 1 identifies these five options (A to E) as well as those options analysed in the Phase 2 study (the green highlighted boxes).

In terms of timing of these changes, where Phase 2 considered changes before the 2018 registration deadline, owing to the proximity of the deadline the Phase 3 study assumes that any changes to the information requirements established under the information options A to E would be made after 2018 and not before. As such, REACH registration dossiers submitted under the current requirements in 2018 would have to be revised or upgraded at a later date to comply with any new revised requirements.

Table 1: Final combinations of options for analysis in Phase 3			
Annex III Options	Information Options		
	Current Annex VII	Annex VII+	Annex VII++
Do nothing	Baseline	Option A	
Remove diffuse/dispersive use criterion (ND)		Option D	Option B
Remove all criteria		Option C	Option E

2.2 Option to extend the CSA/CSR requirement to 1-10t CMRs 1A/1B

2.2.1 Current requirements for 1-10t CMR 1A/1B Substances

As noted above, for all substances of all tonnage bands, where any hazardous properties are identified this is communicated to DUs by means of Safety Data Sheets (SDS) and risk management requirements are triggered under parallel community regulation. For substances identified with a classification for C, M, or R 1A/1B a variety of actions are triggered under a wider set of parallel community legislation than for other hazardous properties. The key requirements of each area is summarised in Box 1.

For CMR 1A/1B substances produced in quantities greater than 10 tonnes per year, environmental and human health exposure assessment, risk characterisation and identification of risk control measures for identified uses is carried out by MIs in a CSA and communicated to DUs via an extended SDS (eSDS). The resulting exposure scenarios and eSDS facilitate and/or provide the documentation necessary for compliance with the parallel legislation triggered by classifications under CLP.

For the 1-10t substances, however, no CSA is required at present and only general advice is provided in the Safety Data Sheet (SDS) supplied to DUs. To comply with obligations under the parallel legislation triggered by classification as CMR 1A/1B, MIs and DUs must rely on the general information presented in the SDS to complete their own in-house assessments of exposure and risk for their own operations.

Box 1: Overview of DU and MI requirements in relation to CMRs 1A/1B under parallel legislation

Worker health and safety regulation:

- **Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD) –** which requires employers (i.e. manufacturers and downstream users) to determine whether any hazardous chemical agents are present at the workplace and assess any risk to the safety and health of workers arising from the presence of those chemical agents;
- **Carcinogens and Mutagens Directive 2004/37/EC (CMD) –** which requires that, as a priority, workers' exposure must be prevented through substitution. If not possible, the employer shall use a closed technological system. Where a closed system is not technically possible, the employer shall reduce exposure to a minimum through a number of risk management measures specified in the Directive;
- **Pregnant and Breastfeeding Workers Directive 92/85/EEC –** which requires that the employer shall assess the nature, degree and duration of exposure, assess any risks to the safety or health and any possible effects on the pregnancy or breastfeeding of workers and then decide what measures should be taken; and
- **Directive 94/33/EC on Young Workers –** under which employers are obliged to assess the hazards to young people, generate new site-specific data on the nature, degree and duration of exposure to chemical agents and adopt the measures necessary to protect the safety and health of young people.

Compliance with product safety requirements:

- **Directive 2001/95/EC on General Product Safety (GPSD) -** under Article 3 of the GPSD producers are obliged to place only safe products on the market. Assessment of the risk to consumers from the presence of a CMR substance in a product would be required where this would include consideration of human exposure to the substance from use of the product;
- **Regulation No 305/2011 for the Marketing of Construction Products -** all manufacturers of construction products containing substances identified with C, M or R properties must consider the implications of this in terms of risk and safety of their products; and
- **Toys Directive 2009/48/EC -** Article 18 of the Toy Safety Directive requires manufacturers, before placing a toy on the market, to carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards.

Compliance with waste legislation:

- **Waste Framework Directive 2008/98/EC** this sets a definition of hazardous waste as waste that fulfils certain properties where these properties include carcinogenic, toxic for reproduction or mutagenic properties, where this would apply in relation to waste containing 1-10t substances classified as C, M or R 1A/1B. This requires the determination of safe and environmentally preferred waste management options.

2.2.2 Changes introduced by extending the CSA/CSR obligation

The option of extending the CSA/CSR obligation to 1-10t CMRs 1A/1B would require MIs of such substances to complete the process established under Article 14 of REACH and the detailed requirements set out in Annex I as summarised in Box 2. For the 1-10t substances with as yet unidentified mutagenic properties the CSA/CSR processes would provide compliance with other parallel regulation or greatly facilitate that compliance. The option effectively moves responsibilities from each DU to the MI(s) and is likely to benefit multiple downstream users of each substance by reducing/eliminating duplication of effort.

2.3 Integrated CSA/CSR and information options

Each option for extending the information requirements represents a different strategy for identifying hazardous substances in the 'pool' of 1-10t substances for which information is currently lacking and for which there is no existing classification. Different numbers of hazardous substances are identified under the different options (including the baseline) and this includes the identification

of substances for which there is little or no toxicological information at present to suggest classification for CMR 1A/1B.

As different numbers of 1-10t CMRs 1A/1B will be identified and registered under the different information options (between around 200 and 670 depending on the option, see Table 6-12 in Section 6.2.1) , the costs and benefits of the option of extending the CSA/CSR obligation to 1-10t CMRs 1A/1B will differ from one option to another.

Box 2: Overview of changes by extension of the CSA/CSR obligation

Complete chemical safety assessment (CSA):

1. **Human health hazard assessment:** to determine the classification of a substance and to derive levels of exposure to the substance above which humans should not be exposed;
2. **Human health hazard assessment of physicochemical properties:** to determine the classification of a substance in relation to, as a minimum, explosivity, flammability and oxidising potential;
3. **Environmental hazard assessment:** to determine the classification of a substance and to identify the Predicted No-Effect Concentration (PNEC);
4. **PBT and vPvB assessment:** to determine if the substance fulfils the criteria for PBT/vPvB (given in Annex XIII of REACH) and, if so, to characterise the potential emissions of the substance;
5. **Exposure assessment:** quantitative or qualitative estimation of the dose/concentration of the substance to which humans and the environment are or may be exposed. This considers all stages of the life-cycle of the substance resulting from its manufacture and identified uses and covers any exposures that may relate to the hazards identified in the above hazard and PBT/vPvB assessments;
6. **Risk characterisation:** for each exposure scenario, this step considers the human populations (exposed as workers, consumers or indirectly via the environment and if relevant a combination of those) and the environmental spheres for which exposure to the substance is known or reasonably foreseeable. Characterisation assumes that the risk management measures described in the exposure scenarios have been implemented. In addition, the overall environmental risk caused by the substance is reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

The Chemical Safety Report (CSR):

The CSR documents the CSA and also provides a summary of all the relevant information used in addressing each of the aspects of the CSA.

Extended Safety Data Sheet:

Where a CSA/CSR has been completed the following are added to the SDS to form an extended SDS (eSDS):

- SDS made consistent with the information in the CSA;
- results of the PBT/vPvB assessment must be reported; and
- the relevant exposure scenario(s) must be included in an annex to the SDS.

Given that the Commission may wish to implement both an extension of the CSA/CSR obligation to 1-10t CMRs 1A/1B and also one of the new information options, this Phase 3 study considers the costs and benefits of the CSA/CSR obligation in combination with the baseline and also in combination with the five information options A to E.

3. Approach to the analysis of options

3.1 Scoping impacts

It is the Commission's intention that the results of this Phase 3 study may ultimately be used as part of the preparation of a Commission Impact Assessment (IA) and Public Consultation. In accordance with the Commission *Impact Assessment Guidelines* and related operational guidance, the Phase 3 study has sought to:

- ***Identify all potential impacts of the options –*** specifying how the options would address the issues that need to be addressed and mapping out impacts (positive and negative) and the parties that would be affected;
- ***Select the significant impacts for deeper assessment*** – justifying selection taking account of expected magnitude, relevance and Commission objectives such as human health, environmental protection, competitiveness and innovation; and
- ***Assess the most significant impacts*** – where this should be quantitative and monetised wherever possible as well as qualitatively described.

Considering the changes brought about under the options, the following overall sets of impacts have been assessed in detail owing to their expected magnitude, relevance for different stakeholders, and importance for the Commission's objectives and policies (particularly in relation to health and environmental protection but also competitiveness, innovation and employment):

- ***Increases in compliance costs under REACH –*** for manufacturers and importers registering 1-10t substances (including 1-10t CMRs 1A/1B needing to produce a CSA/CSR) as well as downstream users of those substances;
- ***Human health and environmental impacts –*** owing to the identification of a greater number of substances with hazardous properties for classification under the information options, more complete information on those substances (permitting more effective/consistent risk management) and enhanced communication of risks and risk management measures in respect of CMRs 1A/1B by the production of CSAs/CSRs; and
- ***Reduced costs of compliance with legislation on worker's health and safety in respect of CMRs 1A/1B*** – where information provided in extended Safety Data Sheets (eSDS) communicated to downstream users satisfies or makes easier the production of risk assessments required under the regulatory instruments that are triggered by classification in accordance with Regulation (EC) No 1272/2008.

The specific impacts considered under each are discussed in detail in Section 3 of the main text and quantified in the subsequent sections.

3.2 Quantifying the impacts of information options

3.2.1 Quantifying compliance costs

The *Better Regulation Guidelines* identify that an assessment should be made of the significant impacts and that this should be quantitative where possible and also monetised where possible. As such, the objective for the assessment in Phase 3 has been to quantify all of the costs and benefits described above and, by consideration of the results, draw conclusions on the scale and significance of impacts of the information options on micro, small, medium and large enterprises, competitiveness, innovation and employment.

An Excel® based Monte Carlo model and simulation has been employed to analyse and explore the options and the baseline (current requirements) in terms of the following five key performance measures:

1. the number of substances with hazardous properties detected;
2. the usefulness of the information generated on these substances in the context of the regulation of risks and risk management;
3. the cost of registering/updating the 1-10t substances (including the generation of information);
4. the likely impact of registration costs at a company level considering that companies will be registering several substances (a portfolio) sometimes as part of a joint (consortium) registration and sometimes as an individual registration; and
5. considering the above, to the extent possible, the likely impacts on SMEs, competition and innovation.

As with previous ex-ante studies on REACH (such as the various Business Impact Assessments – BIAs and studies on REACH benefits), the model and analysis must make predictions on the outcomes based on the best available information of what the outcomes are likely to be (rather than what they certainly are). For those registrations yet to be completed (including the 1-10t substances), there is no certain knowledge on the outcome. It is this paucity of information that REACH itself seeks to address. For the benefit of transparency, all of the assumptions and numbers underlying the modelling and simulation are described in detail in the main text of the report and in the separate, detailed Technical Annex. All of the inputs to the Monte Carlo model and wider assessment have been supplied to (and agreed by) the Commission in advance to enable the analysis to be based on agreed sets of numerical inputs and assumptions.

In terms of the cost-benefit model itself, this has been developed under several different contracts with both DG GROW and DG ENV over a period now approaching 15 years. The Monte Carlo modelling approach was first integrated into the cost-benefit model in 2006 when RPA was engaged by DG GROW to provide Technical Assistance for REACH Impact Assessment Updates (ENTR/05/100) to inform COM's assessments of the impact of the final proposals for the detailed text of REACH. DG GROW used the Monte Carlo spreadsheet model to assist in the determination of the final text of the provisions. The model was resurrected in 2012 for the Phase 1 study for DG ENV, further developed in the 2014 Phase 2 study to enable consideration of a fresh range of options and to take account a number of cost aspects that were being identified by the first REACH review (2013) as being not sufficiently accounted for (such as the cost of letters of access). The model was subsequently employed in the 2015 DG GROW study Monitoring Impacts of REACH on Innovation, Competitiveness and SMEs where further refinements were made to estimate the costs of Registration 2018 before being re-deployed in this Phase 3 study.

3.2.2 Quantifying benefits

As well as providing information for the calculation of compliance costs, the inputs to the Monte Carlo model also provide matching information on the numbers of different types of hazardous substance detected under each option. This, in turn, provides a basis for estimating the benefits of each option in terms of the human health and environmental damages avoided.

The methods used to estimate the benefits are described in full in Section 7 of the main text and in the separate Technical Annex report. The general approach used is one of calculating disease cases/environmental damage avoided per substance identified with a different hazardous classification. Three scenarios are examined to cover different possibilities for average numbers of

uses of substances and average numbers of DUs. Monetary values are applied to these for each case of disease/environmental damage.

3.3 Quantifying the impacts of the CSA/CSR option for CMRs 1A/1B

The costs and benefits of extending the CSA have been quantified to the extent possible using a scenario based approach. Three scenarios have been developed to cover the costs of the various elements summarised in Box 2 as well as the numbers of uses of substances and the numbers of DUs (in common with the benefits approach above). In terms of human health and environmental benefits, though some benefits can be expected, it has not been possible to quantify these in monetary terms and benefits are expressed only in terms of the cost savings to DUs owing to the compliance that the CSA provides/facilitates under parallel legislation and associated requirements (described earlier).

4. Cost impacts under the information options

4.1 Overview

Owing to the fact that 1-10t substances must be registered by June 2018, any changes to the information requirements established under the information options A to E will be made after 2018. At the most basic level, the economic costs of the options comprise:

- The cost of revising and upgrading REACH registrations submitted under the current requirements to new requirements, Options A to E; and
- In cases where the cost of revising and upgrading registrations for certain substances is unsupportable on the grounds of financial cost (and/or its identified properties render it unsuitable for continued use), the cost of withdrawing those substances from the market.

Two major groups of operators will incur such costs under the Options: Manufacturers and Importers (MIs); and Downstream Users (DUs). The types of cost incurred by each are most conveniently considered in terms of:

- ***MI direct costs of upgrading/revising registrations*** – the costs of upgrading/revising registrations of substances will be incurred initially by the MIs who have registered those substances. A proportion of these costs will be absorbed by the MIs themselves and a proportion is expected to be passed down the supply chain (to downstream users – see next bullet) as, for example, an increase in product price;
- ***DU indirect costs of upgrading/revising registrations***: linked to the above, DUs will incur an increase in costs that is proportional to the cost of upgrading/revising registrations not absorbed by the MIs themselves;
- ***MI costs of withdrawal:*** where MIs decide that the cost of revising and upgrading a given registration is unsupportable (e.g. on the grounds of excessive cost) the substance would be withdrawn from the market. MIs will lose any profit that would otherwise have been made in the absence of changes to the Regulation examined under each of the options; and
- ***DU costs of withdrawal:*** where a substance is withdrawn from the market by MIs, DUs will incur costs associated with the need to reformulate or otherwise adjust their business to cope with the withdrawal.

The general approach used for the calculation of all of these costs begins with consideration of the raw data from the Monte Carlo simulation which provides information on the hypothetical cost of revising/updating all substances under each of the options (regardless of whether costs are

supportable financially or not). Substances beyond a certain cost threshold are then assumed to be withdrawn from market and, for the remainder, registration dossiers are revised/upgraded as required under each of the options. The approach is described in detail in Section 4.2.1.

4.2 Costs of Withdrawal

Table 2 provides the estimates of numbers of substances withdrawn under the information options, the number of MIs affected and the costs to MIs and DUs. The cost of withdrawing a substance from the market is associated with both the income foregone from manufacture or import (for MIs[2]) and the need to reformulate products (incurred by DUs). In both cases, the scale of costs is related to the commercial value of the product being withdrawn. In the absence of any better indication of this value, raw data on what the cost of revising/upgrading dossiers for a substance would have been (if it had been carried out) has been used. This method is discussed in more detail in Section 4.2.3.

4.2.1 Business impacts of withdrawal

Variation between companies of different sizes

In terms of variations in the scale of impacts between companies of different sizes (and the potential for disproportionately large impacts on SMEs), the data suggests that the larger the size of enterprise the more likely that one or more substances will be withdrawn from the market. This is simply because the larger the size of enterprise, the larger the portfolios of 1-10t substances and the higher probability that the costs of revising/upgrading dossiers of one (or more) substances in the portfolio will be too high to be justifiable financially (see Section 5.2.1).

Table 2: Costs and impacts of withdrawal under the information options

	Option				
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Number of substances withdrawn	0	187	956	1,132	2,525
Percentage of registered substances withdrawn	n/a	1%	5%	6%	13%
Number of MI Companies impacted by withdrawal	0	187	898	1,062	2,160
Percentage of MI companies impacted	n/a	2.2%	10.7%	12.7%	25.8%
Total costs to MIs (income foregone - € millions)	€ 0.0	€ 7.0	€ 44.2	€ 42.6	€ 112.6
Total costs to DUs (maximum reformulation cost - € millions)	€ 0.0	€ 14.0	€ 88.4	€ 85.2	€ 225.2

[2] Although an importer may find a substitute with lower registration requirements, hence no income would be foregone.

Number of companies experiencing different levels of product withdrawn

Whilst a significant majority of MIs will not experience any impacts from withdrawal under the options, the impacts on those MIs that do vary depending on the number of products that they withdraw. The data suggest that complete withdrawal of the entire portfolio of 1-10t substances is a rare outcome regardless of the option but, where it does occur, is most likely for those companies with smaller portfolios comprised of only a (very) few substances. As such, with smaller portfolios on average, SMEs are more likely to withdraw entire 1-10t substance portfolios but even here this is likely to be a rare outcome.

In relation to other levels of withdrawal, the following can be observed from the data:

- On average very few companies (0.1% to 2% of companies withdrawing depending on the option) are affected by significant (>60% of 1-10t substance production tonnage withdrawn) changes in overall tonnages produced;
- similarly, on average very few companies (0.1% to 2.4% of companies withdrawing depending on the option) are affected by significant changes in overall tonnages produced (40-60% of 1-10t substance production tonnage withdrawn); and
- a larger proportion (1.8% to 19.8% of mainly larger companies withdrawing depending on the option) on average are affected by moderately significant changes in overall tonnages produced (30-40% of 1-10t substance production tonnage withdrawn);
- for the vast majority of companies (75% to 98% of companies withdrawing one or more substances on average depending on the option), less than 30% of the current total tonnage of 1-10t substances produced would be withdrawn;
- owing to the smaller portfolios of SMEs (and hence total production volume) withdrawal of a substance has a greater impact on SME MIs withdrawing substances than those of larger companies At the same time, the data on the number and percentage of companies affected indicates that larger companies are more likely to be impacted by withdrawal than SMEs.

Annual Income foregone owing to withdrawal – MIs

In terms of the financial impact of withdrawal on these companies, Table 3 provides the total annual income foregone by all companies experiencing withdrawal and the average annual income foregone per company.

Table 3: Annual Income foregone owing to withdrawal

	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Total number of companies withdrawing one or more substances	0	187	898	1,062	2,160
Percentage of total companies	n/a	2.2%	10.7%	12.7%	25.8%
Total annual income foregone (annually for five years - € million)	n/a	€ 1.40	€ 8.84	€ 8.52	€ 22.52
Income foregone per company (annually for five years - € thousand)	n/a	€ 7.50	€ 9.84	€ 8.03	€ 10.42

In terms of variations in the scale of cost impacts between companies of different sizes (and the potential for disproportionate impacts on smaller companies), under all of the options the income forgone owing to withdrawal is similar across companies of all sizes and, if anything, slightly higher for larger enterprises suggesting that effects measured in terms of income foregone are not obviously disproportionate. That said, any income losses are likely to be much more easily absorbed by larger companies (so while impacts might not be obviously disproportionate, they may not be proportionate either).

4.3 Costs of upgrading/revising registrations

The registration dossiers of those substances that are not withdrawn under the options are assumed to be revised/upgraded. It is important to note that, owing to the Annex III criteria (and variations of them that are considered in Options B to E) a number of substances do not need to upgrade/revise registration dossiers and incur no costs. This varies from one option to another depending on the Annex III option considered.

Table 4 provides the numbers of substances experiencing no change in costs under the options and those experiencing costs of withdrawal versus costs of upgrading/updating dossiers. The table also provides the total cost of revising and upgrading dossiers and averages per substance and per tonne.

Table 4: Number of substances incurring costs by type and costs under the options

	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Number of substances registered in 2018 (accounting for withdrawal under the baseline)	19,600	19,600	19,600	19,600	19,600
Number of substances where there are costs	7,777	10,438	10,438	19,600	19,600
- of which costs of withdrawal	0	187	956	1,132	2,525
- of which revision/update of dossier	7,777	10,251	9,482	18,468	17,075
Number of substances where no costs under options	11,823	9,162	9,162	0	0
Total costs across all substances (€ millions)	**€ 24.1**	**€ 93.4**	**€ 398.7**	**€ 366.6**	**€ 892.4**
Average cost of upgrading/revising registrations per substance (€)	€ 1,228	€ 4,814	€ 21,382	€ 19,851	€ 52,263
Average cost of substance registration per tonne (€)	€ 58	€ 228	€ 991	€ 915	€ 2,308

4.3.1 Costs to MIs versus DUs

Whilst initially borne by the registering MIs, a proportion of the total costs in Table 4 is expected to be passed on to Downstream Users (DUs) in the form of, for example, increased prices. In the absence of exact information, it is assumed that, across all options, MIs pass half of the registration costs on to Downstream Users (DUs) in increased prices. As such, half of the costs in Table 4 will be absorbed by MIs and half will be passed on to DUs to give the total costs in Table 5.

Table 5: Total costs of upgrading/revising registrations					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
MI costs (revising/upgrading dossiers) (€ millions)	€ 12.0	€ 46.7	€ 199.3	€ 183.3	€ 446.2
DU costs (increased prices) (€ millions)	€ 12.0	€ 46.7	€ 199.3	€ 183.3	€ 446.2

4.3.2 Impact of revising and upgrading dossiers on manufacturers and importers (MIs)

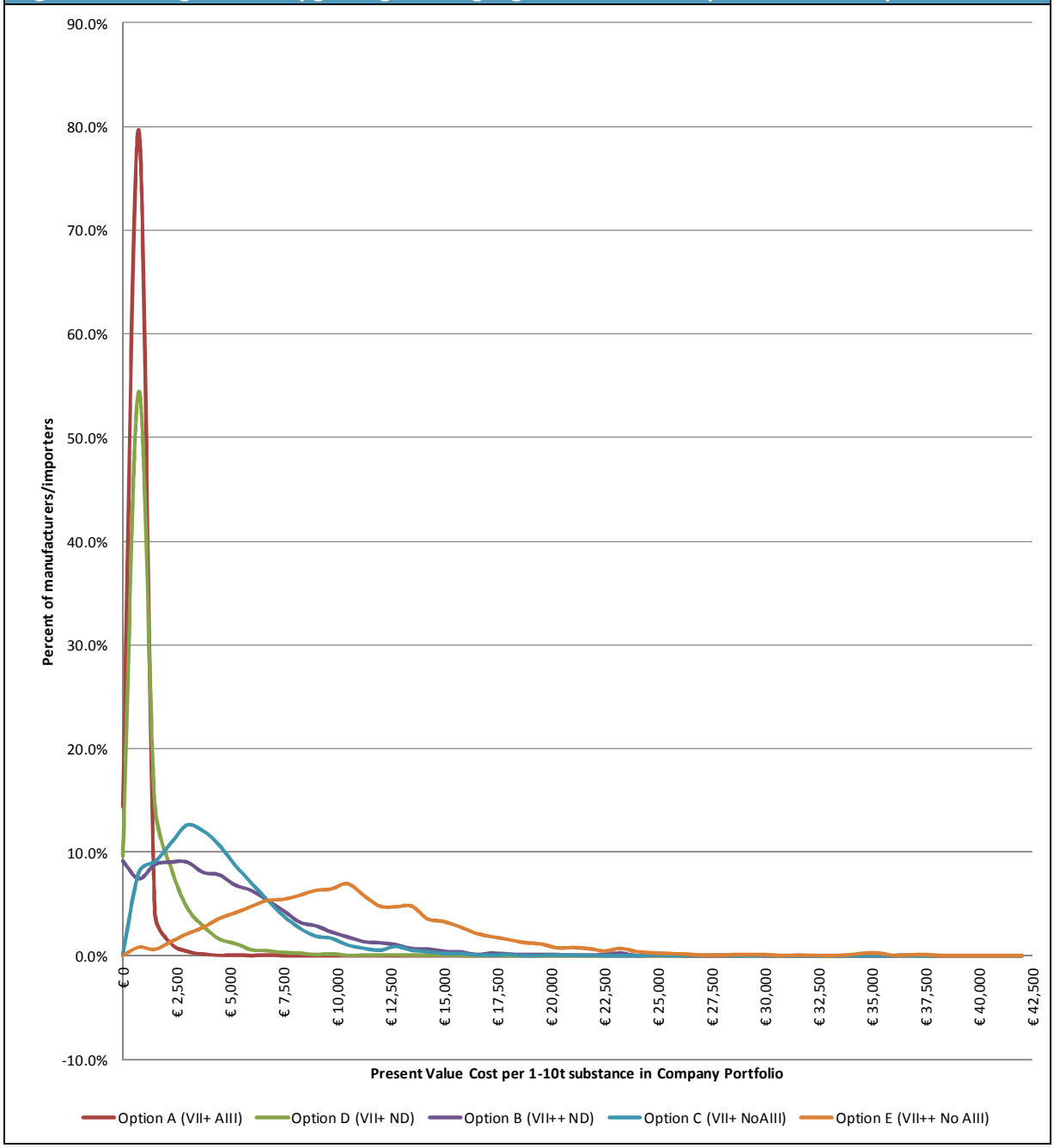
Table 6 provides the average cost of dossier revision/upgrade for companies. These costs are averaged out across all of the substances in the portfolios of each of the companies registering in the simulation and so provide information on the magnitude of costs absorbed for every substance registered. These costs are also provided per tonne of substance produced (over a five year period – so 10t of annual production = 50t total in the period).

A more detailed breakdown of the data by company size suggests that costs per substance (and per tonne of substance) vary only slightly between the micro, small and medium enterprises but are generally slightly lower for the micro and small SMEs.

Table 6: Average costs of updating/revising substance registration for MI companies					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Average cost of registering a substance (across all substances in company portfolios)	€ 266	€ 1,035	€ 4,492	€ 4,147	€ 10,427
Average cost of registering a substance per tonne of produced (across all substances in company portfolios)	€ 6	€ 23	€ 99	€ 92	€ 231

As with any averages, those provided in Table 6 above conceal a variation in costs from one company to another. Figure 1 provides average per company costs per substance and the frequency distribution of different magnitudes of costs faced by companies under the different options.

Figure 1: Average cost of upgrading/revising registrations for MIs per substance in portfolio



4.4 Cost of the option to require a CSA/CSR for CMRs 1A/1B

The costs of the option of extending REACH CSA/CSR obligations (Article 14(1)) to all 1-10t substances known or expected to meet criteria for CMR 1A/1B has been considered in combination with the baseline (as a CSA/CSR option alone) and also in combination with each of the other Information Options A to E.

Costs under the CSA/CSR option can be divided up into:

- Cost of completing the CSA/CSR requirements (summarised earlier in Box 2) for MIs of known and previously unknown CMRs 1A/1B substances;
- Costs to DUs from the duties to: pass information sufficient for an Exposure Assessment up the supply chain and under Article 37(4) to prepare a CSR in Accordance with Annex XII; and
- Offsetting the above costs, the cost savings delivered through reduced costs of compliance with requirements under parallel regulation (summarised earlier in Box 1).

To capture a range of possibilities and uncertainties concerning numbers of downstream uses of a substance for the CSA, numbers of DUs as well as other factors, a low/medium/high scenario approach has been applied to the cost of the individual elements. The estimation and analysis of costs under all three scenarios is described in Section 6. This summary provides an overview of the results under the medium scenario alone.

4.4.1 Costs of CSA/CSR obligation to MIs under the baseline and under each information option

Under REACH, all known CMRs 1A/1B were to be registered by 2010. To date 56 known CMRs 1A/1B have already been registered in the 1-10t band. As well as for known CMRs 1A/1B, the extension of the CSA/CSR obligation would require a CSA/CSR to be completed for as yet unidentified CMRs 1A/1B. Owing to the different information requirements applied under each option and the baseline, different numbers of substances are expected to be newly identified with CMR 1A/1B properties.

Table 7 provides the estimates of the numbers of CMRs identified under each information option and under the baseline. The table also provides estimates of the costs of CSA/CSR to MIs under the medium scenario. These costs are divided into those associated with:

- the withdrawal of substances – where the costs of CSA/CSR (and, for information options A to E, any additional costs of revising/upgrading information in dossiers for these substances) are too high to be commercially sustainable, the substance is assumed withdrawn and costs are calculated in the same way as for other parts of the analysis; and
- costs of completing the CSA/CSR for CMR 1A/1B substances that are not withdrawn from the market.

Note that in the table, costs for completing a CSA/CSR do not include the additional information elements and associated costs for the information options A to E. These are considered the total costs in later sections.

Table 7: Costs of CSA/CSR for CMRs 1A/1B to MIs						
Updating CMRs	**Baseline (Annex VII and Current Annex III)**	**Option A (Annex VII+ and Current Annex III)**	**Option D (Annex VII+ and Annex III with ND)**	**Option B (Annex VII++ and Annex III with ND)**	**Option C (Annex VII+ and No Annex III)**	**Option E (Annex VII++ and No Annex III)**
Known CMRs 1A/1B	56					
Newly identified CMRs	209	209	243	426	385	674
Cost of withdrawal to MIs under the CSA/CSR option (medium scenario)						
Newly identified CMRs withdrawn	0	0	3	13	41	86
MI costs of withdrawal (income foregone - € millions)	€ 0	€ 0	€ 0.1	€ 0.5	€ 1.8	€ 3.1
Average cost of withdrawal (income foregone per MI - €s)	€ 0	€ 0	€ 42,671	€ 35,572	€ 43,443	€ 35,486
Cost of undertaking CSA and associated obligations on newly identified CMRs 1A/1B (medium scenario)						
Newly identified CMRs undertaking CSA	209	209	240	373	344	497
MI cost of CSA (€ millions)	€ 2.1	€ 2.0	€ 2.3	€ 3.9	€ 3.3	€ 5.2
Average cost of CSA per MI (€s)	€ 4,307	€ 4,098	€ 4,183	€ 4,324	€ 4,081	€ 3,892

4.4.2 Costs of CSA/CSR to DUs

As with costs to MIs, the costs of the CSA obligation to DUs are associated with the costs of withdrawal of a substance (and, in the case of DUs, the need to reformulate products) and the costs of engaging with MIs on the CSA. These costs are summarised in Table 8 for the medium scenario alongside matching estimated cost savings in compliance costs.

Table 8: Costs of CSA/CSR obligation to DUs and compliance costs avoided under parallel legislation - medium scenario						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Costs of withdrawal (reformulation) to DUs and compliance costs avoided under parallel legislation						
Newly identified CMRs withdrawn	0	0	3	13	41	86
DU reformulation costs (€ millions)	€ 0	€ 0	€ 0.3	€ 0.9	€ 3.6	€ 6.2
DU compliance costs avoided owing to withdrawal (€ millions)	€ 0.0	€ 0.0	€ 0.5	€ 2.0	€ 6.2	€ 12.9
DU cost of engaging in CSA						
Newly identified CMRs undertaking CSA	209	209	240	373	344	497
DU cost of engaging in CSA (€ millions)	€ 8.8	€ 8.8	€ 10.1	€ 15.7	€ 14.5	€ 20.9
DU compliance costs avoided (€ millions)	€ 31.4	€ 31.4	€ 36.0	€ 56.0	€ 51.6	€ 74.6
Total costs of CSA option to DUs, compliance costs avoided and net costs						
DU costs of CSA for 56 existing CMRs (€ millions)	€ 2.4	€ 2.4	€ 2.4	€ 2.4	€ 2.4	€ 2.4
DU costs of CSA for newly identified CMRs (€ millions)	€ 8.8	€ 8.8	€ 10.4	€ 16.6	€ 18.1	€ 27.1
DU compliance costs avoided (€ millions)	€ 31.4	€ 31.4	€ 36.5	€ 57.9	€ 57.8	€ 87.5
Net cost to DUs	**-€ 20.2**	**-€ 20.2**	**-€ 23.7**	**-€ 38.9**	**-€ 37.3**	**-€ 58.0**

4.5 Total costs of the CSA/CSR option in isolation and in combination with information options

The total costs for MIs and DUs under the information options (and baseline) are presented in Table 9 for the medium scenario. Two sets of estimates are provided, one reflecting the situation where there is no CSA/CSR obligation (as now) and the situation where the CSA/CSR obligation is extended to CMRs 1A/1B. As can be seen from the table, under the baseline (current information requirements) the cost of the CSA/CSR option is negative for the medium scenario. In other words, in the absence of changes to information requirements, there is a net benefit from extending the CSA/CSR obligation to CMRs 1A/1B which is associated with compliance cost savings to DUs for compliance with parallel legislation. The analysis found the same was likely to be true under the low and high scenarios.

Table 9: Total cost of information option in isolation and in combination with CSA option - Medium scenario (€ millions)						
	Baseline (Annex VII and Current Annex III)	**Option A (Annex VII+ and Current Annex III)**	**Option D (Annex VII+ and Annex III with ND)**	**Option B (Annex VII++ and Annex III with ND)**	**Option C (Annex VII+ and No Annex III)**	**Option E (Annex VII++ and No Annex III)**
No CSA/CSR Obligation						
Total costs of revising/upgrading dossiers (MIs and DUs)	€ 0.0	€ 24.1	€ 93.4	€ 398.7	€ 366.6	€ 892.4
MI costs of withdrawal	€ 0.0	€ 0.0	€ 7.0	€ 44.2	€ 42.6	€ 112.6
DU costs of Withdrawal	€ 0.0	€ 0.0	€ 14.0	€ 88.4	€ 85.2	€ 225.2
Total REACH	**€ 0.0**	**€ 24.1**	**€ 114.5**	**€ 531.2**	**€ 494.5**	**€ 1,230.1**
DU cost of complying with parallel regulation on CMRs	€ 31.4	€ 31.4	€ 36.5	€ 57.9	€ 57.8	€ 87.5
Total cost of compliance with legislation	**€ 31.4**	**€ 55.4**	**€ 150.9**	**€ 589.1**	**€ 552.2**	**€ 1,317.6**
With CSA/CSR Obligation						
Total costs of revising/upgrading dossiers (MIs and DUs) and completing CSA/CSR (MIs)	€ 2.5	€ 26.5	€ 95.9	€ 402.0	€ 367.4	€ 891.8
MI costs of withdrawal	€ 0.0	€ 0.0	€ 7.14	€ 44.65	€ 44.36	€ 115.67
DU costs of withdrawal	€ 0.0	€ 0.0	€ 14.3	€ 89.3	€ 88.8	€ 231.3
DU costs of CSA	€ 11.2	€ 11.2	€ 12.5	€ 18.1	€ 16.9	€ 23.3
DU cost of complying with parallel regulation on CMRs	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Total cost of compliance with legislation	**€ 13.7**	**€ 37.6**	**€ 129.8**	**€ 554.0**	**€ 517.5**	**€ 1,262.1**
Cost relative to baseline	**-€ 17.7**	**€ 6.3**	**€ 98.5**	**€ 522.7**	**€ 486.1**	**€ 1,230.8**

5. Benefits under the information and CSA/CSR options

5.1 Benefits that have been quantified

One of the main aims of REACH is to achieve a high level of protection of human health and environment. This is achieved in part by requiring manufacturers and importers to generate data on the substances and, on the basis of that information, making the appropriate classifications for hazardous properties under Regulation (EC) No 1272/2008 (CLP). Where hazardous properties are identified this is communicated to downstream users (DUs) by means of Safety Data Sheets (SDS) and risk management requirements are triggered under parallel community regulation.

The five alternative options for information requirements for 1-10t substances considered in this study aim to extend the numbers of substances required to generate information and/or the nature of the information generated and so identify a greater number of substances with the following hazardous properties:

- Mutagenicity (and via this route, genotoxic carcinogens)[3];
- Dermal, inhalation and/or oral toxicity;
- Aquatic toxicity; and
- Persistence, bioaccumulation and toxicity.

In addition, the options also provide more useful information on substances and their hazardous properties, specifically:

- better information on dermal/inhalation exposure limits for the substances with the relevant classifications;
- identification of substances with properties meeting classification for Single Target Organ Toxicity – repeated exposure (STOT RE 1 or 2); and
- sufficient information to derive a Predicted No Effect Concentration (PNEC) for substances meeting classification for aquatic toxicity and so provide a more robust basis for pollution prevention.

When combined, all of these changes are expected to produce impacts on:

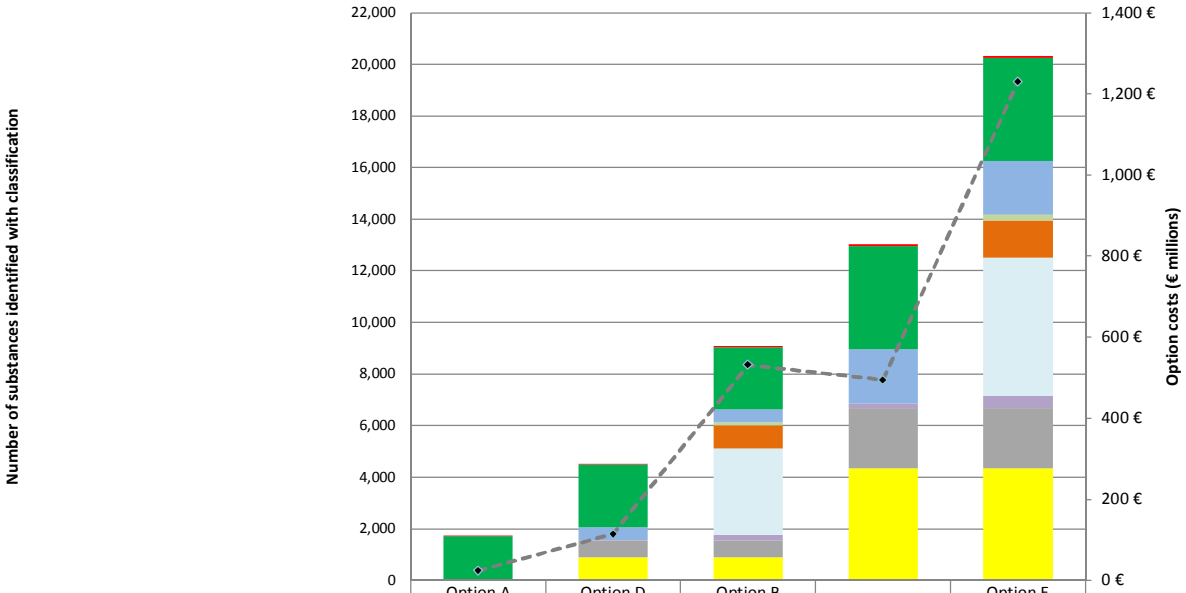
- the incidence of diseases, disorders and impacts (occupational and wider public) associated with each of the classifications for hazardous properties; and
- environmental pollution and impacts on the ecological status of the environment.

Figure 2 provides a plot and a table of the number of additional substance classifications that modelling suggests would be identified under these alternative options. All of the substance classifications in the figure are additional to those identified under the baseline (current requirements) and, as such, can be regarded as hazardous substance classifications that are missed (not detected) under the current requirements.

[3] Note that no testing for carcinogenicity or reproductive toxicity is required in Annex VII of REACH or under any of the options. Thus non-genotoxic carcinogens or reproductive toxins will not be identified for any 1-10t substances.

As can be seen from the figure, the analysis suggests that a large number of hazardous substance classifications not detected under the baseline (current requirements) would be identified under these alternative options. The more extensive the alternative information option in terms of level of information required and substances considered, the more hazardous property classifications are identified (and the greater the cost to MIs and DUs).

Figure 2: Additional hazardous substance classifications identified under options and associated costs



	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
PBTs/vPvB substances	30	34	34	74	74
Substances classified for acute aquatic toxicity with enough information for PNECs	1,709	2,411	2,411	4,005	4,005
Substances classified for acute aquatic toxicity	0	495	495	2,089	2,089
Substances that would have classification for STOT RE 1 or 2	0	0	131	0	210
Substances with long-term toxicity information	0	0	903	0	1,446
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	0	0	3,344	0	5,356
CM(R) 1A/1B	0	34	217	176	465
Substances classified for skin sensitisation	0	640	640	2,351	2,351
Substances classified for skin/eye damage and irritation	0	899	899	4,330	4,330
Option costs (without CSA - € millions)	€ 24.1	€ 114.5	€ 531.2	€ 494.5	€ 1,230.1

As described in full in Section 7 of the main text and in the separate Technical Annex report, the monetary value of identifying additional substances with hazardous classifications has been estimated in terms of the number of disease cases/environmental damage avoided. Three scenarios have been examined to cover different possibilities for average numbers of uses of substances and average numbers of DUs. To these have been applied monetary values for each case of disease/environmental damage. Estimates of the benefits of the information options for the medium scenario are provided in Table 10 and suggest present value (PV) benefits of €33,460 million to €128,491 million depending on the option.

Table 10: Estimated damage cost avoided by the identification of a substance with the corresponding classification – Medium Scenario					
Damage Metrics: representative outcomes	Damage costs avoided (€ millions)				
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Annual damage costs avoided					
Substances classified for skin/eye damage and irritation: Cases of mild acute dermatitis	€ 0.0	€ 37.7	€ 37.7	€ 181.6	€ 181.6
Substances classified for skin sensitisation: Cases of severe chronic dermatitis	€ 0.0	€ 7.4	€ 7.4	€ 27.1	€ 27.1
Substances with better information on exposure limits for oral and dermal/inhalation toxicity: 'Poisoning events'	€ 0.0	€ 0.0	€ 603.5	€ 0.0	€ 966.6
Substances with long-term toxicity information: Cases of kidney disease of short-term duration	€ 0.0	€ 0.0	€ 20.8	€ 0.0	€ 33.3
Substances that would have classification for STOT RE 1 or 2: Cases of chronic kidney disease of longer-term duration	€ 0.0	€ 0.0	€ 109.1	€ 0.0	€ 175.0
Substances classified for acute aquatic toxicity: Improvement of WFD water body status	€ 225.4	€ 318.0	€ 318.0	€ 528.3	€ 528.3
PBTs/vPvBs: WTP to eliminate emissions of PBTs	€ 2,133.7	€ 2,412.9	€ 2,412.9	€ 5,204.6	€ 5,204.6
Non cancer human health damage costs avoided (Benefits) - € millions per year	€ 0.0	€ 45.1	€ 778.5	€ 208.7	€ 1,383.5
Environmental damage costs avoided (Benefits) - € millions per year	€ 2,359.1	€ 2,730.9	€ 2,730.9	€ 5,732.9	€ 5,732.9
Present Values Over 40 year Period (@4% discount rate)					
CMRs 1A/1B: PV cancers avoided over 40 years	€ 0.0	€ 1,688.4	€ 10,776.2	€ 8,740.1	€ 23,091.8
Total PV non-cancer human health damage costs avoided over the benefit period (between 2022 and 2061 inclusive) - € millions total	€ 0.0	€ 13,553.4	€ 3,632.9	€ 784.7	€ 24,086.8
Total PV environmental damage costs avoided over the benefit period (between 2026 and 2061 inclusive) - € millions total	€ 33,460.5	€ 38,733.5	€ 38,733.5	€ 81,312.4	€ 81,312.4
Total Present Value (PV) Benefits (discounted at 4%)	**€ 33,460.5**	**€ 53,975.3**	**€ 53,142.7**	**€ 90,837.3**	**€ 128,491.1**

5.2 Benefits that have not been quantified

A number of benefits could not be adequately/meaningfully assessed in monetary or other terms. These mainly relate to benefits of the CSA/CSR option (as opposed to the information options). These unquantified benefits can be summarised as follows:

- ***Implementation of consistent and adequate risk management measures in relation to worker exposure via CSA/CSR*** - Under the current regulatory regime, each individual MI and DU is required to assess their own situation individually. In the course of duplicating effort in this way, and with the more limited information available to conduct assessments, the result may be the implementation of a range of different risk management measures by different users. Some of these may provide adequate control and some may not. The current regulatory regime does not provide a means of establishing this either way.
- ***Under the CSA/CSR option 1-10t CMR 1A/1B substances also registered at >10t would also be required to communicate information in the supply chain -*** at present there is no requirement for MIs registering at 1-10t to provide an eSDS to downstream users including the relevant exposure scenarios for those uses. Thus, at present, there is a risk that information supplied to downstream users may differ depending on whether the supplier manufactures or imports the substance in quantities of 1-10t or >10t per year. Extending the CSA/CSR obligation to 1-10t CMRs 1A/1B would result in the communication of consistent and robust risk management information to all DUs regardless of the volumes imported or produced by the registrants.
- ***Adequate risk management measures in relation to articles -*** if the CSA/CSR obligation were to be extended to 1-10t substances, the use of a substance in an article at >1t per year would have to be included in the CSA/CSR. This would identify consistent and robust recommended risk management measures where these can be identified or, where the use cannot be supported '*for reasons of protection of human health or the environment*' ECHA will be alerted of this fact and action concerning these articles on the market or to be put onto the market can be implemented. This is not possible under current regulation where the safety of the article is only a consideration under general product safety regulations (or specific product regulations where they are applicable to the article and its use).
- ***Control of environmental risks under the baseline -*** Extending the CSA obligation to 1-10t CMRs 1A/1B would require consideration of environmental exposure, its likely effects, and appropriate risk management for identified uses. Under the current requirements this would not otherwise be considered for these substances other than when action was identified as being required by Member States or the Commission under community regulation.
- ***Benefits for Member States and the Commission -*** Extending the CSA/CSR obligation to 1-10t CMRs 1A/1B and the subsequent consistent documentation of appropriate risk management measures for the concerned substances would simplify and improve the control on safe handling of substances in the workplace under all applicable regulation enforced by all relevant authorities. It would also facilitate the identification of cases for which the Commission or Member States could consider that the manufacture, placing on the market or use of a substance, on its own, in a mixture or in an article poses a risk to human health and for which a restriction procedure could be initiated. In addition, the extended CSA/CSR obligation would further ensure the generation of robust study summaries on selected human and environmental health endpoints. Currently these robust study summaries must be generated by Member States during the development of a harmonised classification and not by manufacturers and importers (as they would were the CSA obligation to be extended).

6. Conclusions

6.1 Information options

This Phase 3 study has examined five alternative options for information requirements for 1-10t substances each of which extends the numbers of substances required to generate information and/or the nature of the information generated. As identified earlier in Figure 2, the analysis presented in this report suggests that a large number of hazardous substance classifications not detected under the baseline (current requirements) would be identified under these alternative options. The more extensive the alternative information option in terms of level of information required and substances considered, the more hazardous property classifications are identified and the greater the human health and environmental benefit and the cost to MIs and DUs. This is apparent from the summary of additional costs and benefits for the medium scenario in Table 11.

REACH aims to "*ensure a high level of protection of human health and the environment*"[4]. Where in 2003 and 2006 (when the text of REACH was being finalised) it was difficult to predict how many substances would be identified with different hazardous properties, new statistical information on the hazardous properties of substances fully registered in 2010/13 makes such prediction more robust and more detailed (in terms of the number of endpoints).

Table 11: Additional costs and benefits of information options (medium scenario - € millions)

	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Increase in costs with information options (without CSA) relative to baseline	€ 24.1	€ 114	€ 531	€ 494	€ 1,230
Total additional health and environmental benefits (€ million)	€ 33,461	€ 53,975	€ 53,143	€ 90,837	€ 128,491

Using the same scenario based approaches to monetary valuation of damage costs applied to the options it is also possible to calculate the accompanying estimates of:

- the human health and environmental damage costs that would result if there were no requirements at all for 1-10t substances (as a PV over 40 years);
- the human health and environmental damage costs avoided under the baseline (current requirements) as a PV over 40 years;
- the percentage of total damage costs avoided under the baseline (current requirements); and
- the damage costs remaining after 2018 as a PV over 40 years.

These are provided in Table 12 for the medium scenario. As can be seen from these data, under the medium scenario it is estimated that the current requirements will reduce human health and environmental damage costs by 10%.

[4] Article 1 (1) of REACH

Table 12: Estimated total human health and environmental damage costs (€ millions) - medium scenario	
	Baseline (Annex VII and Current Annex III)
Damage costs in the absence of any REACH requirements on 1-10t substances	€ 145,784.3
Damage costs avoided under current requirements (the baseline)	€ 14,015.7
Percentage of total damage costs avoided under current requirements	10%
Remaining damage costs after 2018	€ 131,768.6

Table 13 provides accompanying estimates of the impact of each option on total damage costs and also the damage costs remaining after 2018. As is clear from these data, whilst REACH does not define what a "high level of protection of human health and the environment"[5] constitutes in numerical terms, as the current requirements may only address around 10% of the human health and environmental damage costs it is difficult to conclude that REACH will offer a high level of protection in the case of the 1-10t substances. All of the alternative options offer higher levels of protection than the current requirements but it is only the more demanding, higher cost options that appear to offer what a might be more commonly understood as a 'high level of protection'.

Table 13: Percentage impact of options on damage costs (medium scenario)						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Percentage impact on total estimated damage costs (in the absence of REACH requirements)	10%	33%	47%	46%	72%	98%
Percentage impact on damage costs remaining after registration 2018	n/a	25%	41%	40%	69%	98%
Rank level of protection	n/a	5	3	4	2	1

6.3 The CSA/CSR option in combination with the baseline and the information options

This Phase 3 study has also considered the option of extending CSA/CSR requirements to substances known or newly identified as CMR 1A/1B. As noted earlier, while there are costs to DUs for a number of elements associated with CSA/CSR there is a net saving for DUs when this is compared with the costs of complying with current requirements under parallel product and worker health and safety regulation. The CSAs/CSRs provided under this option would provide compliance with this parallel regulation or greatly facilitate that compliance. Moving responsibilities from the DUs to the MIs in this way is likely to benefit multiple downstream users of each substance and reduce duplication of efforts significantly.

[5] Article 1 (1) of REACH

The costs and benefits of the CSA/CSR option have been assessed for both application to the current information requirements (the baseline) and also for each information option. Table 14 provides the costs of the information options with and without the addition of CSA/CSR requirements for CMRs 1A/1B and estimates of the human health and environmental damage costs avoided (i.e. benefits). As can be seen from the table, for almost all information options, costs are reduced by combination with CSA/CSR for CMRs 1A/1B owing to the aforementioned reduction in the costs of compliance with requirements under parallel legislation. Regardless of scenario or option, human health and environmental benefits are estimated to be (significantly) larger than the costs.

Table 14: Additional costs and benefits of information options (medium scenario - € millions)						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Increase in costs with information options (without CSA) relative to baseline	€ 0.0	€ 24.1	€ 114	€ 531	€ 494	€ 1,230
Increase in costs with information options (with CSA) relative to baseline	-€ 17.7	€ 6.3	€ 98.5	€ 523	€ 486	€ 1,231
Total additional health and environmental benefits (€ million)	€ 0.0	€ 33,461	€ 53,975	€ 53,143	€ 90,837	€ 128,491

6.3.1 Cost-effectiveness and benefit cost ratios

Table 15 provides summary information on the cost-effectiveness of each of the options (in isolation and in combination with the CSA/CSR option), benefit-cost ratios for the same and the rank order of options in terms of performance based on these criteria. Cost-effectiveness here expresses the cost (in €) of purchasing €1 of human health and environmental benefits where benefit-cost ratios effectively express the level of benefit gained (in €) for every €1 of investment. The latter are often used to identify/screen out options for which the cost exceeds the benefits (i.e B/C<1) and/or identify those options that perform best.

Table 15 shows how the options are ordered in the medium scenario. However, options B and E (ranked 4 and 5) are reversed under the high scenario with CSA. When considering the rank order it should be borne in mind that all options perform well by these measures and that options B, C and E perform almost equally well[6] and so the 3, 4 and 5 rank order is somewhat artificial. The performance of the options against these criteria must be set against the level of protection offered. Here, from Table 13, the level of protection provided is lower for the options ranking higher for benefit-cost ratio and cost-effectiveness (with Option A providing only a modest increase in levels of protection from the baseline).

[6] With the 'distance' between the third and fifth options being only €0.0046 of cost per € of benefit on the cost-effectiveness scale.

Table 15: Cost-effectiveness and benefit- cost ratios for options (€/€) - medium scenario					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Cost-effectiveness indices					
Cost effectiveness (C/B) - No CSA	€ 0.001	€ 0.002	€ 0.01	€ 0.01	€ 0.01
Cost effectiveness (C/B) - with CSA	€ 0.0002	€ 0.002	€ 0.01	€ 0.01	€ 0.01
Rank cost-effectiveness - No CSA	1	2	5*	3*	4*
Rank cost-effectiveness - with CSA	1	2	5*	3*	4*
Benefit-cost ratios					
Benefit-cost ratio (B/C) - No CSA	1,390	472	100	184	104
Benefit-cost ratio (B/C) - with CSA	5,317	548	102	187	104
Rank Benefit-cost - No CSA	1	2	5*	3*	4*
Rank Benefit-cost - with CSA	1	2	5*	3*	4*
* these options perform almost equally as well as one another and so the rank order is somewhat artificial					

When considering the data in Table 15 it may be useful to make a comparison with the estimated cost-effectiveness of the measures in place at present. Table 16 provides the costs, benefits and cost-effectiveness of the measures in place for registration of 1-10t substances in 2018. As can be seen from this, all of the options, if introduced, would provide levels of cost-effectiveness higher than those expected from registration under current requirements only in 2018. This is not to say that the current requirements are not cost-effective, merely that taking up any of the options in addition to these requirements would offer similarly high levels of cost-effectiveness.

Table 16: Cost-effectiveness and benefit- cost ratios of current requirements for 2018 (€/€) - medium scenario	
	Baseline (Annex VII and Current Annex III)
Total costs for 2018 requirements	€ 410.9
Total benefits of 2018 requirements	€ 14,015.7
Cost effectiveness (C/B)	€ 0.03
Benefit:cost (B/C)	12

6.3.2 Withdrawal of substances

It is clear from this Phase 3 analysis that the alternative options are likely to identify more substances with a larger number of classifications than are identified under the current requirements, that some options perform better in this respect than others (and so the benefits in terms of environmental and human health benefits are larger), and that those same higher performing options also come at greater cost to industry (MIs and DUs).

Given the interplay between generating information suitable for making classifications and the cost of that information, this is not a surprising finding. Throughout the development of REACH from the White Paper though to the final text there was an awareness of the need to strike a balance between the level of information required to "*ensure a high level of protection of human health and the environment*"[7] and the need to keep costs at a level commensurate with "*enhancing competitiveness and innovation*"[38].

[7] Article 1 (1) of REACH

The purpose of this Phase 3 study is not to make a judgement on which would be the best option considering these often competing objectives but rather provide the Commission with the information required to consider, in the light of new information on substance classifications generated by the 2010 and 2013 registration deadlines, which of the options (including do nothing) is likely to strike the 'best' balance. In terms of that balance results of this study suggest that:

- Levels of protection afforded by the current requirements are relatively low (at 10% of total damages in the absence of any requirements under the medium scenario) and are unlikely to satisfy the REACH objective of ensuring "a *high level of protection of human health and the environment"*;
- The lower cost options (such as Option A) produce a slight improvement in this (bringing overall level of protection to around 33% under the medium scenario) but this may still not be regarded as ensuring '*a high level of protection of human health and the environment*' even though these lower cost options are, numerically, the more cost-effective of the alternatives;
- The highest cost option (Option E) would provide a high level of protection by any definition (98% of total damages in the absence of any requirements) but, even though very cost effective, the costs are relatively high and may or may not be commensurate with the REACH objective of "*enhancing competitiveness and innovation*"; and
- The (three) options in the middle of the two extremes provide something in the middle ground in terms of costs, benefits and levels of protection but, depending on the benefit scenario, provide anything between a 46% and 72% reduction in total damage costs which may or may not constitute '*a high level of protection'*.

The analysis of the business impacts of the options found no evidence that costs (withdrawal or updating/upgrading) were likely to have disproportional impacts on SMEs versus large companies. However, as discussed earlier there are differences between the options in terms of the numbers of substances likely to be withdrawn because the costs of updating/revising registration dossiers are likely to be unsupportable. Whilst the costs of these withdrawals are included with the total costs of the options presented in all of the tables in this section, they are also an outcome and can be viewed as providing an indicator of the impact of options on competition and innovation.

Table 17 provides the estimates of the numbers of substances and numbers of MIs affected by withdrawal under the medium scenario. Data are provided as both numbers (substances/MIs) and as percentages (of substances/MIs). As it is the cost of the information elements that largely drives both the total costs of the options and the withdrawals, the trends are the same in terms of which options have the highest impact/costs. The data do, however, provide information that may be of use to deliberations on which of the options (if any) provide the better balance between the competing demands.

Table 17: Number of substances and number of MIs affected by withdrawal					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Number of substances likely to be withdrawn					
Substances withdrawn - No CSA	0	187	956	1,132	2,525
Substances withdrawn - with CSA	0	190	969	1,173	2,612
Percent substances withdrawn - No CSA	0.0%	1.0%	4.9%	5.8%	12.9%
Percent substances withdrawn - with CSA	0.0%	1.0%	4.9%	6.0%	13.3%
Number of MIs affected by withdrawal					
Number of MIs affected by withdrawal - No CSA	0	187	898	1,062	2,160
Number of MIs affected by withdrawal - with CSA	0	190	911	1,103	2,247
Percentage of MIs affected by withdrawal - No CSA	0.0%	2.2%	10.7%	12.7%	25.8%
Percentage of MIs affected by withdrawal - with CSA	0.0%	2.3%	10.9%	13.2%	26.9%

6.3.3 Vertebrate testing

A further consideration for decision making on the options is the number of vertebrates that would be needed for testing (assuming that all testing proposals were granted by ECHA). The estimates are provided in Table 18. These should be understood in context with the 252,677 vertebrates estimated in the Monte Carlo simulation for current requirements for 2018.

Table 18: Additional number of vertebrates used in tests under the options					
	Option A	Option D	Option B	Option C	Option E
Vertebrate animals used in tests	46,374	120,428	416,995	419,410	929,618

1 Introduction

1.1 Background to the Phase 3 study

Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) came into force on 1 June 2007. REACH aims to provide a high level of protection of human health and the environment, while at the same time enhancing the competitiveness and innovative capability of the EU industry. Furthermore, REACH aims to ensure the free movement of substances and the promotion of the development of alternative methods for the hazard assessment of substances (Article 1).

Registration under REACH is staged over three phases with the timescales for registration dependent upon the quantities of substances manufactured or imported. The final phase-in registration deadline will be 1 June 2018 for substances manufactured or imported in quantities starting at 1 tonne but less than 10 tonnes per year per manufacturer or importer (1 to 10 tonne substances) and also for substances manufactured or imported in quantities of 10-100 tonnes per year.

Article 138 of REACH requires the Commission to undertake reviews of the requirements for 1-10t substances. On the basis of these reviews, it may present legislative proposals to modify the requirements for these substances. Here, Article 138 requires reviews of:

- the information that must be submitted in registration dossiers (Article 138(3)); and
- the extension of the obligation to perform a chemical safety assessment (CSA) and to document it in a chemical safety report (CSR) to 1-10 substances (Article 138(1).

Regarding the latter, Article 138(1) distinguishes between substances which meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A or 1B (where the review should be carried out by 1 June 2014) and all other substances (where the review should be carried out by 1 June 2019). This latter review (the extension of CSA/CSR to all substances due by June 2019) is yet to be started and all work to date (including this study) has focussed only on extending the CSA/CSR obligation to CMRs 1A/1B alone.

Following on from an initial (2012) study it had completed for the Commission on these issues, RPA was commissioned (in December 2013) to provide technical assistance to the review of information requirements and the review of CSA/CSR requirements for CMRs 1A/1B and, in particular to:

- identify, refine and analyse options for an extension of the current information requirements and provide sufficient information on the costs, benefits and impact on innovation and competitiveness of each of the options;
- provide a clear description of the envisaged main benefits and drawbacks of the extension of CSA/CSR obligations to 1-10t CMR 1A/1B substances including estimation of costs for manufacturers, importers and downstream users and distribution of the costs along the supply chain; and
- therein, provide the Commission with a solid basis to report on the issues and to envisage any (legislative) proposals.

On the basis of the outputs from the Phase 2 study and internal discussions, the Commission has selected five options for extending information requirements for further evaluation (hereafter referred to as information options).

In addition to these five information options, the Commission wishes to further examine the option to extend REACH CSA/CSR obligations (Article 14(1)) to all 1-10t substances known or expected to meet criteria for CMR 1A or 1B criteria for further evaluation alongside the information options.

RPA has been commissioned to generate further information on the selected policy options using the methods developed in Phase 2 suitably adjusted to take into consideration the new combination of options and changes in context and timing of any changes since Phase 2 was undertaken.

Ultimately the information from this Phase 3 study may be used as part of the preparation of a Commission Impact Assessment (IA) and Public Consultation. As such it has been important that the assessment is carried out in accordance with the Commission *Impact Assessment Guidelines* and related operational guidance.

1.2 Structure of the Report

This (main) report provides an overview of the options, the methods applied to assess them and the costs, benefits and wider implications and business impacts of the options in isolation and in combination with one another.

Section 2 provides an overview of the options and their development while Section 3 summarises the approach taken to analyse the options and a scoping of the impacts.

Section 4 assesses the aggregated cost impacts under the information options and business impacts are assessed in more detail in Section 5.

The costs of the option to require a CSA/CSR for CMRs 1A/1B are estimated in Section 6, which also provides the costs of the information options in combination with the CSA/CSR option.

Section 7 provides a summary of the approach to the assessment of benefits and the estimated benefits of the options and Section 8 provides a comparison of the costs and benefits of all options.

A full description of all methods and data inputs applied has been provided in the separate Technical Annex Report.

2 Overview of the options and their development

2.1 Overview

This Phase 3 study builds on work undertaken on the Phase 2 study that was completed in March 2015. Amongst other things this earlier work identified and refined options for an extension of the current (Annex VII) information requirements for 1-10t substances[8] and, in a separate report, provided a clear description of the envisaged main benefits and drawbacks of the extension of CSA/CSR obligations to 1-10t CMR 1A/1B substances.

In relation to the information options, nine options (including the do-nothing baseline) were identified and, as required by the Phase 2 study specification, the costs and benefits of five of these information options (excluding the do nothing baseline) were examined in detail.

On the basis of the outputs from the Phase 2 study and internal discussions, drawing on the same set of nine information options the Commission has selected a different set of five information options for an updated evaluation with updates taking into consideration combination of the information options with the CSA/CSR option and also any changes in context and timing since the Phase 2 study was undertaken.

Sections 2 and 3 and Annex 1 of the March 2015 Phase 2 report provide a detailed description of the current requirements and the development of the array of nine options. This has not been duplicated in full in this Phase 3 report and this section provides a summary of the current requirements, the reasoning behind the options and a description of what they entail as background to the further assessment.

2.2 The 'information options'

2.2.1 Current requirements for 1-10t substances

The aim of REACH as a whole is to achieve:

- a high level of protection of human health and environment;
- free movement of substances on their own, in mixtures, and in articles; while
- enhancing competitiveness and innovation.

A chief driver for the adoption of REACH was the situation that, prior to its adoption, information on the inherent properties needed to manage chemicals safely was not available for a significant percentage of the substances that have historically been placed on the European market (of which more than half – around 20,000 - are expected to be registered in the 1-10t band only).

[8] The term substances here refers to substances used on their own or in mixtures (as defined in Article 3 of REACH) and also in articles where the substance is used in quantities of 1 tonne or more and the substance is intended to be released under normal or reasonably foreseeable conditions of use.

One of the main ways by which REACH addresses these issues and achieves its aims is by requiring manufacturers and importers to generate data on the substances they manufacture or import and, on the basis of that information, making the appropriate classifications for and hazardous properties under Regulation (EC) No 1272/2008 (CLP).

Where hazardous properties are identified this is communicated to downstream users (DUs) by means of Safety data Sheets (SDS) and risk management requirements are triggered under parallel community regulation including:

- Worker health and safety regulation;
- Product safety requirements;
- Waste regulation; and
- Regulation that sets limit values and exposure limits.

For substances produced in quantities greater than 10 tonnes per year, environmental and human health exposure assessment, risk characterisation and identification of risk control measures for identified uses is carried out by manufacturers and importers (MIs) under a process of Chemical Safety Assessment (CSA) under REACH, reported on in a Chemical Safety Report (CSR) and communicated to downstream users via an extended Safety Data Sheet (eSDS). The resulting exposure scenarios and eSDS facilitate/provide documentation necessary for compliance with the parallel regulatory instruments (identified above) triggered by classifications under CLP.

As the requirement to conduct a CSA does not currently apply to the 1-10t substances, risk management is achieved only via classification under CLP and the parallel regulation that is triggered by any classifications for hazardous properties (as in the first bullet above).

The obligation to undertake CSA/CSR is not the only requirement that differs by volume of production. The requirements for generation of information on substances under REACH is also tiered according to the volumes of manufacture or importation of a substance as follows:

- **For substances produced in quantities exceeding 10t per year:** the full physico-chemical, toxicological and ecotoxicological information set out in the appropriate Annexes (VII to X) must be provided (as defined in Article 12 of the Regulation); and

- **For substances produced at 1-10t per year**: all substances must provide the physicochemical information in Annex VII and for "priority substances" the toxicological and ecotoxicological information in Annex VII must be provided.

'*Priority substances*' are 1-10t substances that meet the criteria in Annex III of the Regulation. This identifies them as "*substances for which it is **predicted** (i.e. by the application of (Q)SARs or other evidence) that they are likely to meet the criteria for":*

- classification as C, M or R 1A/1B or PBT/vPvB; or
- any health or environmental hazard classes or differentiations under CLP **and also** have a dispersive or diffuse use.

2.2.2 Options for extending the number of substances required to provide information

The requirements of Article 12 and Annex III mean that, in practice, only a subset of the 1-10t substances are to be tested for toxicological and ecotoxicological endpoints under REACH. Accordingly, it will only be possible to identify the appropriate classifications under CLP for this sub-set of substances. The successfulness (or otherwise) of this strategy is highly dependent on the extent to which hazardous properties will/can be correctly "*predicted by the application of (Q)SARs or other evidence*". This is because:

- ***For the identification of priority substances:*** the successfulness of the strategy depends on the extent to which QSARS or other evidence are able to correctly identify substances that **do have** (as yet unknown) hazardous properties – any substances which are not correctly identified as priority 1-10t substances will not have to provide the Annex VII toxicological and ecotoxicological information (and their hazardous properties will not be identified, classified and associated risks managed); and

- ***For reducing the possible economic impact on low volume substances:*** the successfulness of the strategy depends on the extent to which QSARS or other evidence are able to correctly identify substances that **do not have** hazardous properties – those substances that are incorrectly identified as priority 1-10t substances would have to incur the costs of providing Annex VII toxicological and ecotoxicological information despite the fact that no hazardous properties would be identified by undertaking the testing (because there are none).

As no prediction by QSARs or other evidence is 100% accurate in its predictions, the Phase 2 study identified that an obvious option for extending/improving the information requirements is to extend the number of substances required to provide this information by making adjustments to the Annex III criteria. This led to the development of the following three 'Annex III' options:

- **Do nothing**- the baseline;
- **Remove the diffuse/dispersive use criterion in Annex III ('ND')** – which would result in all 1-10t substances identified by QSARs or other information to have any human health or environmental classification to provide toxicological and ecotoxicological information (as opposed to only those identified and having dispersive/diffuse uses); and
- **Remove all criteria in Annex III** – i.e. require all 1-10t substances to provide toxicological and ecotoxicological information.

2.2.3 Options for extending and refining the information required

Besides the option of extending the number of substances required to provide toxicological and ecotoxicological information there is also the option to refine the information that is required to be generated. The Phase 2 study provided a detailed examination of:

- the nature of the toxicological and ecotoxicological information required for 1-10t substances under Annex VII;
- the usefulness of that information; and

- whether any refinements could be made which would further enhance the benefits in terms of the identification and hazardous properties and implementation of suitable controls (within acceptable cost boundaries[9]).

The development of options for refining the toxicological and ecotoxicological information in the Phase 2 study focussed on the merits of including human health and environmental endpoints that currently only apply to substances manufactured/imported in quantities of greater than 10t per year under Annex VIII.

When selecting endpoints from Annex VIII, the overarching consideration was the opportunities that the additional information might provide for enhanced risk management given that, as described above, a CSA is not required for 1-10t substances and a number of the information requirements in Annex VIII are present specifically to provide the enhanced information required to perform a CSA.

As well as considering the merits of additional information from inclusion of Annex VIII endpoints, alterations to the use of information that already forms a part of Annex VII was considered. This applied only to information that must already be gathered and could, in principle, be used to screen for PBT/vPvB properties. As screening for PBT/vPvB properties is currently exclusively part of the CSA process (that, as noted, does not apply to 1-10t substances at present), there is the option to require screening as part of Annex VII.

The following options for extending information requirements based on the inclusion of selected Annex VIII endpoints were developed in Phase 2:

- **Annex VII (the baseline):** Current Annex VII toxicological and ecotoxicological information;
- **Annex VII+:** Current Annex VII toxicological and ecotoxicological information plus endpoints and requirements selected from Annex VIII to deliver additional classifications and information with the smallest possible likely increase in cost;
- **Annex VII++**: As Annex VII+ above but with the addition of certain key elements/changes from Annex VIII that may deliver further benefits in terms of identification of hazardous properties and substances with hazardous properties but would represent a more significant increase in costs.

Annex I of the Phase 2 report describes the detailed reasoning behind the selection of endpoints for the Annex VII+ and VIII++ options, examining each section of the Annexes in turn. The final list of endpoints for inclusion in the Annex VII, VII+ and VII++ information options is provided in Table 2-1 overleaf.

[9] A full description of this is provided in Annex 1 of the Phase 2 report *Extension of the registration requirements for substances manufactured or imported between 1 and 10 tonnes per year on 1-10t information requirements* (ENV.A.3/SER/2013/0057r) available at http://ec.europa.eu/environment/chemicals/reach/pdf/1-10t%20InfReq%20Final.pdf

Table 2-1: Summary of Extended Information Options			
REACH Annex Section	**Annex VII+**	**Annex VII++**	**Overview of Benefit of Additional Information**
8.1 Skin irritation /skin corrosion	Maintain as at present	As Annex VII+	N/A
Section 8.2 Eye Irritation	Maintain as at present	As Annex VII+	N/A
Section 8.3 Skin Sensitisation	Maintain as at present	As Annex VII+	N/A
Section 8.4 Mutagenicity	Maintain current approach (GMBact)	Extend to a two test battery (GMBact plus MNTvitro)	Enables the detection of a greater number of genotoxic substances
Section 8.5 Acute Toxicity	Maintain as at present	Classification for acute oral toxicity in accordance with Section 8.5.1 of Annex VII triggers consideration of dermal and inhalation toxicity in accordance with Sections 8.5.2 and 8.5.3 of Annex VIII.	Provides additional classifications and information for exposure assessments required to be undertaken by manufacturers and downstream users under parallel regulation.
Section 8.6 Repeated Dose Toxicity	Maintain as at present (no short repeated dose toxicity testing)	Short term repeated dose toxicity in accordance with Section 8.6.1 of Annex VIII for substances identified by testing under 8.5.1 as Acute Tox 4.	As above.
Section 8.7 Reproductive Toxicity	Maintain as at present (no reproductive toxicity testing)	As Annex VII+	N/A
Section 8.8 Toxico-kinetics	Assessment of the toxicokinetic behaviour of the substance in accordance with Section 8.8.1 Annex VIII may be carried out where a new requirement to screen for PBT/vPvB properties identifies a substance as a potential PBT/vPvB and this will be useful to assessment.	As Annex VII+	Only required if contributes to assessment of PBT/vPvB – provided only for completeness.

Section 9.1 Aquatic Toxicity	Testing in accordance with Section 9.1.3 - short-term toxicity testing on fish would be undertaken: • for any substances identified with a classification as hazardous to the aquatic environment by testing in accordance with Section 9.1 of Annex VII; and • for any substances where screening for P and B in PBT/vPvB identifies that criteria for both P and B (or vP and vB) are met.	As Annex VII+	Enables the generation of PNECs for use by regulators and others in relation to assessing the need for action under parallel environmental regulation.
• **Section 9.2 Degradation**	• information from the ready biodegradability test in Annex VII will be used to inform screening of P in PBT/vPvB; • information on the octanol-water partitioning coefficient experimentally determined in accordance with Section 7.8 of Annex VII will be used to screen for B in PBT/vPvB; • if the above screening for P and B identifies that a substance may meet the criteria for **both** P and B (or vP and vB), information will be gathered as per Section 9.1.3 of Annex VIII, short-term toxicity testing on fish (if it has not already been gathered as part of the option). This will be used to screen for T in PBT; • if the above screening identifies the substance as a potential PBT or vPvB, any additional information to make an assessment will be gathered in accordance with Annex XIII of REACH.	As Annex VII+	Allows the detection of PBT/vPvB substances (where no detection occurs at present because PBT/vPvB assessment is a requirement of Annex XIII alone and this Annex does not apply to 1-10t substances)
Section 9.3. Fate and behaviour in the environment	Maintain as at present (i.e. not required)	As Annex VII+	N/A

2.2.4 Final information options

With three options for Annex III requirements and three options for information options, the total number of possible combinations is nine. One of these nine combinations (current Annex III requirements combined with current Annex VII requirements) comprises the baseline for the study and so is not an option in itself.

On the basis of the outputs from the Phase 2 study and internal discussions, the Commission selected five information options for further evaluation in Phase 3. Table 2-2 identifies these five options (A to E) as well as those options analysed in the Phase 2 study (the green highlighted boxes).

Table 2-2: Final combinations of options for analysis in Phase 3			
Annex III Options	**Information Options**		
	Current Annex VII	**Annex VII+**	**Annex VII++**
Do nothing	**Baseline**	**Option A**	
Remove diffuse/dispersive use criterion (ND)		**Option D**	**Option B**
Remove all criteria		**Option C**	**Option E**

2.3 Options in relation to the extension of the CSA/CSR requirement for CMRs 1A/1B

2.3.1 Overview

As noted in Section 2.1, in addition to assessing the information options, the Commission wishes to analyse the option of extending CSA/CSR obligations (Article 14(1)) to all 1-10t substances known or expected to meet criteria for CMR 1A or 1B.

2.3.2 Current requirements for 1-10t 'CMR 1A/1B' Substances

As noted in Section 2.2.1, for all substances of all tonnage bands, where any hazardous properties are identified this is communicated to DUs by means of Safety data Sheets (SDS) and risk management requirements are triggered under parallel community regulation.

For substances produced in quantities greater than 10 tonnes per year, environmental and human health exposure assessment, risk characterisation and identification of risk control measures for identified uses is carried out by MIs in a CSA and communicated to DUs via an extended SDS (eSDS) and the resulting exposure scenarios and eSDS facilitate/provide documentation necessary for compliance with the parallel regulatory instruments triggered by classifications under CLP.

For the 1-10t substances, however, no CSA is required and, as such, only general advice is required in the Safety Data Sheet (SDS) supplied to downstream users with information on "handling and storage" and "exposure controls/personal protection" in Sections 7 and 8 of the SDS being drawn from the generic precautionary statements (P-statements) in CLP.

Classification as C, M, or R 1A/1B triggers a variety of actions on the part of MIs and DUs to comply with a wider set of parallel community legislation than for other hazardous properties. The key requirements of each area summarised in the sub-sections below.

Worker health and safety regulation

Key regulations and associated requirements in relation to worker health and safety include:

- **Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD) –** which requires employers (i.e. manufacturers and downstream users) to determine whether any hazardous chemical agents are present at the workplace and assess any risk to the safety and health of workers arising from the presence of those chemical agents;

- **Carcinogens and Mutagens Directive 2004/37/EC (CMD) –** which requires that, as a priority, workers' exposure must be prevented through substitution. If not possible, the employer shall use a closed technological system. Where a closed system is not technically possible, the employer shall reduce exposure to a minimum through a number of risk management measures specified in the Directive;

- **Pregnant and Breastfeeding Workers Directive 92/85/EEC –** which requires that the employer shall assess the nature, degree and duration of exposure, assess any risks to the safety or health and any possible effects on the pregnancy or breastfeeding of workers and then decide what measures should be taken; and

- **Directive 94/33/EC on Young Workers –** under which employers are obliged to assess the hazards to young people, generate new site-specific data on the nature, degree and duration of exposure to chemical agents and adopt the measures necessary to protect the safety and health of young people.

To comply with their obligations, MIs and DUs of 1-10t 'CMRs 1A/1B' substances must rely on the general information presented in the SDS to complete their assessments where this will not include detailed information on the technical considerations in relation to exposure, risk and safety that would be present for substances produced at >10t registered under REACH (because no CSA/CSR is required for 1-10t substances).

Compliance with product safety requirements

Annex XVII of REACH (entries 28 to 30) prohibits the placing on the market and the use of CMRs 1A/1B as substances or as constituents of other substances or mixtures for supply to the general public when the individual concentration in the substance or the mixture is equal to or greater to the generic/specific concentration limit of Regulation (EC) No 1272/2008 (CLP). Currently consumer articles are not in the scope of the entries 28 to 30, but some specific legislation applies to some of these articles and all products in general. This includes:

- **Directive 2001/95/EC on General Product Safety (GPSD) -** under Article 3 of the GPSD producers are obliged to place only safe products on the market. Assessment of the risk to consumers from the presence of a CMR substance in a product would be required where this would include consideration of human exposure to the substance from use of the product;

- **Regulation No 305/2011 for the Marketing of Construction Products -** all manufacturers of construction products containing substances identified with C, M or R properties must consider the implications of this in terms of risk and safety of their products; and

- **Toys Directive 2009/48/EC -** Article 18 of the Toy Safety Directive requires manufacturers, before placing a toy on the market, to carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards.

To comply with their obligations, manufacturers of products containing 1-10t 'CMRs 1A/1B' substances must rely on the general information presented in the SDS to complete their assessments where this will not include detailed information on the technical considerations in relation to exposure, risk and safety (as no CSA is required).

Compliance with waste legislation

The Waste Framework Directive 2008/98/EC sets a definition of hazardous waste as waste that fulfils certain properties where these properties include carcinogenic, toxic for reproduction or mutagenic properties, where this would apply in relation to waste containing 1-10t substances classified as C, M or R 1A/1B. This requires the determination of safe and environmentally preferred waste management options.

In relation to the 1-10t substances, the information provided in the SDS in respect of waste management will be of a general nature with no specific quantitative analysis of risk and exposure in relation to the recommended risk management measures in relation to waste and the technical means to achieve this (as no CSA is required).

2.3.3 Changes introduced by extending the CSA/CSR obligation

The main requirements in relation to CSA/CSR are established under Article 14 of REACH and Annex I provides the detailed requirements regarding the content and structure of the CSA and CSR.

The chemical safety assessment (CSA)

The steps required in preparing a CSA are, in the first instance:

1. **Human health hazard assessment:** to determine the classification of a substance and to derive levels of exposure to the substance above which humans should not be exposed;

2. **Human health hazard assessment of physicochemical properties:** to determine the classification of a substance in relation to, as a minimum, explosivity, flammability and oxidising potential;

3. **Environmental hazard assessment:** to determine the classification of a substance and to identify the Predicted No-Effect Concentration (PNEC); and

4. **PBT and vPvB assessment:** to determine if the substance fulfils the criteria for PBT/vPvB (given in Annex XIII of REACH) and, if so, to characterise the potential emissions of the substance.

If, as a result of steps 1-4 the substance meets one or more of the criteria in Paragraph 0.6.3 of Annex I (which include classification as a category 1A/1B C, M or R) then the following additional steps are required:

5. **Exposure assessment:** quantitative or qualitative estimation of the dose/concentration of the substance to which humans and the environment are or may be exposed. This considers all stages of the life-cycle of the substance resulting from its manufacture and identified uses and covers any exposures that may relate to the hazards identified in the above hazard and PBT/vPvB assessments;

6. **Risk characterisation:** for each exposure scenario, this step considers the human populations (exposed as workers, consumers or indirectly via the environment and if relevant a combination of those) and the environmental spheres for which exposure to the substance is known or reasonably foreseeable. Characterisation assumes that the risk management measures described in the exposure scenarios have been implemented. In addition, the overall environmental risk caused by the substance is reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

The Chemical Safety Report (CSR)

The CSR documents the CSA and also provides a summary of all the relevant information used in addressing each of the aspects of the CSA. As such:

"*The chemical safety report documents the chemical safety assessment undertaken as part of the REACH registration process, and is the key source from which the registrant provides information to all users of chemicals through the exposure scenarios. It also forms a basis for other REACH processes including substance evaluation, authorisation and restriction*"[10].

The structure and format of a CSR is defined in Annex I of REACH and covers the following sections:

- Part A
  - Summary of risk management measures
  - Declaration that risk management measures are implemented
  - Declaration that risk management measures are communicated
- Part B
  1. Identity of the substance and physical and chemical properties
  2. Manufacture and uses
  3. Classification and labelling
  4. Environmental fate properties
  5. Human health hazard assessment
  6. Human health hazard assessment of physicochemical properties
  7. Environmental hazard assessment
  8. PBT and vPvB assessment
  9. Exposure assessment
  10. Risk characterisation

Here, the physico-chemical, toxicological and ecotoxicological information generated in relation to Annexes VII to XI is compiled in the appropriate Sections 1 to 7 (and also summarised in the SDS).

[10] https://www.echa.europa.eu/web/guest/regulations/reach/registration/the-registration-dossier/chemical-safety-report

The PBT/vPvB assessment that forms Section 8 is based upon the relevant data from Sections 4 and 5 and Sections 9 and 10 (exposure assessment and risk characterisation) are based upon all of the information in Sections 1 to 8.

Safety Data Sheets

As already described, it is already a requirement to provide a SDS for all substances with hazardous properties (i.e. including those produced in quantities of 1-10t per year). The SDS itself must be consistent with the information provided in the registration generally. Where a CSA/CSR has been completed for a substance the following additional requirements apply in respect of SDS (where the resulting SDS is known as an extended SDS (eSDS)):

- the SDS must be consistent with the information in the CSA;
- the results of the PBT/vPvB assessment must be reported; and
- in the case of substances where exposure assessment is required as part of the CSA, the relevant exposure scenario(s) must be included in an annex to the SDS.

2.3.4 Integration of the CSA/CSR option with the information options

Extending CSA/CSR obligations (Article 14(1)) to all 1-10t substances known or expected to meet criteria for CMR 1A or 1B will affect two distinct types of substances:

- **Known C, M or R 1A/1B substances:** substances that, prior to REACH, were already known to have C, M or R 1A/1B properties. These substances have already been registered owing to the requirements of Article 23(1)(a) of REACH. ECHA's latest (June 2016) records suggest that 56 unique substances have been fully registered with such properties in the 1-10t band; and
- **Substances that will be identified with C, M, or R 1A/1B properties:** substances for which there is little or no toxicological information at present to suggest such a classification but the need for such classification may be identified in the course of generating the toxicological and ecotoxicological information required in Annex VII (to XI).

Section 2.2 has described the options for extending the information requirements by a combination of changes to Annex III (which alters the numbers of substances required to generate toxicological and ecotoxicological information) and changes to the information required to be generated (Annex VII, VII+ and VII++). As is noted there, when developing these information options the overarching objective was one of maximising opportunities for enhanced risk management both in terms of the identification of more substances with hazardous properties and providing more useful information on those substances and properties.

Each information option represents a different strategy for identifying hazardous substances in the 'pool' of 1-10t substances for which information is currently lacking and there is no existing classification. As might be expected, different numbers of hazardous substances are identified under different options (including the baseline) and this includes the identification of substances for which there is little or no toxicological information at present to suggest classification for CMR 1A/1B.

As different numbers of 1-10t CMRs 1A/1B will be identified and registered under the different information options (between around 200 and 670 depending on the option, see Table 6-12 in Section 6.2.1) , so the costs and benefits of the option of extending the CSA/CSR obligation to 1-10t CMRs 1A/1B will differ from one option to another.

As the Commission may wish to implement both an extension of the CSA/CSR obligation to 1-10t CMRs 1A/1B and also one of the new information options, this Phase 3 study also considered the costs and benefits of the CSA/CSR obligation in combination with the baseline and the five information options A to E.

3 Approach to option analysis

3.1 Scoping of impacts

3.1.1 Overview

It is the Commission's intention that the results of this Phase 3 study may ultimately be used as part of the preparation of a Commission Impact Assessment (IA) and Public Consultation. As such the Phase 3 analysis has taken note of and been carried out in accordance with the Commission *Impact Assessment Guidelines* and related operational guidance. The core elements of the guidelines and operational guidance are that assessments should:

- ***Identify all potential impacts of the options –*** specifying how the options would address the issues that need to be addressed and mapping out impacts (positive and negative) and the parties that would be affected;

- ***Select the significant impacts for deeper assessment*** – justifying selection taking account of expected magnitude, relevance and Commission objectives such as human health, environmental protection, competitiveness and innovation; and

- ***Assess the most significant impacts*** – where this should be quantitative and monetised wherever possible as well as qualitatively described.

The assessments completed for the 2012 study, the 2014 study and adjusted/carried through to this (current) study were all developed with the eventual need to undertake an impact assessment in mind. As such, considering the changes brought about under the options, the following overall sets of impacts were considered as being significant and worthy of deeper assessment owing to their expected magnitude, relevance for different stakeholders, and importance for the Commission's objectives and policies (particularly in relation to health and environmental protection but also competitiveness, innovation and employment):

- ***Increases in compliance costs under REACH –*** for manufacturers and importers registering 1-10t substances (including 1-10t CMRs 1A/1B needing to produce a CSA/CSR) as well as downstream users of those substances;

- ***Human health and environmental impacts –*** owing to the identification of a greater number of substances with hazardous properties for classification under the information options, more complete information on those substances (permitting more effective/consistent risk management) and enhanced communication of risks and risk management measures in respect of CMRs 1A/1B by the production of CSAs/CSRs; and

- ***Reduced costs of compliance with legislation on worker's health and safety in respect of CMRs 1A/1B*** – where information provided in extended Safety Data Sheets (eSDS) communicated to downstream users satisfies or makes easier the production of risk assessments required under the regulatory instruments that are triggered by classification in accordance with Regulation (EC) No 1272/2008.

The specific impacts considered under each are summarised briefly in the following sub-sections.

3.1.2 Compliance costs

The information options and the extension of the CSA/CSR obligation to 1-10t CMRs 1A/1B have various effects on different elements of REACH compliance and also parallel legislation. The information policy options are expected to impact on the following compliance costs under REACH (and so are being assessed in detail):

- ***Information Costs -*** cost of generating (and purchasing Letters of Access to) toxicological and ecotoxicological information including QSARs/Read Across (increase relative to the baseline);

- ***Registration Dossier costs*** - the costs of drafting and finalising a revised/upgraded REACH registration dossier for submission (increase relative to the baseline) ;

- ***Cost of producing study summaries*** –which increases and varies from information option to information option because of differences in the information generated by different options and outcome in terms of any further mutagenicity testing and/or PBT/vPvB assessment that is required (increase relative to the baseline);

- ***Joint registration and SIEF administrative costs*** - where there is more than one registrant of the substance, the costs of liaising with the other registrants as part of sharing information on the substance increases with the options depending on the information generated by different options and the outcome (increase relative to the baseline);

- ***Costs of revising Substance Safety Data Sheets (SDSs)*** – where there is a change in classification for a substance in the light of any new information generated there is a need to update the SDS (increase relative to the baseline);

- ***Costs of testing proposals for animal tests*** – where there is a need to undertake animal testing by virtue of following the Integrated Testing Strategy (ITS) for mutagenicity or for PBT/vPvB assessment there is a need to submit proposals for animal tests before testing can take place (increase relative to the baseline); and

- ***Registration fees*** – which vary by size of enterprise (micro, small, medium and large) but under the Fees Regulation are zero for substances submitting all of the information in Annex VII (decrease relative to the baseline for substances submitting full Annex VII information [which increases under the options]).

The direct impact of the options on compliance costs (identified above) also have the potential to increase the number of substances withdrawn from the market. Withdrawal may occur under the baseline and the options when the increase in the cost of registering certain substances is unsupportable on the grounds of financial cost and/or because the newly identified substance's properties render it unsuitable for continued use.

Costs of compliance and withdrawal are considered for MIs as a direct cost and also as indirect costs for Downstream Users (DUs) [where the latter is associated with the passing of registration costs downstream and/or the costs to DUs of withdrawal of a substance and the need to reformulate or otherwise adjust their business to cope with the withdrawal].

In relation to the CSA/CSR option, the following REACH compliance costs have been identified as relevant and potentially significant for MIs (and so have been assessed in detail):

- ***Production of Robust Study Summaries*** **–** these would have to be produced as part of the CSR for 1-10t CMRs 1A/1B (increase relative to the baseline);
- ***Undertaking PBT/vPvB Assessment*** **–** where screening for PBT/vPvB properties required for substances undertaking a CSA/CSR suggests that the substance meets the criteria in Annex XIII, additional information would be required to complete the assessment (increase relative to the baseline);
- ***Cost of Human Health Exposure Assessment and Risk Characterisation*** **–** MIs undertaking a CSA/CSR would have to consider downstream uses of the substance in the CSA and exposure assessment and recommend risk management measures and the technical means to achieve them (increase relative to the baseline);
- ***Cost of Environmental Exposure Assessment and Risk Characterisation*** **-** MIs undertaking a CSA/CSR would have to consider environmental exposures for identified uses (increase relative to the baseline); and
- ***Cost of increased Communication in the Supply Chain*** **-** MIs undertaking a CSA/CSR would have to provide an extended SDS to downstream users (increase relative to the baseline).

The extension of the CSA/CSR obligation to 1-10t CMRs 1A/1B is also expected to impact on the downstream users' compliance costs in the following ways:

- ***Costs associated with the duty to pass information sufficient for an exposure assessment up the supply chain*** **-** for all of the 1-10t substances with known or unknown 'CMR' properties, documentation that is useful for the exposure assessment must be passed up the supply chain by the DUs (increase relative to the baseline);

- ***Costs associated with the duty to prepare a CSR in accordance with Annex XII (under Article 37(4))*** **-** downstream users are required to prepare a CSR in accordance with Annex XII for any use outside either the conditions described in an exposure scenario or a use and exposure category in a SDS or for any use his supplier advises against. This situation is thought likely to be a rare event but in principle there may be additional costs for a limited number of DUs (increase relative to the baseline); and

- ***Costs of Compliance with Parallel Regulation*** **–** under the current requirements, classification of a substance as C, M or R 1A/1B in accordance with Regulation (EC) No 1272/2008 (CLP) triggers provisions of a number of regulatory instruments. Under these provisions both MIs and DUs must conduct their own bespoke assessments of risk and exposure using the general information supplied in the SDS. Under the CSA/CSR option DU and MI compliance with these provisions is facilitated and provided by the CSA/CSR[11]. As

[11] For example, the Commission issued a guidance document for employers on controlling risks from chemicals concerning the interface between the CAD and REACH at the workplace. It states that, while the obligations of the CAD continue to apply after the adoption of the REACH Regulation, there is no duplication between the two acts. It is also observed that one risk assessment can often meet the requirements of both REACH and CAD.
http://ec.europa.eu/social/main.jsp?catId=716&langId=en&intPageId=223

such, the cost of compliance with parallel legislation is reduced under the CSA/CSR option (decrease relative to the baseline).

3.1.3 Human health and environmental impacts

REACH aims to provide a high level of protection of human health and the environment while at the same time enhancing the competitiveness and innovative capability of the EU industry. The main changes brought about by the options to extend the requirements for 1-10t are:

- improved detection of substances with hazardous properties and their classification under CLP;
- provision of more useful information on the properties of those hazardous substances and;
- through a combination of the above (and also CSA/CSR for CMRs 1A/1B), improved risk management and communication in a way that would increase the level of protection afforded to human health and environment through REACH (and parallel legislation).

The impacts on human health and environment are considered to stem from the identification of more substances with hazardous properties and better information on those substances in particular regarding the numbers of substances identified with the following properties:

- Mutagenicity (and via this route, genotoxic carcinogens)[12] (increase relative to the baseline);
- Dermal, inhalation and/or oral toxicity (increase relative to the baseline);
- Aquatic toxicity (increase relative to the baseline); and
- Persistence, bioaccumulation and toxicity (increase relative to the baseline).

In addition, the higher information options are expected to also provide for:

- better information on dermal/inhalation exposure limits for the substances with the relevant classifications (increase relative to the baseline);
- identification of substances with properties meeting classification for Single Target Organ Toxicity – repeated exposure (STOT RE 1 or 2) (increase relative to the baseline); and
- sufficient information to derive a Predicted No Effect Concentration (PNEC) for substances meeting classification for aquatic toxicity (increase relative to the baseline) and so provide a more robust basis for pollution prevention.

The CSA/CSR option is expected to have an impact on:

- Implementation of consistent and adequate risk management measures in relation to worker exposure (increase relative to the baseline);
- Adequate risk management measures in relation to articles (increase relative to the baseline);
- Identification and control of CMRs 1A/1B that are also PBT/vPvB substances (increase relative to the baseline); and
- Control of environmental risks (increase relative to the baseline).

[12] Note that no testing for carcinogenicity or reproductive toxicity is required in Annex VII of REACH or under any of the options. Thus non-genotoxic carcinogens/reproductive toxins will not be identified for any 1-10t substances.

When combined, all of these changes are expected to produce impacts on:

- the incidence of diseases, disorders and impacts (occupational and wider public) associated with each of the classifications for hazardous properties (reduction relative to baseline); and
- environmental pollution and impacts on the ecological status of the environment (reduction relative to baseline).

3.2 Methods used to quantify the significant impacts of the information options

3.2.1 Overview

The *Better Regulation Guidelines* identify that an assessment should be made of the significant impacts and that this should be quantitative where possible and also monetised where possible. As such, the objective for the assessment in Phase 3 has been to quantify all of the costs and benefits described above and, by consideration of the results, draw conclusions on the scale and significance of impacts of the information options on micro, small, medium and large enterprises, competitiveness, innovation and employment.

3.2.2 Quantification of compliance costs

In terms of the methods used to quantify and attribute costs, the assessments completed for the 2012 study, the 2014 study and adjusted/carried through to this Phase 3 study have all sought to improve upon past assessments of REACH such as the original and revised Business Impact Assessments (BIAs) (undertaken by RPA in 2003 and 2006 respectively) and the Commission's Extended Impact assessment (ExIA) of 2006 which drew on the BIAs.

A particular shortcoming of these past studies was the (low) resolution of costs. Here, because the focus was initially on producing estimates of the total (overall) cost of the proposals to industry as a whole[13] to inform negotiations on REACH, when it came to (later) assessment of likely effects on sub-groups such as small to medium sized enterprises (SMEs), it was difficult to break down the estimates of total costs into representative estimates of the costs to individual enterprises or groups of enterprises. The highest resolution that could be obtained by breaking down the total costs was by expressing costs as averages per substance or per tonne of substance. Whilst this enabled some consideration of likely impacts on individual and groups of enterprises, assessments had no means of identifying the impacts of costs that were higher and lower than the average.

In the light of these issues, in 2006 RPA was engaged by DG ENT (now DG GROW) to provide Technical Assistance for REACH Impact Assessment Updates (ENTR/05/100) to inform COM's assessments of the impact of the final proposals for the detailed text of REACH. One of the issues of concern for DG ENT was the impact of final proposals (and options) for low tonnage (1-10t) substances and the impact of the proposals on company level costs (owing to the fact that it was considered that a higher proportion of the low tonnage substances would be manufactured by SMEs).

[13] i.e. chemical manufacturers/importers (MIs) and downstream users (DUs) as a single block.

The solution that RPA (and DG ENT) developed to address this question was one of calculating costs at an individual substance level first and aggregating to a total cost later; so reversing the order used in the preceding BIAs and the ExIA. When considering how this could be achieved it was clear that the costs of registration would be different under different circumstances. For example, costs would be different for substances requiring:

- a full information dossier but no additional testing;
- a full information dossier using non testing information (such as QSARs) to fulfil (all or some of) the missing test endpoints;
- a full information dossier requiring additional tests to be undertaken; or
- a physico-chemical only dossier.

To be able to capture these differences it was necessary to have an analysis capable of distinguishing between (and accounting for) substances with different cost outcomes.

To achieve this, the 2006 analysis for DG ENT began by considering the factors that would dictate each outcome. Continuing the above (simplified) example, owing to requirements under Article 12 and Annex III, the following factors logically dictate the eventual outcome:

- whether a substance is likely to be identified as potential CMR/PBT/vPvB;
- whether a substance has a diffuse/dispersive use;
- whether a substance is likely to be identified with any other HH or ENV classification;
- whether there is toxicological and ecotoxicological information already available for the substance; and
- whether non-testing methods (such as QSARs) could be used instead of full testing for the substance.

By describing each of these factors statistically (using real data or, where not available, informed assumptions) it becomes possible to calculate the percentage of substances that would be exposed to each of the different circumstances or, put another way, the statistical probability that a given substance would be exposed to costs of each type (and magnitude).

Using a simple example based on illustrative data, *if* the following is the case (please note that these are not real statistical values):

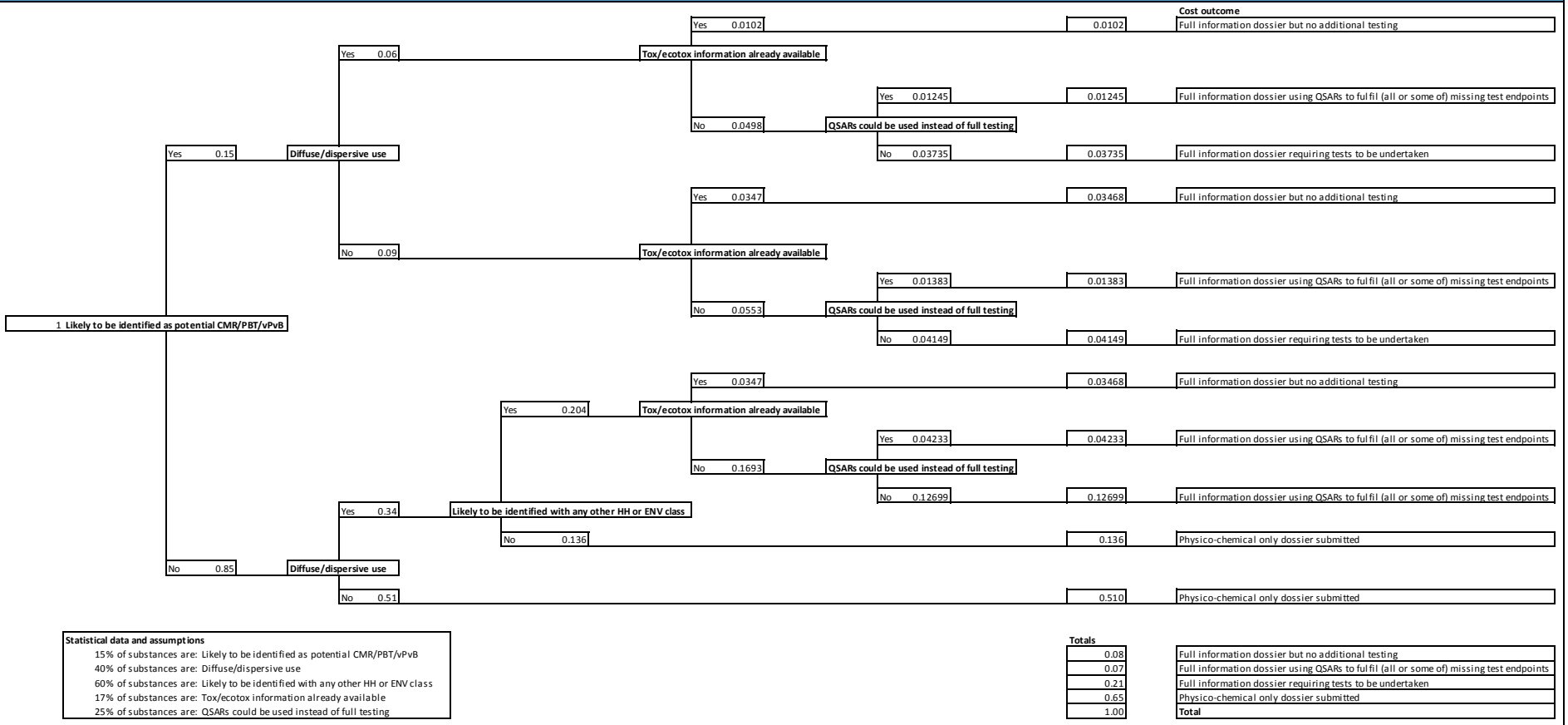
- 15% of substances are likely to be identified as potential CMR/PBT/vPvB by the application of QSARs or existing information;
- 40% of substances have a diffuse/dispersive use;
- 60% of substances are likely to be identified with any other human health (HH) or environmental (ENV) classification;
- 17% of substances already have toxicity/ecotoxicity information;
- 25% of substances could use non-testing information (such as QSARs) instead of full testing to complete information requirements;

one can begin to construct a simple probability tree such as that in the figure overleaf. In the figure, each branch of the tree represents a divide passing down the above list. So, at the first branch 15% of substances are likely to be identified as potential CMR/PBT/vPvBs (i.e. there is a probability of 0.15) and 85% will not. Of the 85% that are not, 40% may have a dispersive/diffuse use – so, overall 34% would not be identified as CMR/PBT/vPvBs but would have a dispersive/diffuse use (i.e. a

probability of 0.35). As can be seen from the figure, continuing this to the end of the tree and grouping by outcome would suggest that, using these 'dummy' assumptions, overall:

- 8% of substances would require a full information dossier but no additional testing (i.e. the probability of this outcome is 0.08);
- 7% of substances would require a full information dossier using QSARs to fulfil (all or some of) missing test endpoints (i.e. the probability of this outcome is 0.07);
- 21% of substances would require a full information dossier requiring additional tests to be undertaken (i.e. the probability of this outcome is 0.21); and
- 65% of substances would require only a physico-chemical dossier to be submitted (i.e. the probability of this outcome is 0.65).

Figure 3-1: Probability tree example



Building on these principles the analysis undertaken in 2006 sought to build cost estimates that were sensitive to multiple factors. Unlike the example in the figure, however, the analysis needed to consider many more factors than the six used in the tree diagram. Around 80 individual factors were applied to estimate costs with additional factors including descriptors of:

- physicochemical factors – which dictated waiving of tests;
- level of existing data available – which dictated for which endpoints there was already information available;
- availability/applicability of QSARs – which dictated, for each endpoint, the likelihood that a reliable QSAR would/would not be available; and
- classification – which, for each endpoint, dictated whether or not a classification would be made or could be predicted (depending on the availability of information and QSARs for the endpoint).

Considering all of the factors necessary required an alternative methodological approach to that of a probability tree (which would have been difficult/impossible to develop for this number of factors).

As with similar problems in risk analysis and other applications, a Monte Carlo simulation approach was applied to generate 'draws' from the long sequence of probabilities and probability distributions associated with all of the factors combined. Applied to this particular problem, the Monte Carlo approach generates a 'draw' for a substance based on the string of probabilities and their magnitude, attributing a cost to the outcome of that 'draw'. Repeating this 20,000 times provides 20,000 draws, describing 20,000 1-10t substances.

This process can be likened to that of dropping marbles one by one into a marble run such as that pictured in Figure 3-2 below. Unlike the marble run in the picture, however, the probabilities are not equal (50:50 left:right) at each set of gates but vary from one set of gates to another (c.f. the tree diagram).

Figure 3-2: Marble run

The Monte Carlo simulation model that was developed in 2006 was provided to DG ENT and used by the Commission to assess the options and final REACH proposals for the 1-10t substances. The same model was applied by RPA in 2012 in a thematic study (the Phase 1 study) for DG ENV to contribute to the first general report[14] on the functioning of REACH which was published on 5 February 2013.

The conclusion of the General Report on the 1-10t requirements, however, was that "*The Commission has […] insufficient information on the impact on innovation and competitiveness to propose changes to the information requirements for substances produced in low tonnages*" but that "*given the potential benefits whilst also considering the costs, the Commission will continue to work in these areas in co-operation with Member States and other stakeholders..*"

As such, in 2014 DG ENV commissioned RPA to re-examine the issue and provide a more detailed analysis of the impacts on innovation and competitiveness (the Phase 2 study). This work required modelling of costs to provide even greater resolution than that already achieved for DG ENT in 2006 (and subsequently DG ENV in 2012) where, as described above, the range of costs at the level of a substance had been calculated.

In order to provide the necessary information it was necessary to calculate costs down to the level of each of the MIs registering each of the substances (rather than across all MIs of each substance) and then calculate the likely cost burden of REACH registration for all substances registered by each MI. To enable assessment of impacts on SMEs, this also had to distinguish between micro, small, medium and large MIs.

As with the other factors dictating costs, all of these factors could be incorporated using statistics describing the:

- The number of companies of different sizes; and
- The number of 1-10t substances likely to be in the portfolios of companies of different sizes.

Adding these factors into the string of probabilities used by the Monte Carlo model and combining these with cost assumptions specific to the size of an enterprise, allowed the Monte Carlo model to be used to predict costs for every MI of every substance. This allowed the outputs of the model to be grouped and examined by size of MIs, allowing estimation and comparison of the costs to companies of different sizes as well as the overall burden. This, in turn, permitted a more detailed appreciation of the likely business impacts and, therein, information to inform consideration of the impacts on innovation and competitiveness as well as equity and fairness.

The estimates of the costs are described in full in Section 4 and the separate Technical Annex report provides a detailed description of all of the inputs to the model and sources for them.

3.2.3 Quantification of Benefits

Next to providing information for the calculation of costs, the string of probabilities used in the Monte Carlo simulation also provides matching information on the numbers of different types of hazardous substance detected under each option. This, in turn, provides a basis for estimating the benefits of each option in terms of the human health and environmental damages avoided.

[14] COM/2013/049 final

The estimates of the benefits are described in full in Section 7 and the separate Technical Annex report provides a detailed description of the calculation of disease cases/environmental damage avoided per substance identified with a different hazardous classifications. It also provides a full description of the monetary values applied to each case of disease/environmental damage.

3.3 Methods used to quantify the significant impacts of the CSA/CSR option for CMRs 1A/1B

3.3.1 Quantification of compliance costs and benefits

The costs and benefits of extending the CSA have been quantified to the extent possible using a scenario based approach. Three scenarios have been developed to cover the costs of the various elements described in Section 3.1 as well as the numbers of uses of substances and the numbers of downstream users. Estimates of the costs for all three scenarios (low, medium and high costs) are described in full in Section 6 for both the baseline (current) information requirements and also in the case of each of the information options A to E. Estimates of the benefits for the same are provided in Section 7.

4 Cost impacts under the information options

4.1 Approach to Estimation

4.1.1 Monte Carlo Outputs

As noted in Section 3.2.2, a Monte Carlo model has been developed to calculate costs of the information options and the separate Technical Annex report provides a detailed description of all of the inputs to the model and sources for them as well as a detailed description of how each element is calculated.

Applying these approaches the Monte Carlo simulation produces around 46,000 rows of data on the registration of 20,000 'virtual' 1-10t substances. Each row of data records the estimated cost for each **individual MI** of registration for each **individual substance** required to do so under the baseline and under Options A to E. As the assumptions and data underpinning the Monte Carlo modelling allow for between one and 15 MIs of each substance, there can be anything between one and 15 rows of data for the registration of an individual substance with **each row** providing information on the:

- identity of the MI (as a numbered code);
- size of the MI (micro, small, medium or large);
- identity of the substance being registered by the MI (as a numbered code);
- volume of that substance currently produced by that MI (always between 1 and 10t[15]);
- cost of the registering that substance (under the baseline and each option);
- other useful descriptors (such as whether mutagenicity tests or PBT assessment was required for that substance, etc.)

Using Excel pivot tables, these costs and descriptors can be aggregated to provide information aggregated to the level of either individual substances or individual companies. The latter, in particular, allows examination of differences in costs and impacts on companies of different sizes as part of wider assessment of business impacts which are considered in more detail in Section 5. This section restricts itself to analysis of the raw data from the Monte Carlo simulation and using it to estimate the total and average costs of the options per substance.

4.1.2 Costs and Receptors

Owing to the fact that 1-10t substances must be registered by June 2018, any changes to the information requirements established under the information options A to E will be made after 2018. At the most basic level, the economic costs of the options comprise:

- The cost of revising and upgrading REACH registrations submitted under the current requirements; and

[15] The Monte Carlo simulation applies a normal inverse distribution with a mean of 8 and a standard deviation of 1.5.

- In cases where the cost of revising and upgrading registrations for certain substances is unsupportable on the grounds of financial cost (and/or its identified properties render it unsuitable for continued use), the cost of withdrawing those substances from the market.

Two major groups of operators will incur such costs under the Options: Manufacturers and Importers (MIs); and Downstream Users (DUs). The types of cost incurred by each are most conveniently considered in terms of:

- ***MI direct costs of upgrading/revising registrations*** –the costs of upgrading/revising registrations of substances will be incurred initially by the MIs who have registered those substances. A proportion of these costs will be absorbed by the MIs themselves and a proportion will be passed down the supply chain (to downstream users – see next bullet) as, for example, an increase in product price;

- ***DU indirect costs of upgrading/revising registrations***: linked to the above, DUs will incur an increase in costs that is proportional to the cost of upgrading/revising registrations not absorbed by the MIs themselves;

- ***MI costs of withdrawal:*** where MIs decide that the cost of revising and upgrading a given registration is unsupportable (e.g. on the grounds of excessive cost) the substance would be withdrawn from the market. MIs will lose any profit that would otherwise have been made in the absence of changes to the Regulation examined under each of the options; and

- ***DU costs of withdrawal:*** where a substance is withdrawn from the market by MIs, DUs will incur costs associated with the need to reformulate or otherwise adjust their business to cope with the withdrawal.

The general approach used for the calculation of all of these costs begins with consideration of the raw data from the Monte Carlo simulation which provides information on the hypothetical cost of revising/updating all substances under each of the options (regardless of whether costs are supportable financially or not). Substances beyond a certain cost threshold are then assumed to be withdrawn from market and, for the remainder, registration dossiers are revised/upgraded as required under each of the options.

4.2 Substances withdrawn from the market

4.2.1 Numbers of substances withdrawn from the market

The decision to withdraw a substance from the market is not a straightforward one and may depend on a number of factors of which the most important are likely to be the cost of complying with registration requirements considering the value of the product.

Using its microeconomic model, the Commission estimated in its ExIA that some 1-2% of substances across all tonnage bands were likely to be withdrawn owing to registration costs across all of the scenarios it examined. The ExIA also assumed higher levels of withdrawal for lower tonnage tonnage suggesting that the higher end of the range (i.e. 2%) of 1-10t substances might be expected to be withdrawn under the current registration requirements and 98% would be registered.

The costs of registration in 2018 under the current requirements have been estimated by the Monte Carlo simulation alongside those for the options[16]. As described in Section 6.2.1, the analysis assumes that the most expensive 2% of these substances would be withdrawn from the market under the baseline. As such, substances at or below the 98 percentile value hypothetical registration costs will be registered in 2018 and substances above this 98 percentile value would be withdrawn.

The 98 percentile value across the hypothetical registration costs for all 20,000 1-10t substances under the baseline (current requirements) is calculated as €1,662 per tonne produced over 5 years[17]. By extension, any substance with costs for revising/upgrading dossiers under the options in excess of €1,662 per tonne is assumed to be withdrawn from the market under the options (and any substance with costs below this is assumed to revise/upgrade dossiers).

This partition between withdrawn and revised/upgraded substances is illustrated in Figure 4-1 showing hypothetical costs of revising/upgrading dossiers per tonne of production and the number of substances (as a percentage) with costs of each magnitude. The analysis suggests that 2% of the 20,000 1-10t substances (400) would be withdrawn from the market and not registered in 2018 under the baseline (current requirements). Of the remaining 19,600 substances that would be registered in 2018, the following numbers of substances would be withdrawn from the market under each of the options (if one of them was implemented after the 2018 deadline):

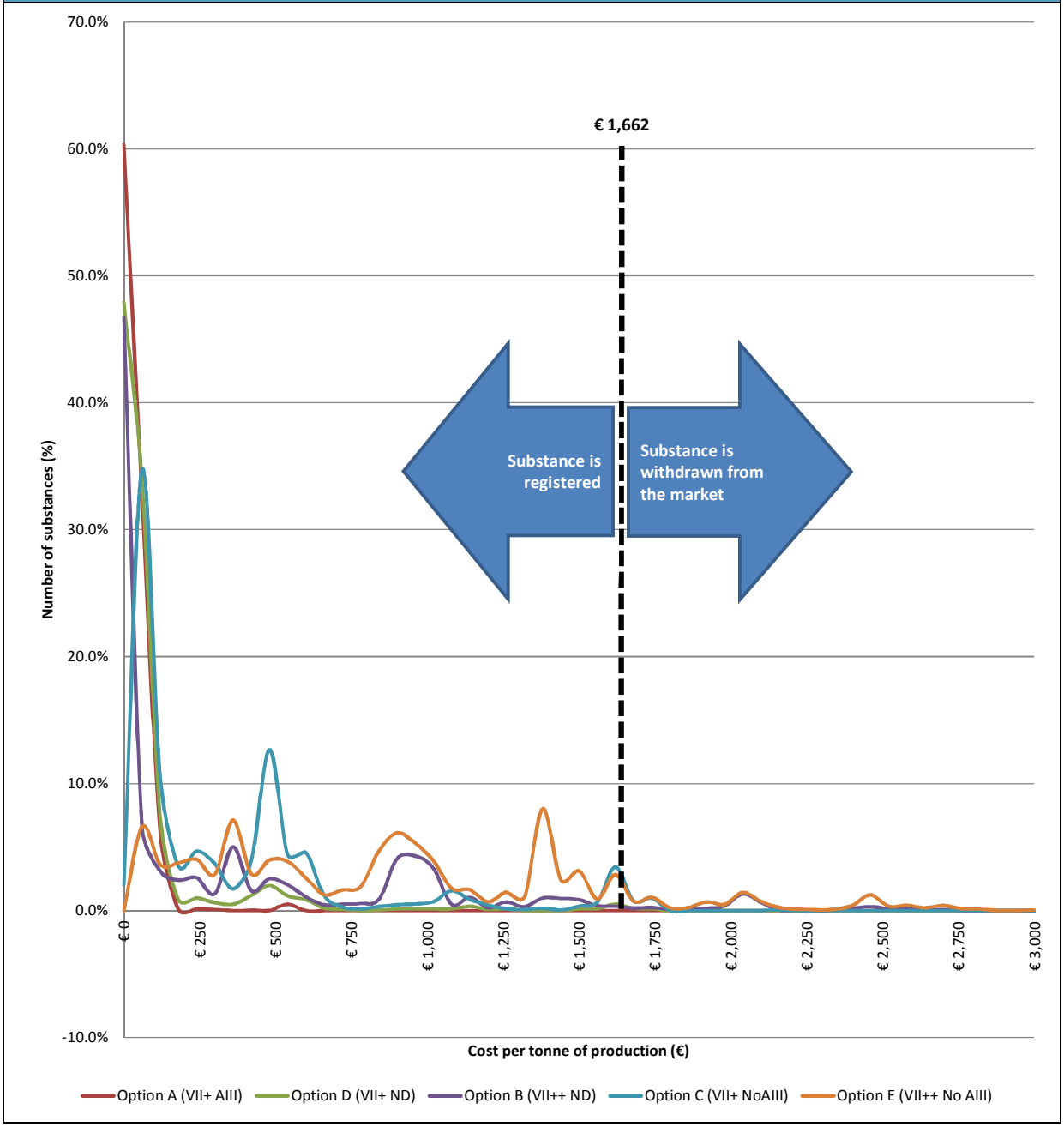
- **Option A (Annex VII+ and Current Annex III):** 0 (zero) substances withdrawn;
- **Option D (Annex VII+ and Annex III with ND[18]):** 187 substances withdrawn;
- **Option B (Annex VII++ and Annex III with ND):** 956 substances withdrawn;
- **Option C (Annex VII+ and No Annex III):** 1,132 substances withdrawn; and
- **Option E (Annex VII++ and No Annex III):** 2,525 substances withdrawn.

[16] Using the same assumptions and data inputs.

[17] Tonnes calculated on the basis of 5 years of production – so, 10 tpa would be 50t

[18] Removal of the diffuse/dispersive use criterion in Annex III

Figure 4-1: Partition of substances into withdrawn versus revised/upgraded



4.2.2 Attributes of Substances withdrawn from the Market

Analysis of the Monte Carlo simulation data for each of the substances withdrawn provides some insight into the factors that may cause costs to be financially unsupportable for the withdrawn substances under each of the options.

For each option, Table 4-1 provides data on the numbers of substances withdrawn, the total volume of production withdrawn and key factors that influence costs and their financial affordability including the number of MIs and the number that would have been required to undertake further

mutagenicity testing or further testing to assess PBT/vPvB properties. As can be seen from the table, all/almost all of the withdrawn substances would have had to undertake further (*in vivo*) mutagenicity testing under the options (which is expensive) and all are manufactured by only one MI. The combination of the relatively high costs of further testing and the absence of other MIs with whom such costs can be shared appears to be the dominant driver for withdrawal according to the Monte Carlo simulation. The same statistics suggest that PBT/vPvB screening and further assessment are not significant drivers of withdrawal.

Table 4-1: Attributes of substances withdrawn from the market under the different options					
	Option				
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Number of substances withdrawn	0	187	956	1,132	2,525
Percentage of registered substances withdrawn	n/a	1%	5%	6%	13%
Total tonnes of production withdrawn across all withdrawn substances	n/a	1,870	9,579	11,320	25,380
Percentage manufactured by only 1 MIs (would be registrants)	n/a	100%	100%	100%	100%
Number that would have been subject to further mutagenicity testing (true or false positives in *in vitro* screening tests)	n/a	187	865	1,132	2,295
Number that would be identified as potential PBT/vPvB by screening (requiring further testing)	n/a	0	40	15	40

4.2.3 Cost of substance withdrawal

The cost of withdrawing a substance from the market is associated with both the income foregone from manufacture or import (for MIs[19]) and the need to reformulate products (incurred by DUs). In both cases, the scale of costs is related to the commercial value of the product being withdrawn. In the absence of any better indication of this value, raw data on what the cost of revising/upgrading dossiers for a substance would have been (if it had been carried out) has been used. In the rest of the document this is referred to as the 'hypothetical cost of registration' for a substance.

[19] Although an importer may find a substitute with lower registration requirements, hence no income would be foregone.

Here, the underlying assumption is that, for all of the substances withdrawn from the market on the grounds of cost, the hypothetical cost of revising/upgrading that triggers the decision to withdraw is at the 'break-even' point and so equals the maximum value of the substance. Owing to the fact that there are differences in costs between the options, for withdrawn substances the 'break even' point for a substance is taken as being the lowest of the hypothetical costs triggering that withdrawal. So, for example, if a substance is withdrawn under Option D with a hypothetical registration cost of €n but €(3n) under another (more resource intensive) option, the break-even point or commercial value of the substance is €n across all of the options.

The annual income foregone by a MI is a function of the commercial value of the substance. As there is no data from which to extrapolate from one to the other, in the absence of any other information, on the basis of the economic consultants' expert judgement, lost annual income has been taken as being equal to 10% of the indicative 'commercial value' for each substance per year and costs are incurred for five years. The resulting totals have been discounted at 4% to provide Present Value (PV) costs. This provides a means to make a fair comparison between the options because the same assumption applies equally across all.

In addition to income foregone by MIs through withdrawal, there are costs to the downstream users (DUs) associated with, for example, reformulation. Regarding the level of these costs, logically, if reformulation costs were higher than the hypothetical costs of revising/upgrading dossiers then DUs would be keen to help sponsor the substance (and so it wouldn't be withdrawn). By extension, in the absence of any other information, the maximum costs of re-formulation are taken as being equal to the hypothetical costs of revising/upgrading dossiers. In practice, the value of some substances may be considerably less but, by the same token, some may be more. Applying this same value across all withdrawn substances provides a means to account for these costs and make fair comparisons between options (because the same assumption applies equally across all options).

Table 4-2 provides the resulting total costs of withdrawal to MIs and to DUs under the baseline and the options. The impact of these costs on different sizes of businesses is considered in Section 5.2 on Business Impacts.

Table 4-2: Costs of substance withdrawal under the options

	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Total costs to MIs (income foregone - € millions)	€ 0.0	€ 7.0	€ 44.2	€ 42.6	€ 112.6
Total costs to DUs (maximum reformulation cost - € millions)	€ 0.0	€ 14.0	€ 88.4	€ 85.2	€ 225.2

4.3 Substances upgrading/revising registrations

4.3.1 Costs of upgrading/revising dossiers

Having identified those substances that would be withdrawn under the options, the substances that remain in the Monte Carlo dataset are carried through to analysis of the costs of revising/upgrading under the options.

Owing to the Annex III criteria (and variations of them that are considered in the Options B to E) a number of substances do not need to upgrade/revise registration dossiers and incur no costs. This varies from one option to another depending on the Annex III option considered. Table 4-3 provides the numbers of substances experiencing no change in costs under the options and those experiencing costs of withdrawal versus costs of upgrading/updating dossiers.

Table 4-4 provides the total cost of revising and upgrading dossiers and averages per substance and per tonne.

Table 4-3: Number of substances incurring costs by type

	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Number of substances registered in 2018 (accounting for withdrawal under the baseline)	19,600	19,600	19,600	19,600	19,600
Number where there are costs	7,777	10,438	10,438	19,600	19,600
- of which costs of withdrawal	0	187	956	1,132	2,525
- of which revision/update of dossier	7,777	10,251	9,482	18,468	17,075
Number of substances where no costs under options	11,823	9,162	9,162	0	0

Table 4-4: Total costs of revising/upgrading registration under the options (all values expressed as Present Value over 4 years at 4%)					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Total costs across all substances (€ millions)	**€ 24.1**	**€ 93.4**	**€ 398.7**	**€ 366.6**	**€ 892.4**
Average cost of upgrading/revising registrations per substance (€)	€ 1,228	€ 4,814	€ 21,382	€ 19,851	€ 52,263
Average cost of substance registration per tonne (€)	€ 58	€ 228	€ 991	€ 915	€ 2,308

Whilst initially borne by the registering MIs, a proportion of the total costs in Table 4-4 will be passed on to Downstream Users (DUs) in the form of, for example, increased prices. In the absence of information to the contrary, it is assumed that, across all options, MIs pass half of the registration costs on to Downstream Users (DUs). As such, half of the costs in Table 4-4 will be absorbed by MIs and half will be passed on to DUs. The impact of these costs on MIs and DUs is considered in Section 5.4 on business impacts and total costs are reported in Table 4-5.

4.4 Total costs of the options

4.4.1 Change in total PV costs between options

The total costs to MIs, DUs and overall are summarised in Table 4-5 for the baseline and each option. Working through the changes brought about under the options the following changes in total PV costs are observed:

- ***Baseline:*** under the baseline the Annex III and Annex VII information requirements would remain unchanged, there would be no requirement to revise/update dossiers and costs would be zero;

- ***Option A (Annex VII+ and Current Annex III):*** Retaining the current Annex III criteria but slightly adding to the toxicicological and ecotoxicological information required (Annex VII+) will affect substances that have submitted full registration dossiers for 2018. The Monte Carlo simulation suggests that revising/upgrading the dossiers with the new information will have a total PV cost of **€24.1 million**;

- ***Option D (Annex VII+ and Annex III with ND):*** As with Option A, slightly increasing the level of toxicicological and ecotoxicological information required (Annex VII+) will affect substances that have submitted full registration dossiers for 2018. Revising/upgrading these dossiers with the new information will have a PV cost of €24.1 million. As well as this, the removal of the diffuse/dispersive use criterion (ND) from Annex III will result in additional substances being required to provide full toxicological/ecotoxicological information (and at the higher Annex VII+ level) at a cost of around €90.4 million to give a total PV cost of the option of **€114.5 million**;

Table 4-5: Summary and total costs of the options					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Costs of Withdrawal					
MI costs of withdrawal (income foregone) (€ m)	€ 0.0	€ 7.0	€ 44.2	€ 42.6	€ 112.6
DU costs of withdrawal (maximum reformulation cost) (€ m)	€ 0.0	€ 14.0	€ 88.4	€ 85.2	€ 225.2
Upgrading/revising registration costs					
MI costs (revising/upgrading dossiers) (€ m)	€ 12.0	€ 46.7	€ 199.3	€ 183.3	€ 446.2
DU costs (increased prices) (€ m)	€ 12.0	€ 46.7	€ 199.3	€ 183.3	€ 446.2
Total Costs					
Total Costs to MIs (€ m)	€ 12.0	€ 53.7	€ 243.5	€ 225.9	€ 558.8
Total costs to DUs (€ m)	€ 12.0	€ 60.7	€ 287.7	€ 268.6	€ 671.4
Total costs (€ millions)	**€ 24.1**	**€ 114.5**	**€ 531.2**	**€ 494.5**	**€ 1,230.1**

- ***Option B (Annex VII++ and Annex III with ND):*** As with Option D, this option involves removal of the diffuse/dispersive use criterion (ND) from Annex III with the result that additional substances would be required to provide full toxicological/ecotoxicological information. However, it also extends the information requirements further (to Annex VII++) for these substances and also for those that have submitted full registration dossiers for 2018. Registration dossiers for these (latter) substances would have to be revised/upgraded with the new (Annex VII++) information. The Monte Carlo simulation suggests that these changes would have a total cost of **€531.2 million**;

- ***Option C (Annex VII+ and No Annex III):*** As with Options A and D, slightly increasing the level of toxicicological and ecotoxicological information required (Annex VII+) will affect substances that have submitted full registration dossiers for 2018. Revising/upgrading these dossiers with the new information will have a PV cost of €24.1 million. As well as this, the removal of Annex III criteria will mean that all other substances (i.e. those for which 2018 registration contained physico-chemical data only) would be required to provide full toxicological/ecotoxicological information (and at the higher Annex VII+ level) at a cost of around €470.4 million to give a total PV cost of the option of **€494.5**;

- ***Option E (Annex VII++ and No Annex III):*** As with Option C, this option involves removal of Annex III criteria with the result that additional substances would be required to provide full toxicological/ecotoxicological information. However, it also extends the information requirements further (to Annex VII++) for these substances and also for those that have submitted full registration dossiers for 2018. Registration dossiers for these (latter) substances would have to be revised/upgraded with the new (Annex VII++) information. The Monte Carlo simulation suggests that these changes would have a total cost of **€1,230.1 million**.

5 Business impacts under the information options

5.1 Overview

Section 4.4 has provided the estimates of the overall costs to manufacturers and importers (MIs) and downstream users (DUs) that would be incurred under the baseline and the options. Drawing on the dataset produced by the Monte Carlo simulation the following sub-sections explore the distribution of different costs in more detail and, where outputs from the Monte Carlo simulation make it possible, at the level of micro, small, medium and large enterprises. This, in turn, provides insight into the potential impacts on SMEs and on innovation and competitiveness.

5.2 Impact of substance withdrawal on manufacturers and importers (MIs)

The total costs of substance withdrawal to MIs have been described in Section 4.2.3 which estimates the income foregone by MIs with the withdrawal of substances from the market. These costs are summarised in Table 5-1.

Table 5-1: Summary and total costs of the options (all values expressed as Present Values discounted at 4%)

	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
MI costs of withdrawal (income foregone) (€millions)	€ 0.0	€ 7.0	€ 44.2	€ 42.6	€ 112.6
Total Costs to MIs (€millions)	€ 12.0	€ 53.7	€ 243.5	€ 225.9	€ 558.8
Total costs (MIs and DUs - € millions)	**€ 24.1**	**€ 114.5**	**€ 531.2**	**€ 494.5**	**€ 1,230.1**
MI costs of withdrawal as % of total cost to MIs	0%	13%	18%	19%	20%
MI costs of withdrawal as % of total costs (MIs and DUs)	0%	6%	8%	9%	9%

The sub-sections below explore these costs further, providing information from the modelled simulation on the impacts of withdrawal on different sizes of enterprise and overall providing information on the number of MIs impacted by withdrawal and the associated company level reductions in tonnes produced and annual income foregone owing to withdrawals.

5.2.1 Number of MIs impacted by withdrawal

As the Monte Carlo simulation generates and records information on the manufacturers, size of those manufacturers, volumes produced by each manufacturer as well as other information, these

data can be analysed to produce a profile of the withdrawn substances in terms of the same attributes. Table 5-2 summarises the data from the Monte Carlo simulation in terms of the number of MI companies withdrawing one or more substances from their portfolios and the same numbers expressed as a percentage of the total number of companies in the appropriate size category.

Variation between companies of different sizes

In terms of variations in the scale of impacts between companies of different sizes (and the potential for disproportionate impacts on SMEs), the data suggests that the larger the size of enterprise the more likely that one or more substances will be withdrawn from the market. This is simply because the larger the size of enterprise, the larger the portfolios of 1-10t substances and the higher probability that the costs of revising/upgrading dossiers of one (or more) substances in the portfolio will be too high to be justifiable financially.

Table 5-2: Number of MI Companies impacted by withdrawal					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Number of companies					
Micro companies	0	10	28	50	88
Small Companies	0	12	48	85	164
Medium Companies	0	19	101	112	230
Large Companies	0	146	721	815	1,678
Total	**0**	**187**	**898**	**1,062**	**2,160**
Percentage of total companies in size category					
Micro companies	n/a	1.4%	3.8%	6.8%	11.9%
Small Companies	n/a	1.1%	4.3%	7.7%	14.8%
Medium Companies	n/a	1.5%	7.8%	8.6%	17.7%
Large Companies	n/a	2.8%	13.8%	15.6%	32.2%
Total	**n/a**	**2.2%**	**10.7%**	**12.7%**	**25.8%**

Variation in withdrawals between options

A consistent trend can be observed working across companies of all sizes from the baseline and through the options:

- ***Retaining the current Annex III criteria:***
    - ***Baseline (Current Annex III and Annex VII information):*** Under the baseline there are no costs and no withdrawals;
    - ***Extending the information requirements to Annex VII+ (Option A):*** costs of revising/upgrading apply only to those substances that already submitted full Annex VII information for the 2018 registration deadline. These costs appear insufficiently high to result in the withdrawal of any substances;
- ***Removal of the diffuse/dispersive use criterion in Annex III (ND):*** has the effect of increasing the number of substances required to generate and submit full tox and ecotox information to include those identified by QSARs and other information as likely to have any human

health or environmental classifications but without any diffuse/dispersive uses. When combined with options for changing the information required in Annex VII, this has the following effects:

- ***Annex VII+ and No Diffuse Dispersive Use Criterion in Annex III (Option D):*** Where removal of the diffuse/dispersive use criterion (ND) is combined with slight changes to the information required (Annex VII+), around 2.2% of registering MIs would withdraw one or more products from the market;

- ***Annex VII++ and No Diffuse/Dispersive Use Criterion in Annex III (Option B):*** Where removal of the diffuse/dispersive use criterion (ND) is combined with more significant changes to the information required (Annex VII++), the effect is an increase to around 10.7% of registering MIs withdrawing one or more products from the market;

- ***Removal of Annex III:*** has the effect of requiring full tox and ecotox information to be submitted for all substances (and so significantly increasing the number of substances submitting full information from that under the baseline). When combined with options for changing the information required in Annex VII, this has the following effects:

  - ***Annex VII+ and No Annex III (Option C):*** Where removal of Annex III is combined with slight changes to the information required (Annex VII+), 12.7% of registering MIs would withdraw one or more products from the market; and

  - ***Annex VII++ and No Annex III (Option E):*** Where removal of the diffuse/dispersive use criterion (ND) is combined with more significant changes to the information required (Annex VII++), the effect is an increase to around 25.8% of registering MIs withdrawing one or more products from the market.

5.2.2 Levels of production withdrawn by MIs

Clearly, within the population of companies withdrawing substances (given in Table 5-2), withdrawal of substances will affect the production of some companies more than others with the most extreme case being that withdrawal of substances leads to withdrawal of all (100%) of existing production from the market.

Number of companies where all of 1-10t substance production withdrawn

Table 5-3 provides data from the Monte Carlo simulation profiling the number of companies withdrawing all of the 1-10t substances in their portfolios. Thus, for these companies, 100% of existing production is discontinued owing to the revisions and additional data required under each of the options. Data are provided on numbers of companies by size and as a percentage of all companies.

The data in Table 5-3 suggest that complete withdrawal of the entire portfolio of 1-10t substances is a rare outcome regardless of the option. Though rare, it is most likely to occur in companies with smaller portfolios comprised of only a (very) few substances. As such, with smaller portfolios on average, SMEs are more likely to withdraw entire 1-10t substance portfolios but even here this is likely to be a rare outcome.

Table 5-3: Number of companies where all of production withdrawn					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Number of companies					
Micro companies	n/a	3	6	8	16
Small Companies	n/a	1	4	3	11
Medium Companies	n/a	0	9	4	20
Large Companies	n/a	1	2	3	5
Total	**n/a**	**5**	**21**	**18**	**52**
As a percentage of all companies					
Micro companies	n/a	0.4%	0.8%	1.1%	2.2%
Small Companies	n/a	0.1%	0.4%	0.3%	1.0%
Medium Companies	n/a	0.0%	0.7%	0.3%	1.5%
Large Companies	n/a	0.0%	0.0%	0.1%	0.1%
Total	**n/a**	**0.1%**	**0.3%**	**0.2%**	**0.6%**

Number of companies experiencing different levels of reduction in annual tonnage production

Whilst complete withdrawal of entire portfolios of 1-10t substances is likely to be a relatively rare outcome for companies, clearly some reduction production is inevitable when a company withdraws one or more substances.

Table 5-4 provides information from the Monte Carlo simulation on the number of companies experiencing different levels of production loss (measured in tonnes per year) of 1-10t substances. The data in Table 5-4 suggest the following:

- On average very few companies (0.1% to 2% of companies withdrawing depending on the option) are affected by very significant changes in overall tonnages produced (>60% of 1-10t substance production tonnage withdrawn);
- similarly, on average very few companies (0.1% to 2.4% of companies withdrawing depending on the option) are affected by significant changes in overall tonnages produced (40-60% of 1-10t substance production tonnage withdrawn); and
- a larger proportion (1.8% to 19.8% of mainly larger companies withdrawing depending on the option) on average are affected by moderately significant changes in overall tonnages produced (30-40% of 1-10t substance production tonnage withdrawn);
- for the vast majority of companies (75% to 98% of companies withdrawing one or more substances on average depending on the option), less than 30% of the current total tonnage of 1-10t substances produced would be withdrawn.

Table 5-4: Number of companies experiencing different levels of reduction in annual tonnage production as a percentage of the total number of companies					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Percentage of companies where >80% of production tonnage withdrawn but <100%					
Micro companies	n/a	0.0%	0.0%	0.1%	0.3%
Small Companies	n/a	0.0%	0.1%	0.1%	0.6%
Medium Companies	n/a	0.1%	0.2%	0.2%	0.5%
Large Companies	n/a	0.0%	0.0%	0.0%	0.1%
Total	**n/a**	**0.0%**	**0.1%**	**0.1%**	**0.2%**
Percentage of companies where >60% of production tonnage withdrawn but <80%					
Micro companies	n/a	0.3%	1.5%	1.4%	3.6%
Small Companies	n/a	0.4%	1.1%	1.9%	3.8%
Medium Companies	n/a	0.3%	0.9%	1.6%	3.2%
Large Companies	n/a	0.0%	0.2%	0.2%	0.8%
Total	**n/a**	**0.1%**	**0.5%**	**0.7%**	**1.8%**
Percentage of companies where >40% of production tonnage withdrawn but <60%					
Micro companies	n/a	0.3%	0.7%	1.8%	2.6%
Small Companies	n/a	0.2%	0.8%	1.8%	3.4%
Medium Companies	n/a	0.2%	1.4%	2.0%	3.6%
Large Companies	n/a	0.1%	0.5%	0.5%	1.9%
Total	**n/a**	**0.1%**	**0.7%**	**1.0%**	**2.4%**
Percentage of companies where >30% of production tonnage withdrawn but <40%					
Micro companies	n/a	0.4%	0.7%	2.3%	3.0%
Small Companies	n/a	0.5%	1.7%	3.3%	5.2%
Medium Companies	n/a	0.8%	4.0%	4.2%	8.3%
Large Companies	n/a	2.5%	12.4%	14.3%	28.1%
Total	**n/a**	**1.8%**	**8.6%**	**10.2%**	**19.8%**

Owing to the smaller portfolios of SMEs (and hence total production volume) withdrawal of a substance has a greater impact on SME MIs withdrawing substances than those of larger companies. Table 5-5 provides the average percentage production withdrawn by companies withdrawing one or more substances along with the numbers of companies (expressed as numbers and percentage of the total number of companies) from Table 5-2 as context. Whilst these data suggest that the impact on the SMEs is higher than for larger companies in terms of the percentage of production reduced, the data on the number and percentage of companies affected by withdrawal in Table 5-5 (duplicated from Table 5-2) identifies that larger companies are more likely to be impacted by withdrawal than SMEs. Thus, across all options that result in some level of withdrawal (i.e. all except Option A), whilst the production of affected SMEs is likely to be more impacted by withdrawal than larger companies, SMEs are less likely to be affected than the larger companies and *vice versa*.

Table 5-5: Average percentage of annual production withdrawn by affected companies					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Total number of companies in size category withdrawing one or more substances					
Micro companies	0	10	28	50	88
Small Companies	0	12	48	85	164
Medium Companies	0	19	101	112	230
Large Companies	0	146	721	815	1,678
Total	**0**	**187**	**898**	**1,062**	**2,160**
Percentage of total companies in size category withdrawing one or more substances					
Micro companies	n/a	1.4%	3.8%	6.8%	11.9%
Small Companies	n/a	1.1%	4.3%	7.7%	14.8%
Medium Companies	n/a	1.5%	7.8%	8.6%	17.7%
Large Companies	n/a	2.8%	13.8%	15.6%	32.2%
Total	**n/a**	**2.2%**	**10.7%**	**12.7%**	**25.8%**
Average percentage of annual production tonnage withdrawn by affected companies					
Micro companies	n/a	54.2%	51.6%	44.9%	49.2%
Small Companies	n/a	40.9%	37.8%	35.6%	39.2%
Medium Companies	n/a	34.7%	37.1%	34.1%	37.5%
Large Companies	n/a	15.4%	16.1%	15.9%	17.7%
Total	**n/a**	21.0%	20.7%	20.8%	22.7%
Average percentage of annual production tonnage withdrawn across all companies of different size					
Micro companies	n/a	0.7%	2.0%	3.0%	5.9%
Small Companies	n/a	0.4%	1.6%	2.7%	5.8%
Medium Companies	n/a	0.5%	2.9%	2.9%	6.6%
Large Companies	n/a	0.4%	2.2%	2.5%	5.7%
Total	**n/a**	0.5%	2.2%	2.6%	5.9%

5.2.3 Annual Income foregone owing to withdrawal - MIs

In terms of the financial impact of withdrawal on these companies, Table 5-6 provides the total annual income foregone by companies of different sizes and the average annual income foregone per company by size. The numbers of companies (expressed as numbers and percentage of the total number of companies) from Table 5-2 are also provided as context. Thus, for example, under Option D, 10 micro companies (1.4% of the total) would withdraw one or more substances where this would represent an income foregone of around €7,700 on average per company per year for five years (or €77,000 per year across all 10 micro companies).

Variation between companies of different sizes

In terms of variations in the scale of impacts between companies of different sizes (and the potential for disproportionate impacts on smaller companies), under all of the options the income forgone owing to withdrawal is similar across companies of all sizes and, if anything, slightly higher for larger enterprises suggesting that effects measured in terms of income foregone are not obviously disproportionate. That said, any income losses are likely to be much more easily absorbed by larger companies (so while impacts might not be obviously disproportionate, they may not be proportionate either).

Table 5-6: Annual Income foregone owing to withdrawal					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Total number of companies in size category withdrawing one or more substances					
Micro companies	0	10	28	50	88
Small Companies	0	12	48	85	164
Medium Companies	0	19	101	112	230
Large Companies	0	146	721	815	1,678
Total	**0**	**187**	**898**	**1,062**	**2,160**
Percentage of total companies in size category withdrawing one or more substances					
Micro companies	n/a	1.4%	3.8%	6.8%	11.9%
Small Companies	n/a	1.1%	4.3%	7.7%	14.8%
Medium Companies	n/a	1.5%	7.8%	8.6%	17.7%
Large Companies	n/a	2.8%	13.8%	15.6%	32.2%
Total	**n/a**	**2.2%**	**10.7%**	**12.7%**	**25.8%**
Total annual income foregone (annually for five years - € million)					
Micro companies	n/a	€ 0.08	€ 0.24	€ 0.40	€ 0.81
Small Companies	n/a	€ 0.09	€ 0.46	€ 0.68	€ 1.61
Medium Companies	n/a	€ 0.14	€ 1.00	€ 0.88	€ 2.21
Large Companies	n/a	€ 1.09	€ 7.14	€ 6.57	€ 17.90
Total	**n/a**	**€ 1.40**	**€ 8.84**	**€ 8.52**	**€ 22.52**
Average annual income foregone per company (annually for five years - € thousand)					
Micro companies	n/a	€ 7.67	€ 8.63	€ 7.96	€ 9.18
Small Companies	n/a	€ 7.58	€ 9.57	€ 7.97	€ 9.79
Medium Companies	n/a	€ 7.54	€ 9.88	€ 7.85	€ 9.59
Large Companies	n/a	€ 7.47	€ 9.90	€ 8.06	€ 10.67
Overall	**n/a**	**€ 7.50**	**€ 9.84**	**€ 8.03**	**€ 10.42**

5.3 Impact of substance withdrawal on downstream users (DUs)

5.3.1 Costs and impacts

The overall costs of substance withdrawal to DUs have been described in Section 4.2.3 where these focus on the costs of reformulation to DUs after the withdrawal of substances from the market by MIs. As can be seen from the summary Table 5-7, DU costs of substance withdrawal (maximum costs of reformulation) makes up between 0% and 34% of the total cost of the baseline and options to DUs (and between 0% and 18% overall).

Table 5-7: DU costs of substance withdrawal (all values expressed as Present Values discounted at 4%)					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Costs of Withdrawal					
DU costs of withdrawal (maximum reformulation cost) (€ millions)	€ 0.0	€ 14.0	€ 88.4	€ 85.2	€ 225.2
Total costs to DUs (€ millions)	€ 12.0	€ 60.7	€ 287.7	€ 268.6	€ 671.4
Total costs (€ millions)	**€ 24.1**	**€ 114.5**	**€ 531.2**	**€ 494.5**	**€ 1,230.1**
DU costs of withdrawal as % of total cost to DUs	0%	23%	31%	32%	34%
DU costs of withdrawal as % of total costs (MIs and DUs)	0%	12%	17%	17%	18%

In terms of the impacts on individual downstream users, little is known about the numbers of downstream users other than, despite the low tonnages involved, there may be several on average, each using low volumes of the substances.

An estimate has been made on the cost of each option to individual downstream users by assuming two uses per substance and 30 DUs per use on average (i.e. 60 DUs per substance on average)[20]. This results in the average cost per downstream user provided in Table 5-8. As can be seen from the table, average costs per DU are fairly similar across the options ranging between €1,250 and €1,500 per substance per DU under the options involving withdrawal. The more significant factor governing the total costs of withdrawal for DUs is the number of substances withdrawn (and hence number of products that will need to be re-formulated and number of DUs affected). As there may be more than one withdrawn substance in each DU product for re-formulation, however, it cannot be assumed that each substance withdrawn equals one product reformulated. I.e. there will be some overlap but the extent of this overlap is not known.

[20] Where this is the middle scenario used in the calculation of the costs of the CSA/CSR requirement for CMRs 1A/1B and the calculation of benefits across all options.

Table 5-8: Reformulation costs to Downstream Users					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Total number of substances withdrawn	0	187	956	1,132	2,525
Maximum total cost of re-formulation - (€ millions)	n/a	€ 14.0	€ 88.4	€ 85.2	€ 225.2
Average maximum total cost of re-formulation per substance (€s)	n/a	€ 74,970	€ 92,433	€ 75,308	€ 89,176
Number of Dus impacted	n/a	11,220	57,360	67,920	151,500
Average cost per downstream user (€s)	n/a	€ 1,250	€ 1,541	€ 1,255	€ 1,486

5.4 Impact of revising and upgrading dossiers on manufacturers and importers (MIs)

5.4.1 Costs and impacts

The total costs of revising/upgrading dossiers to MIs have been described in Section 4.3.1 and costs are summarised in Table 5-9. The data suggest that MI costs of revising/upgrading under the options make up the majority of the cost to MIs as a whole and between 36% and 50% of the total costs of the options (to MIs and DUs). The relative weight of the revising/upgrading costs within the total costs to MIs is lower for the higher options because of the higher number of substances are withdrawn from the market in the higher options.

Table 5-9: Summary and total costs of the options (values expressed as Present Values discounted at 4%)					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
MI costs of upgrading/revising registrations (€m)	€ 12.0	€ 46.7	€ 199.3	€ 183.3	€ 446.2
Total Costs to MIs (€m)	€ 12.0	€ 53.7	€ 243.5	€ 225.9	€ 558.8
Total costs (€ m)	**€ 24.1**	**€ 114.5**	**€ 531.2**	**€ 494.5**	**€ 1,230.1**
MI costs of upgrading/revising as % of total cost to MIs	100%	87%	82%	81%	80%
MI costs of upgrading/revising as % of total costs (MIs and DUs)	50%	41%	38%	37%	36%

Where Section 4.3.1 has focussed on the costs of registering substances on a substance by substance basis, this section explores the impact of registration viewed across all of the substances in the portfolios of companies of different sizes and, hence, on company profit and loss accounts overall.

Variation between companies of different sizes

In terms of variations in the scale of impacts between companies of different sizes (and the potential for disproportionate impacts on smaller companies), Table 5-10 provides the average cost of revising/upgrading dossiers for companies of each size category. These costs are averaged out across all of the substances in the portfolios of each of the companies registering in the simulation and so provide information on the magnitude of costs absorbed for every substance registered. These costs are also provided per tonne of substance produced (over a five year period – so 10t of annual production = 50t total in the period).

As can be seen from the table, for each of the options costs per substance (and per tonne of substance) vary only slightly between the micro, small and medium enterprises but are generally slightly lower for the micro and small SMEs.

Table 5-10: Average costs of substance registration for MIs					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Average cost of registering a substance (across all substances in company portfolios)					
Micro companies	€ 236	€ 888	€ 4,077	€ 4,310	€ 10,275
Small Companies	€ 253	€ 943	€ 4,183	€ 4,419	€ 10,664
Medium Companies	€ 279	€ 1,137	€ 4,631	€ 4,444	€ 10,848
Large Companies	€ 266	€ 1,038	€ 4,520	€ 4,085	€ 10,369
Total	**€ 266**	**€ 1,035**	**€ 4,492**	**€ 4,147**	**€ 10,427**
Average cost of registering a substance per tonne of produced (across all substances in company portfolios)					
Micro companies	€ 5	€ 20	€ 91	€ 96	€ 231
Small Companies	€ 6	€ 21	€ 93	€ 98	€ 237
Medium Companies	€ 6	€ 25	€ 102	€ 98	€ 240
Large Companies	€ 6	€ 23	€ 100	€ 90	€ 229
Total	**€ 6**	**€ 23**	**€ 99**	**€ 92**	**€ 231**

Change in company average per substance registration costs between options

Working from the baseline and through the options the following changes in company average per substance registration costs are predicted:

- ***Baseline:*** under the baseline the Annex III and Annex VII information requirements would remain unchanged, there would be no requirement to revise/update dossiers and costs would be zero;

- ***Option A (Annex VII+ and Current Annex III):*** Retaining the current Annex III criteria but slightly adding to the toxicicological and ecotoxicological information required (Annex VII+) will affect only substances that have submitted full registration dossiers for 2018 where these will have to supply additional information. The Monte Carlo simulation suggests that

revising/upgrading the dossiers with the new information will cost around **€266 per substance** on average;

- ***Option D (Annex VII+ and Annex III with ND):*** As with Option A, slightly increasing the level of toxicicological and ecotoxicological information required (Annex VII+) will affect substances that have submitted full registration dossiers for 2018. Revising/upgrading these dossiers with the new information will cost on average €266 per substance (as with Option A). As well as this, the removal of the diffuse/dispersive use criterion (ND) from Annex III will result in additional substances being required to provide full toxicological/ecotoxicological information[21] (and at the higher Annex VII+ level) at a cost of around €769 per substance on average to give a total average cost of **€1,035 per substance** on average;

- ***Option B (Annex VII++ and Annex III with ND):*** As with Option D, this option involves removal of the diffuse/dispersive use criterion (ND) from Annex III with the result that additional substances would be required to provide full toxicological/ecotoxicological information[21]. However, it also extends the information requirements further (to Annex VII++) for these substances and also for those that have submitted full registration dossiers for 2018. Registration dossiers for these (latter) substances would have to be revised/upgraded with the new (Annex VII++) information. The Monte Carlo simulation suggests that these changes would have a cost of **€4,492 per substance** on average;

- ***Option C (Annex VII+ and No Annex III):*** As with Options A and D, slightly increasing the level of toxicicological and ecotoxicological information required (Annex VII+) will affect substances that have submitted full registration dossiers for 2018. Revising/upgrading these dossiers with the new information will cost on average €266 per substance (as with Option A). As well as this, the removal of Annex III criteria will mean that all other substances (i.e. those for which 2018 registration contained physico-chemical data only) would be required to provide full toxicological/ecotoxicological information (and at the higher Annex VII+ level) at a cost of around €3,881 per substance on average to give a total cost of **€4,147 per substance** on average;

- ***Option E (Annex VII++ and No Annex III):*** As with Option C, this option involves removal of Annex III criteria with the result that additional substances would be required to provide full toxicological/ecotoxicological information. However, it also extends the information requirements further (to Annex VII++) for these substances and also for those that have submitted full registration dossiers for 2018. Registration dossiers for these (latter) substances would have to be revised/upgraded with the new (Annex VII++) information. The Monte Carlo simulation suggests that these changes would cost **€10,427 per substance** on average.

Variations in costs

As with any averages, those provided in Table 5-12 above conceal a variation in costs from one company to another. Figure 5-1 and Figure 5-2 provide average per company costs per substance

[21] Substances identified by QSARs and other information as likely to have any human health or environmental classifications but without any diffuse/dispersive uses.

(Figure 5-1) and per tonne of substance (Figure 5-2) graphically, showing the frequency distribution of different magnitudes of costs faced by companies under the different options. From this it can be observed that:

- ***Option A (Annex VII+ and Current Annex III):*** As the cost of increasing toxicicological and ecotoxicological information required (to Annex VII+ levels) only affects substances that have submitted full registration dossiers for 2018, for a large percentage of companies there are no or low costs. Higher costs are faced by companies with several substances requiring the additional information and there are no costs for substances for which only physico-chemical information is required;

- ***Option D (Annex VII+ and Annex III with ND):*** As with Option A, Option D affects substances that have submitted full registration dossiers for 2018. However, the removal of the diffuse/dispersive use criterion (ND) from Annex III results in additional substances being required to provide (Annex VII+ level) toxicological/ecotoxicological information[22], changing the distribution of company costs;

- ***Option B (Annex VII++ and Annex III with ND):*** The same distribution trend as Option D (Annex VII+ information) is accentuated under Option B as the requirements for still higher information under Annex VII++ increases the costs for both substances already registered with full Annex VII information in 2018 and those with physico-chemical only data in their 2018 registrations;

- ***Option C (Annex VII+ and No Annex III):*** Option C requires that all substances submit full Annex VII+ data. This is relatively low cost for substances already registered with full Annex VII data but higher for substances registered only with physico-chemical data. The greater the proportion of physico-chemical only registrations in a company's portfolio, the higher the cost and so the distribution of costs is wider; and

- ***Option E (Annex VII++ and No Annex III):*** Option E is as Option C but with higher information and associated costs to upgrade to Annex VII++ levels, further widening the cost distribution curve.

[22] Substances identified by QSARs and other information as likely to have any human health or environmental classifications but without any diffuse/dispersive uses.

Figure 5-1: Average cost of upgrading/revising registrations for MIs per substance in portfolio

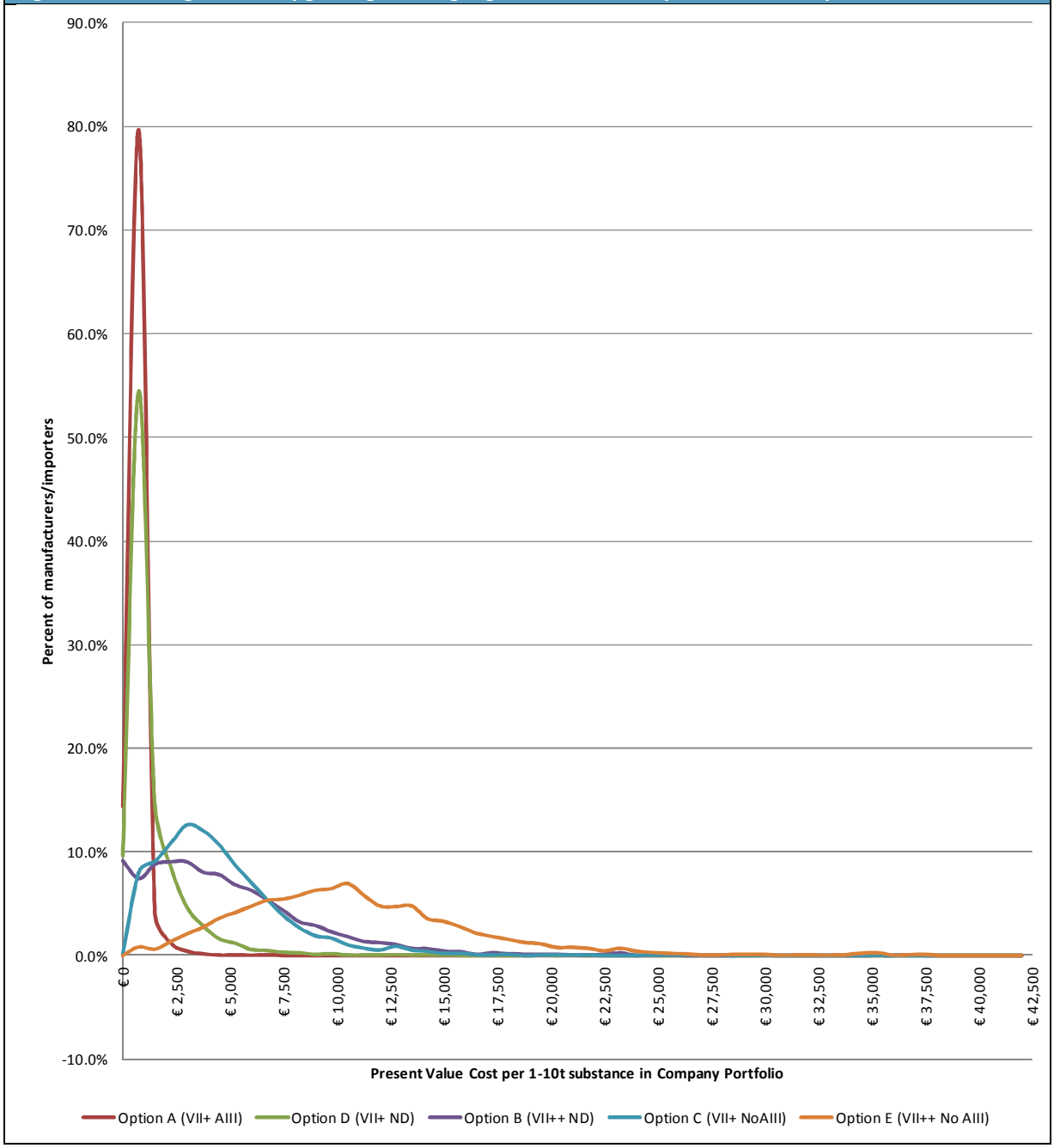
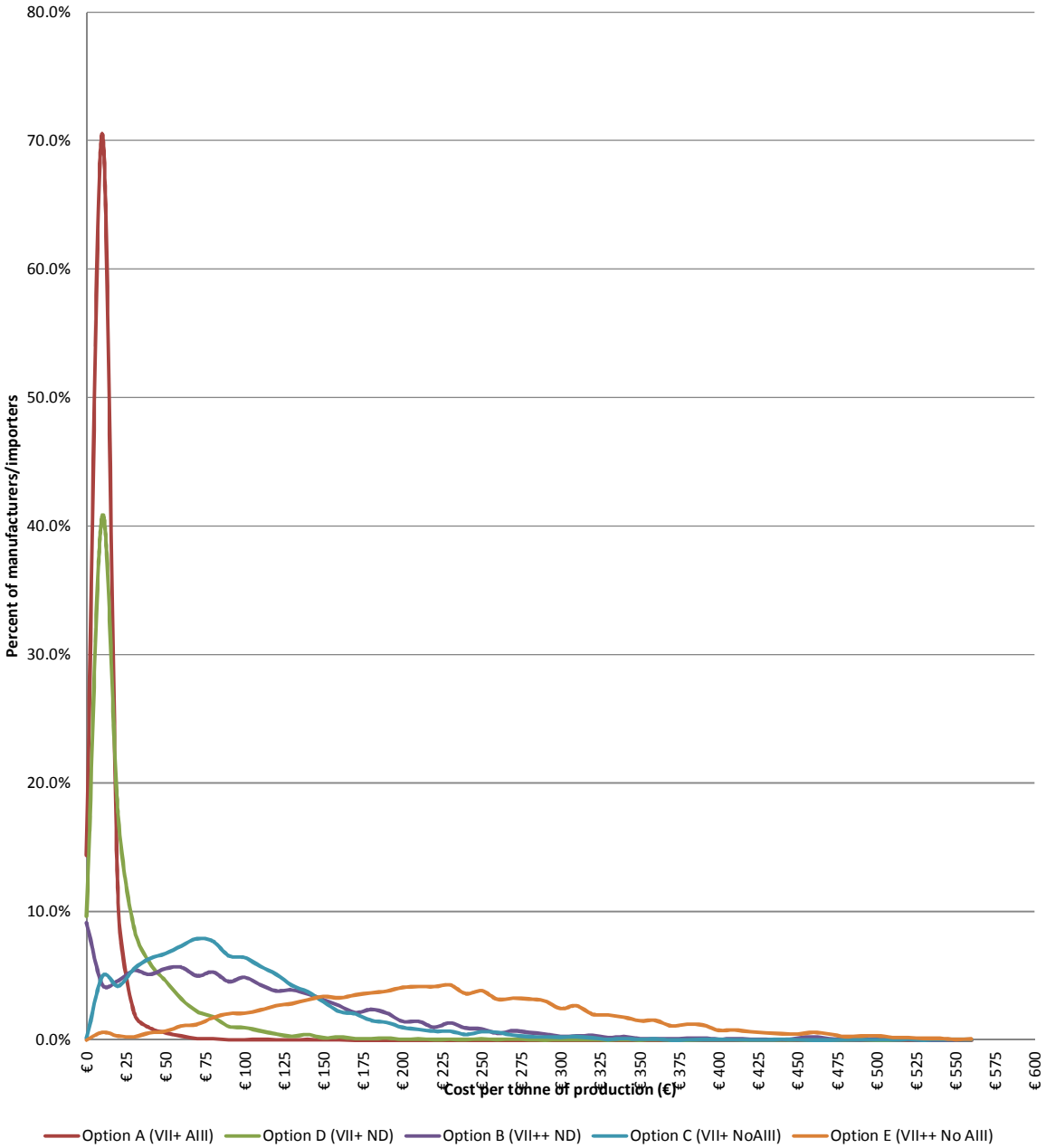


Figure 5-2: Cost of upgrading/revising registrations for MIs per tonne of chemical produced (and registered)



5.5 Impact of revising/upgrading dossiers on downstream users (DUs)

5.5.1 Cost and impact

The overall costs of revising/upgrading registration dossiers to DUs have been described in Section 4.3.1 where these are associated with 50% of the costs of substance registration being passed on to DUs in prices. Costs are summarised in Table 5-11 showing that DU costs of revising/upgrading make up between 66% and 100% of the total cost of the options to DUs (and between 36% and 50% overall). As for the MIs, the relative weight of the revising/upgrading costs within the total costs to DUs is lower for the higher options because of the higher number of substances that are withdrawn from the market in the higher options.

Table 5-11: Summary and total costs of the options (all values expressed as Present Values discounted at 4%)

	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
DU costs of upgrading/revising registrations (€ millions)	€ 12.0	€ 46.7	€ 199.3	€ 183.3	€ 446.2
Total costs to DUs (€millions)	€ 12.0	€ 60.7	€ 287.7	€ 268.6	€ 671.4
Total costs (€ millions)	**€ 24.1**	**€ 114.5**	**€ 531.2**	**€ 494.5**	**€ 1,230.1**
DU costs of upgrading/revising registrations as % of total cost to DUs	100%	77%	69%	68%	66%
DU costs of upgrading/revising registrations as % of total costs (MIs and DUs)	50%	41%	38%	37%	36%

In terms of the impact of costs on individual DUs through price rises, little is known about the numbers of downstream users other than, despite the low tonnages involved, there may be several on average, each using low volumes of the substances.

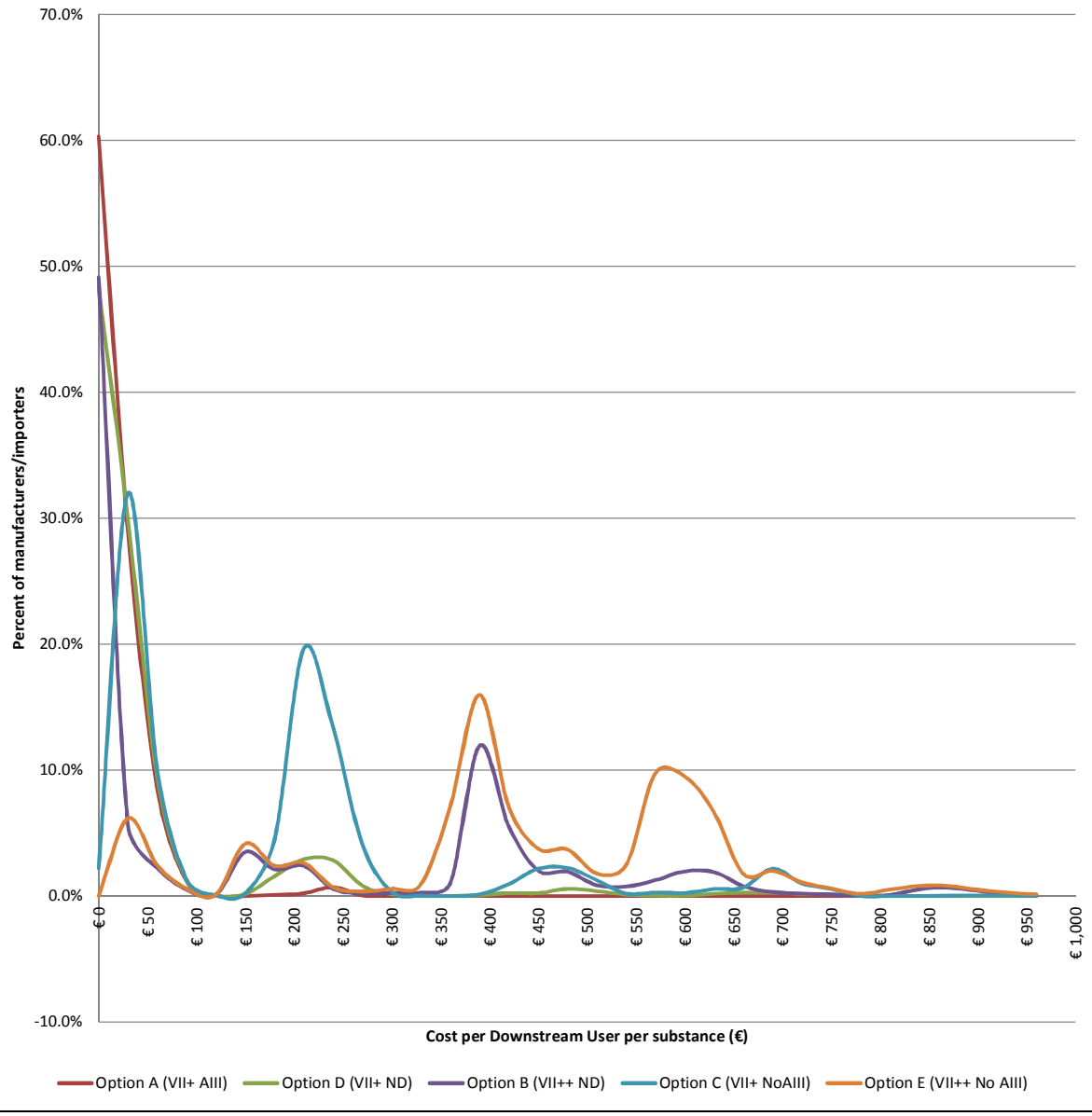
An estimate has been made on the cost of each option to individual downstream users by assuming two uses per substance and 30 DUs per use on average (i.e. 60 DUs per substance on average)[23]. This results in the total overall cost per substance per downstream user provided in Table 5-12. As can be seen from these data, ranging between €10 and €436 per substance per DU, the average cost varies significantly between the options. Whilst the differences in the cost of additional information

[23] Where this is the middle scenario used in the calculation of the costs of the CSA/CSR requirement for CMRs 1A/1B and the calculation of benefits across all options.

under different options plays some part in this variation, the dominant factor is that of the number of substances requiring any additional information (owing to differences between options in terms of the Annex III criteria) and, consequently, the number of DUs facing increased costs. There is, therefore, substantial variation around the average. This variation in costs to DUs between options is provided graphically in Figure 5-3, showing the frequency distribution of different magnitudes of costs under the different options.

Table 5-12: Average costs of upgrading/revising registrations for Downstream Users					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Total number of substances registered	19,600	19,413	18,644	18,468	17,075
Average cost of registration for DUs per substance (€s)	€ 614	€ 2,407	€ 10,691	€ 9,926	€ 26,131
Average price increase per DU per substance (€s)	€ 10	€ 40	€ 178	€ 165	€ 436

Figure 5-3: Average cost of upgrading/revising registrations per DU per substance



6 Cost of the option to require a CSA/CSR for CMRs 1A/1B

6.1 Estimation of unit costs per CMR 1A/1B substance undergoing CSA/CSR

6.1.1 Overview

The costs of the option of extending REACH CSA/CSR obligations (Article 14(1)) to all 1-10t substances known or expected to meet criteria for CMR 1A/1B have been considered in combination with the baseline (as a CSA/CSR option alone) and also in combination with each of the other Options A to E).

As described in the scoping of impacts in Section 3.1.2, costs under the CSA/CSR option can be divided up into the following costs to MIs:

- Human Health and Environmental Hazard Assessment and the provision of robust study summaries;
- PBT/vPvB screening and assessment;
- Human Health Exposure Assessment and Risk Characterisation;
- Environmental Exposure Assessment and Risk Characterisation; and
- Communication in the supply chain.

DUs will also be impacted and there are cost implications in relation to:

- The duty to pass information sufficient for an Exposure Assessment up the supply chain;
- The duty under Article 37(4) to prepare a CSR in Accordance with Annex XII; and
- Reduced costs of compliance with parallel regulation.

To capture a range of possibilities and uncertainties concerning numbers of DUs as well as other factors, a low/medium/high scenario approach has been applied to the cost of the individual elements. The estimation and analysis of these costs is described in the following sub-sections.

6.1.2 Costs to Manufacturers and Importers

Human Health and Environmental Hazard Assessment

For MIs, the following costs apply:

- Production of robust study summaries in relation to the human health hazard assessment (upgraded from study summaries currently required in the dossier); and
- Production of robust study summaries in relation to environmental hazard assessment (upgraded from study summaries currently required in the dossier).

Owing to the fact that the information generated for a substance differs between the information options (A to E) and also the baseline (current requirements), the total cost of upgrading studies from 'simple' summaries to robust summaries will be different for each option and the baseline.

To capture these differences in the analysis, estimates have been made of the cost of upgrading for the following three different types of endpoint – each varying in terms of likely complexity:

- Standard tests excluding GM Bact;
- Mutagenicity and further mutagenicity; and
- Any additional tests under the options (including PBT screening/assessment).

Table 6-1 below provides the estimates of the costs of upgrading to Robust Study Summaries used in the analysis.

Table 6-1: Cost of Producing Robust Study Summaries	
	Cost of upgrading study summaries to robust study summaries (€ per study required)
Standard tests excluding GM Bact	€ 300
Mutagenicity and further mutagenicity	€ 500
Others	€ 400

PBT/vPvB Screening and Assessment

No additional information is required to carry out screening and assessment for PBT/vPvB properties under the Information Option A to E because this is already integrated into the information requirements of these options.

In the case of the baseline (Annex VII) situation, however, the requirements in relation to PBT/vPvB assessment are additional. As with the options, PBT/vPvB screening is assumed to cost €750 per substance. Where the screening suggests that the substance meets the criteria in Annex XIII full assessment is required which will require the generation of more information. As with the information options (A to E) this is estimated to cost €20,000 per substance. Per substance costs are summarised in the table below.

Table 6-2: Cost of PBT/vPvB Screening and Assessment	
Cost of PBT Screening per substance	€ 750
Cost of PBT Assessment per substance	€ 20,000

Human Health Exposure Assessment and Risk Characterisation

Manufacturers would have to consider downstream uses of the substance in the CSA and exposure assessment and recommend risk management measures and the technical means to achieve them.

At the same time, where the substance is a non-threshold CMR 1A/1B substance (as will be the case in 70% of cases according to information supplied to the study by ECHA), the emphasis of the exposure scenarios and risk management measures will be on closed systems and the technical means to achieve them.

The measures and technical means applied for the manufacturers' own uses (as should already be identified under parallel regulation for substances with known C, M or R 1A/1B properties or will be required in the case of substances yet to be identified and classified) may also be relevant and sufficient to cover downstream uses. Here, as noted in paragraph 0.8 of Annex I "*Exposure scenarios*

may describe the appropriate risk management measures for several individual processes or uses of a substance". As such, one exposure scenario may be sufficient to cover multiple uses and processes.

Thus, it cannot be automatically assumed that a different exposure scenario will be required for each use (including the manufacturers' own use). One may be sufficient to cover all and, where the exposure and risk management measures for manufacturer's own use are sufficient to cover the downstream uses, there are no additional costs. However, for a number of cases the exposure scenario for a manufacturer's own use may not cover the other uses (where this includes the assessment of consumer exposures for identified uses). For the purpose of the analysis, where the exposure scenario for a manufacturer's use does not cover all uses it has been assumed that an exposure scenario is required for each additional use (where this may be an exaggeration of the numbers of additional scenarios required).

Environmental Exposure Assessment and Risk Characterisation

In relation to the assessment of environmental exposures for identified uses (including the manufacturers' own uses) this is not currently required under parallel regulation. As such, this represents an additional cost.

As with the human health exposure assessment, it should not be automatically assumed that a different exposure scenario will be required for each use (including the manufacturer's own use). One exposure scenario may be sufficient to cover multiple uses and processes. The same assumptions have been applied as for human health.

Estimation of Costs of Exposure Assessment and Risk Characterisation

The estimated costs of exposure assessment and risk characterisation are provided in Table 6-3 below. These assume that the exposure scenario for a manufacturer's own use also covers downstream uses for a percentage of substances (with this varying by scenario as shown in the table). For the remaining substances, separate assessments for each use must be generated. No grouping of uses is assumed (meaning that one exposure scenario will be produced for each use - which may exaggerate the actual costs of producing exposure scenarios).

Table 6-3: Cost of Human Health and Environmental Exposure Assessments and Risk Characterisation

Scenario	Low	Medium	High
Percentage of substances where the exposure scenarios for the manufacturer's own use also covers downstream uses	90%	50%	20%
Number of uses per substance	1	2	5
Cost of Human Health Exposure Assess and Risk Characterisation per use	€ 1,500	€ 3,000	€ 5,000
Cost of Environmental Exposure Assess and Risk Characterisation per use	€ 1,000	€ 2,000	€ 3,000

Communication in the Supply Chain

The addition of the following elements to provide an extended SDS would represent an additional administrative burden on manufacturers and importers over and above what is required at present:

- adding the results of the PBT/vPvB assessment to the SDS;

- expanding sections of the SDS in relation to, in particular, Sections 7 and 8 (Handling and storage; Exposure controls/personal protection) to reflect the relevant risk management measures and the technical means to achieve them; and
- including the relevant exposure scenario(s) in an annex to the SDS.

Estimated costs of communication in the supply chain are provided in Table 6-4 below for the three scenarios (low, medium and high). The estimates include the costs of translation which is assumed to be required for 50% of substances (for all uses and exposure scenarios). Translation into three languages is assumed at a cost of €150 per language (€450 in total).

Table 6-4: Costs of Communication in the Supply Chain			
	Low	Medium	High
Cost of adding the results of the PBT/vPvB assessment to the SDS per substance	€ 10	€ 10	€ 10
Cost of expanding sections of the SDS in relation to Sections 7 and 8 (Handling and storage; Exposure controls/personal protection) per use	€ 50	€ 50	€ 50
Cost of including the relevant exposure scenario(s) in an annex to the SDS per use	€ 200	€ 300	€ 500
Percentage of substances where translation of eSDS will be needed	30%	50%	70%
Number of languages to translate into	3	3	3
Cost of translation per language	€ 100	€ 150	€ 200

Resulting overall average costs per substance for CSA/CSR

The average costs to MIs per substance for CSA/CSR generated by all of the cost inputs and scenarios discussed above are provided in the table below for each information option (A to E) and for known (already registered) CMRs 1A/1B. As can be seen from the table, the average costs per substance vary from the baseline and also from one option to another. As has been highlighted in the text above in relation to each cost element, this is because there are differences between the baseline and each option regarding:

- the information that must be generated (and hence the number of study summaries that must be updated to robust study summaries); and
- the cost of PBT/vPvB screening and assessment (where this already forms a part of Options A to E and hence is only additional for the baseline Annex VII situation).

Table 6-5: Average per substance costs to Manufacturers/Importers			
	Low scenario	Medium scenario	High scenario
Baseline	€ 4,676	€ 10,180	€ 40,857
Option A	€ 4,183	€ 9,687	€ 40,364
Option D	€ 4,179	€ 9,691	€ 40,340
Option B	€ 4,920	€ 10,446	€ 41,059
Option C	€ 4,185	€ 9,692	€ 40,410
Option E	€ 4,919	€ 10,447	€ 41,199
All known CMRs 1A/1B already registered	€ 1,357	€ 6,727	€ 36,989

6.1.3 Costs to Downstream Users

Duty to Pass Information Sufficient for an Exposure Assessment up the Supply Chain

For all of the 1-10t CMRs 1A/1B under the CSA/CSR option, documentation that is useful for the exposure assessment must be passed up the supply chain by DUs. This requires an amount of additional time.

Table 6-6 below provides estimates of the number of uses, DUs and costs to each DU for passing information up the supply chain for each of the scenarios (low, medium and high).

Table 6-6: Cost of Passing Information up the Supply Chain			
	Low	Medium	High
Number of uses per substance	1	2	5
Number of Downstream Users (DUs) per use	20	30	40
Cost for DU to provide information to Human Health Exposure Scenario	€ 200	€ 350	€ 500
Cost for DU to provide information to Environmental Exposure Scenario	€ 200	€ 350	€ 500

Article 37(4) - Duty to prepare a CSR in Accordance with Annex XII

Article 37(4) requires a DU to prepare a CSR in accordance with Annex XII for any use outside either the conditions described in an exposure scenario or a use and exposure category in a SDS or for any use his supplier advises against.

Whilst it is unlikely that a downstream user would consider using a substance classified as C, M or R 1A/1B for a use advised against or not included as an identified use in a CSA, downstream users are already required to undertake risk assessments of their own uses under several pieces of parallel regulation including worker health and safety and product safety regulation.

That said, some additional work may be required in relation to environmental risk and exposure in these (probably rare) cases. This does not extend to PBT/vPvB assessment as no separate assessment is required from that already carried out by the MI.

The table below provides estimated costs for Article 37(4) provisions to DUs. The provisions are assumed to apply to 5% of substances, requiring production of an Annex XII CSA for an additional use not covered in the MI CSA/CSR.

Table 6-7: Cost of CSAs under Article 37(4)			
	Low	Medium	High
Percentage of substances where Article 37(4) might apply	5%	5%	5%
Cost of Environmental Exposure Assess and Risk Characterisation per use	€ 1,000	€ 2,000	€ 3,000
Costs of Communication in the Supply Chain	As described above in relation to MIs' CSA/CSR		

Resulting overall average costs per substance for CSA/CSR

The average costs to DUs per substance for CSA/CSR generated by all of the cost inputs and scenarios discussed above are provided in the table below for each information option (A to E) and for known (already registered) CMRs 1A/1B.

Table 6-8: Average per substance costs to Downstream Users			
	Low scenario	Medium scenario	High scenario
Baseline	€ 8,068	€ 42,130	€ 200,199
Option A	€ 8,068	€ 42,130	€ 200,199
Option D	€ 8,068	€ 42,130	€ 200,199
Option B	€ 8,068	€ 42,130	€ 200,199
Option C	€ 8,068	€ 42,130	€ 200,199
Option E	€ 8,068	€ 42,130	€ 200,199
All known CMRs 1A/1B	€ 8,068	€ 42,130	€ 200,199

6.1.4 Cost of Compliance with Parallel Legislation

An important positive impact of the CSA/CSR option is that the provision of a CSA/CSR by MIs negates or reduces compliance costs associated with the many regulatory instruments that are triggered by classification of CMR 1A/1B in accordance with Regulation (EC) No 1272/2008. Here, in the event that a substance is identified as meeting the criteria, the change in classification triggers actions on the part of manufacturers, importers and downstream users to comply with other pieces of community regulation covering areas including worker health and safety, product safety, and waste. Each area of regulation requires action to assess exposure, risks and implement risk management measures. The key requirements are summarised below.

Worker Health and Safety Regulation

Key regulations and associated requirements in relation to worker health and safety include:

- Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD) – which requires employers (i.e. manufacturers and downstream users) to determine whether any hazardous chemical agents are present at the workplace and assess any risk to the safety and health of workers arising from the presence of those chemical agents;
- Carcinogens and Mutagens Directive 2004/37/EC (CMD) – which requires that, as a priority, workers' exposure must be prevented through substitution. If not possible, the employer shall use a closed technological system. Where a closed system is not technically possible, the employer shall reduce exposure to a minimum through a number of risk management measures specified in the Directive;
- Pregnant and Breastfeeding Workers Directive 92/85/EEC – which requires that the employer shall assess the nature, degree and duration of exposure, assess any risks to the safety or health and any possible effects on the pregnancy or breastfeeding of workers and then decide what measures should be taken; and
- Directive 94/33/EC on Young Workers – under which employers are obliged to assess the hazards to young people, generate new site-specific data on the nature, degree and duration of exposure to chemical agents and adopt the measures necessary to protect the safety and health of young people.

At present, as there is no obligation to conduct a CSA under REACH, there is no obligation to provide exposure scenarios detailing the technical means to achieve risk management for identified uses in an extended SDS in relation to human exposures in the workplace. As such, under this parallel regulation, in the absence of a CSA/CSR, each manufacturer and downstream user must conduct their own bespoke assessments of exposure, risk and identification of risk management measures based on the general information provided in the SDS.

Compliance with Product Safety Requirements

In addition to worker health and safety requirements, classification as C, M or R 1A/1B has implications in terms of safety of products. Annex XVII of REACH (entries 28 to 30) prohibits the placing on the market and the use of CMRs 1A/1B as substances or as constituents of other substances or mixtures for supply to the general public when the individual concentration in the substance or the mixture is equal to or greater to the generic/specific concentration limit of Regulation (EC) No 1272/2008. Currently consumer articles are not in the scope of the entries 28 to 30, but some specific legislation applies to some of these articles and all products in general. This includes:

- Directive 2001/95/EC on General Product Safety - under Article 3 of the GPSD producers are obliged to place only safe products on the market. Assessment of the risk to consumers from the presence of a CMR substance in a product would be required where this would include consideration of human exposure to the substance from use of the product;
- Regulation No 305/2011 for the Marketing of Construction Products - all manufacturers of construction products containing substances identified with C, M or R properties must consider the implications of this in terms of risk and safety of their products; and
- Toys Directive 2009/48/EC - Article 18 of the Toy Safety Directive requires manufacturers, before placing a toy on the market, to carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards.

To comply with their obligations, manufacturers of products containing 1-10t CMRs 1A/1B substances would have to rely on the general information presented in the SDS to complete their assessments where this will not include detailed information on the technical considerations in relation to exposure, risk and safety (as no CSA is required).

Compliance with Waste Regulation

The Waste Framework Directive 2008/98/EC sets a definition of hazardous waste as waste that fulfils certain properties where these properties include carcinogenic, toxic for reproduction or mutagenic properties, where this would apply in relation to waste containing 1-10t substances classified as C, M or R 1A/1B. This would require the determination of safe and environmentally preferred waste management options.

In relation to the 1-10t substances, the information provided in the SDS in respect of waste management will be of a general nature with no specific quantitative analysis of risk and exposure in relation to the recommended risk management measures in relation to waste and the technical means to achieve this (as no CSA is required).

Estimated cost of compliance with parallel regulations

For 1-10t substances for which mutagenic properties are, as yet, unidentified (and the substance is not yet registered), downstream users will not have compiled the information necessary to comply with parallel regulation (because, currently, the substance is not classified for mutagenicity). For these substances, the CSAs/CSRs provided under the CSA/CSR option would provide compliance with other parallel regulation or greatly facilitate that compliance. Moving responsibilities from the DUs to the MIs in this way is likely to benefit multiple downstream users of each substance and reduce duplication of effort significantly.

Estimates of the cost of compliance with parallel regulation in the absence of CSA/CSR are provided in the table below for the low, medium and high scenarios. These assume that assessments for compliance with parallel legislation (using the general information currently required to be provided in the SDS for a substance) would cost each downstream user between €1,500 and €3,500 for substances with (as yet) unidentified 'CMR 1A/1B' properties. For known 1-10t CMRs 1A/1B it is assumed that all downstream users have already complied with requirements under parallel regulation and, as such, for known CMRs there are no cost-savings to DUs from undertaking CSA/CSR.

Table 6-9: Costs of Compliance with Parallel Regulation under the existing arrangements (no CSA/CSR for 1-10t CMRs 1A/1B)

	Low	Medium	High
Number of uses per substance	1	2	5
Number of Downstream Users (DUs) per use	20	30	40
Cost for a DU to conduct assessments to comply with parallel regulation	€ 1,500	€ 2,500	€ 3,500

Resulting overall average cost of complying with existing requirements under parallel legislation

The average cost of complying with existing requirements under parallel legislation generated by all of the inputs and scenarios discussed above are provided in Table 6-11 below for each information option (A to E) and for known (already registered) CMRs 1A/1B.

Under the CSA/CSR option, the costs of compliance with parallel legislation are zero under the baseline and other information options because the CSA/CSR provides this compliance. Thus, the compliance costs in Table 6-10 are predicted savings that can be deducted from the costs of providing a CSA/CSR under the CSA/CSR option.

Table 6-10: Average per substance cost of complying with existing requirements on CMRs 1A/1B under existing arrangements under parallel legislation

	Low scenario	Medium scenario	High scenario
Baseline	€ 30,000	€ 150,000	€ 700,000
Option A	€ 30,000	€ 150,000	€ 700,000
Option D	€ 30,000	€ 150,000	€ 700,000
Option B	€ 30,000	€ 150,000	€ 700,000
Option C	€ 30,000	€ 150,000	€ 700,000
Option E	€ 30,000	€ 150,000	€ 700,000
All known CMRs 1A/1B	€ 0	€ 0	€ 0

Setting these cost savings against the costs of duties to pass information up the supply chain and of Article 37(4) (see Table 6-8), results in the average net costs per substance to DUs in Table 6-11 below.

Table 6-11: Average per substance net costs of the CSA/CSR option to Downstream Users (a negative cost is a benefit)			
	Low scenario	Medium scenario	High scenario
Baseline	-€ 21,933	-€ 107,871	-€ 499,801
Option A	-€ 21,933	-€ 107,871	-€ 499,802
Option D	-€ 21,933	-€ 107,871	-€ 499,801
Option B	-€ 21,933	-€ 107,871	-€ 499,801
Option C	-€ 21,933	-€ 107,871	-€ 499,802
Option E	-€ 21,933	-€ 107,871	-€ 499,802
All known CMRs 1A/1B	€ 8,068	€ 42,130	€ 200,199

6.2 Aggregated costs of the CSA/CSR option to MIs and DUs of CMR substances

6.2.1 Approach to aggregation

To estimate the total cost of the CSA/CSR option applied to the baseline and each of the information options, the unit costs of undertaking CSA/CSR described in Section 6.1 must be applied to the numbers of CMRs identified under each of the options. Here, while there are 56 known CMRs 1A/1B already registered, owing to the different information requirements applied under each option and the baseline, different numbers of substances will be newly identified as possessing CMR 1A/1B properties. Based on the numbers predicted in the Monte Carlo model, Table 6-12**Error! Unknown switch argument.** provides the numbers of CMRs identified under each information option.

Table 6-12: Numbers of known and newly identified CMRs 1A/1B						
Updating CMRs	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Known CMRs 1A/1B	56					
Newly identified CMRs	209	209	243	426	385	674

As discussed in relation to the costs of the information options (see Section 4.2), for some substances the cost of complying with requirements may be unsupportable on the grounds of financial cost. In the analysis of information options, any substance where the costs of the additional requirements are in excess of €1,662 per tonne[24] is assumed to be withdrawn.

[24] Based on 98 percentile value of the per substance cost of testing and registration under the baseline - tonnes calculated on the basis of 5 years of production – so, 10 tpa would be 50t

The same 'unsupportable cost' rule has been applied to the aggregation of costs of CSA/CSR under each of the options. Here, for each of the identified CMRs 1A/1B the costs of undertaking CSA/CSR have been added to the costs of updating/revising registration dossiers under each scenario. Where this total cost for a CMR substance is greater than the threshold value it is assumed to be withdrawn owing to unsupportable costs and where it is below it is assumed that a CSA/CSR is carried out. Table 6-13 provides the resulting numbers going down each route under each of the scenarios.

Table 6-13: Numbers of CMRs withdrawn versus updated with CSA/CSR						
Updating CMRs	**Baseline (Annex VII and Current Annex III)**	**Option A (Annex VII+ and Current Annex III)**	**Option D (Annex VII+ and Annex III with ND)**	**Option B (Annex VII++ and Annex III with ND)**	**Option C (Annex VII+ and No Annex III)**	**Option E (Annex VII++ and No Annex III)**
Low scenario						
Newly identified CMRs undertaking CSA	209	209	243	381	379	558
Newly identified CMRs withdrawn	0	0	0	5	6	25
Medium scenario						
Newly identified CMRs undertaking CSA	209	209	240	373	344	497
Newly identified CMRs withdrawn	0	0	3	13	41	86
High scenario						
Newly identified CMRs undertaking CSA	209	209	224	251	272	339
Newly identified CMRs withdrawn	0	0	19	135	113	244

6.2.2 Costs of CSA/CSR to MIs for newly identified CMRs

The costs of the CSA/CSR requirements to MIs (and DUs) are associated with the costs of withdrawal (for newly identified substances withdrawn) and the costs of completing a CSA/CSR (for those that are not withdrawn).

MI costs of withdrawal

The cost of withdrawing a substance from the market is associated with both the income foregone from manufacture or import (for MIs[25]) and the need to reformulate products (incurred by DUs). The calculation of these costs has been described in Section 4.2.3 for each of the information options and the same methods have been employed here when considering the addition of the

[25] Although an importer may find a substitute with lower registration requirements, hence no income would be foregone.

CSA/CSR option alongside the information requirements under the options. The resulting costs of withdrawal for MIs under each of the three scenarios are provided in Table 6-14.

Table 6-14: Cost of withdrawal to MIs under the CSA/CSR option						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Low scenario						
Newly identified CMRs withdrawn	0	0	0	5	6	25
MI costs of withdrawal (income foregone - € millions)	€ 0	€ 0	€ 0.0	€ 0.2	€ 0.3	€ 0.9
Average cost of withdrawal (income foregone per MI - €s)	€ 0	€ 0	€ 0	€ 35,572	€ 47,742	€ 35,572
Medium scenario						
Newly identified CMRs withdrawn	0	0	3	13	41	86
MI costs of withdrawal (income foregone - € millions)	€ 0	€ 0	€ 0.1	€ 0.5	€ 1.8	€ 3.1
Average cost of withdrawal (income foregone per MI - €s)	€ 0	€ 0	€ 42,671	€ 35,572	€ 43,443	€ 35,486
High scenario						
Newly identified CMRs withdrawn	0	0	19	135	113	244
MI costs of withdrawal (income foregone - € millions)	€ 0	€ 0	€ 0.8	€ 4.9	€ 4.8	€ 9.1
Average cost of withdrawal (income foregone per MI - €s)	€ 0	€ 0	€ 41,575	€ 35,370	€ 42,517	€ 35,200

MI cost of undertaking CSA/CSR for newly identified CMRs 1A/1B

Applying the unit costs defined in Section 6.1.2 to the numbers of CMRs newly identified under the baseline and the options provides the costs for MIs in total and as an average per MI manufacturing the substances. These are provided in Table 6-15.

Table 6-15: Cost of undertaking CSA and associated obligations on newly identified CMRs 1A/1B - MIs						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Low scenario						
Newly identified CMRs undertaking CSA	209	209	243	381	379	558
MI cost of CSA (€ millions)	€ 1.0	€ 0.9	€ 1.0	€ 1.9	€ 1.6	€ 2.7
Average cost of CSA per MI (€s)	€ 1,978	€ 1,770	€ 1,817	€ 2,062	€ 1,861	€ 1,966
Medium scenario						
Newly identified CMRs undertaking CSA	209	209	240	373	344	497
MI cost of CSA (€ millions)	€ 2.1	€ 2.0	€ 2.3	€ 3.9	€ 3.3	€ 5.2
Average cost of CSA per MI (€s)	€ 4,307	€ 4,098	€ 4,183	€ 4,324	€ 4,081	€ 3,892
High scenario						
Newly identified CMRs undertaking CSA	209	209	224	251	272	339
MI cost of CSA (€ millions)	€ 8.5	€ 8.4	€ 9.0	€ 10.3	€ 11.0	€ 14.0
Average cost of CSA per MI (€s)	€ 17,286	€ 17,077	€ 16,734	€ 13,298	€ 14,774	€ 12,019

Total costs to MIs of CSA/CSR to newly identified and existing (known) CMRs 1A/1B

The total costs to all MIs are a combination of the costs of withdrawal (for those substances withdrawing) and the costs of undertaking CSA as outlined in Section 6.1.2 and applied to numbers of newly identified CMRs and existing (known) CMRs. Total costs of the CSA option under each of the options for the CMRs 1A/1B are provided in Table 6-16. Note that, in relation to the options these costs do not include the additional information elements and associated costs. The total costs of the combined options (information elements plus CSA elements) are provided in Section 6.3.

Table 6-16: Total cost of the CSA obligation to MIs (costs of withdrawal plus costs of CSA)						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Low scenario						
MI costs of CSA for existing CMRs (€ millions)	€ 0.1	€ 0.1	€ 0.1	€ 0.1	€ 0.1	€ 0.1
MI costs of CSA for newly identified CMRs (€ millions)	€ 1.0	€ 0.9	€ 1.0	€ 2.1	€ 1.9	€ 3.6
Total (€ millions)	**€ 1.1**	**€ 1.0**	**€ 1.1**	**€ 2.1**	**€ 1.9**	**€ 3.7**
Medium scenario						
MI costs of CSA for existing CMRs (€ millions)	€ 0.4	€ 0.4	€ 0.4	€ 0.4	€ 0.4	€ 0.4
MI costs of CSA for newly identified CMRs (€ millions)	€ 2.1	€ 2.0	€ 2.5	€ 4.4	€ 5.1	€ 8.3
Total (€ millions)	**€ 2.5**	**€ 2.4**	**€ 2.8**	**€ 4.7**	**€ 5.5**	**€ 8.7**
High scenario						
MI costs of CSA for existing CMRs (€ millions)	€ 2.1	€ 2.1	€ 2.1	€ 2.1	€ 2.1	€ 2.1
MI costs of CSA for newly identified CMRs (€ millions)	€ 8.5	€ 8.4	€ 9.8	€ 15.2	€ 15.8	€ 23.1
Total (€ millions)	**€ 10.6**	**€ 10.5**	**€ 11.9**	**€ 17.3**	**€ 17.9**	**€ 25.2**

6.2.3 Costs of CSA/CSR to DUs for newly identified CMRs

As with costs to MIs, the costs of the CSA obligation to DUs is associated with the costs of withdrawal of a substance (and, in the case of DUs, the need to reformulate products) and the costs of engaging with MIs on the CSA as described in Section 6.1.3.

Costs of withdrawal to DUs (reformulation)

The costs of reformulating products owing to the withdrawal of CMRs under the options (including the baseline) are provided in Table 6-17 for each scenario. As with the costs to MIs, these are calculated in the same way as for costs of the information options (as described in Section 4.2.3).

The table also provides the compliance costs that would be avoided by withdrawal of these substances. Here, were a substance not to be withdrawn, in the absence of CSA DUs would have to complete their own bespoke assessments of risk and risk control under parallel legislation. Thus the withdrawal of substances newly classified with CMR 1A/1B properties under the CSA/CSR option also reduces the burden of compliance with parallel legislation which otherwise would have applied to the substances.

Table 6-17: Costs of withdrawal (reformulation) to DUs and compliance costs avoided under parallel legislation						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Low scenario						
Newly identified CMRs withdrawn	0	0	0	5	6	25
DU reformulation costs (€ millions)	€ 0	€ 0	€ 0.0	€ 0.4	€ 0.6	€ 1.8
DU compliance costs avoided owing to withdrawal (€ millions)	€ 0.0	€ 0.0	€ 0.0	€ 0.2	€ 0.2	€ 0.8
Medium scenario						
Newly identified CMRs withdrawn	0	0	3	13	41	86
DU reformulation costs (€ millions)	€ 0	€ 0	€ 0.3	€ 0.9	€ 3.6	€ 6.2
DU compliance costs avoided owing to withdrawal (€ millions)	€ 0.0	€ 0.0	€ 0.5	€ 2.0	€ 6.2	€ 12.9
High scenario						
Newly identified CMRs withdrawn	0	0	19	135	113	244
DU reformulation costs (€ millions)	€ 0	€ 0	€ 1.6	€ 9.8	€ 9.6	€ 18.2
DU compliance costs avoided owing to withdrawal (€ millions)	€ 0.0	€ 0.0	€ 13.3	€ 94.5	€ 79.1	€ 170.8

DU cost of undertaking CSA/CSR for newly identified CMRs 1A/1B

Applying the unit costs defined in Section 6.1.3 to the numbers of CMRs newly identified under the baseline and the options provides the costs for DUs for each scenario in Table 6-18.

As has already been noted, the provision of a CSA/CSR and associated eSDS for 1-10t CMRs 1A/1B provides/facilitates compliance with requirements under parallel legislation. DU compliance costs avoided are also provided in the table for each option and under each scenario.

Table 6-18: DU cost of engaging in CSA						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Low scenario						
Newly identified CMRs undertaking CSA	209	209	243	381	379	558
DU cost of engaging in CSA (€ millions)	€ 1.7	€ 1.7	€ 2.0	€ 3.1	€ 3.1	€ 4.5
DU compliance costs avoided (€ millions)	€ 6.3	€ 6.3	€ 7.3	€ 11.4	€ 11.4	€ 16.7
Medium scenario						
Newly identified CMRs undertaking CSA	209	209	240	373	344	497
DU cost of engaging in CSA (€ millions)	€ 8.8	€ 8.8	€ 10.1	€ 15.7	€ 14.5	€ 20.9
DU compliance costs avoided (€ millions)	€ 31.4	€ 31.4	€ 36.0	€ 56.0	€ 51.6	€ 74.6
High scenario						
Newly identified CMRs undertaking CSA	209	209	224	251	272	339
DU cost of engaging in CSA (€ millions)	€ 41.8	€ 41.8	€ 44.8	€ 50.2	€ 54.5	€ 67.9
DU compliance costs avoided (€ millions)	€ 146.3	€ 146.3	€ 156.8	€ 175.7	€ 190.4	€ 237.3

Total costs to DUs of CSA/CSR to newly identified and existing (known) CMRs 1A/1B

The total costs to all DUs are a combination of the costs of withdrawal (for those substances withdrawing) and the costs of undertaking CSA as outlined in Section 6.1.3 and applied to numbers of newly identified CMRs and existing (known) CMRs. Total costs of the CSA option under each of the options for the CMRs 1A/1B are provided in Table 6-19 along with total compliance costs avoided and the net costs of the options for DUs under each scenario.

Note that, as with total costs for MIs, these costs do not include the additional information elements and associated costs. The total costs of the combined options (information elements plus CSA elements) are provided in Section 6.3.

Table 6-19: Total costs of CSA option to DUs, compliance costs avoided and net costs						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Low scenario						
DU costs of CSA for 56 existing CMRs (€ millions)	€ 0.5	€ 0.5	€ 0.5	€ 0.5	€ 0.5	€ 0.5
DU costs of CSA for newly identified CMRs (€ millions)	€ 1.7	€ 1.7	€ 2.0	€ 3.4	€ 3.6	€ 6.3
DU compliance costs avoided (€ millions)	€ 6.3	€ 6.3	€ 7.3	€ 11.6	€ 11.6	€ 17.5
Net cost to DUs	**-€ 4.1**	**-€ 4.1**	**-€ 4.9**	**-€ 7.7**	**-€ 7.5**	**-€ 10.8**
Medium scenario						
DU costs of CSA for 56 existing CMRs (€ millions)	€ 2.4	€ 2.4	€ 2.4	€ 2.4	€ 2.4	€ 2.4
DU costs of CSA for newly identified CMRs (€ millions)	€ 8.8	€ 8.8	€ 10.4	€ 16.6	€ 18.1	€ 27.1
DU compliance costs avoided (€ millions)	€ 31.4	€ 31.4	€ 36.5	€ 57.9	€ 57.8	€ 87.5
Net cost to DUs	**-€ 20.2**	**-€ 20.2**	**-€ 23.7**	**-€ 38.9**	**-€ 37.3**	**-€ 58.0**
High scenario						
DU costs of CSA for 56 existing CMRs (€ millions)	€ 11.2	€ 11.2	€ 11.2	€ 11.2	€ 11.2	€ 11.2
DU costs of CSA for newly identified CMRs (€ millions)	€ 41.8	€ 41.8	€ 46.4	€ 60.0	€ 64.1	€ 86.1
DU compliance costs avoided (€ millions)	€ 146.3	€ 146.3	€ 170.1	€ 270.2	€ 269.5	€ 408.1
Net cost to DUs	**-€ 93.2**	**-€ 93.2**	**-€ 112.5**	**-€ 199.0**	**-€ 194.2**	**-€ 310.8**

6.3 Total costs of the CSA/CSR option in combination with information options

The costs of the CSA/CSR option in combination with the information options presented in Section 6.2 focus on the costs to MIs and DUs of the CSA/CSR component and not the extension of information. Table 6-20 provides the total cost of the combination of the CSA/CSR option with the information options relative to the baseline for each of the three scenarios. A breakdown of the costs is provided in Table 6-21 to Table 6-23 for the low, medium and high scenarios respectively.

As can be seen from Table 6-20, under the baseline (current information requirements) costs are negative under all scenarios. In other words there is a net benefit where this is associated with compliance cost savings to DUs for compliance with parallel legislation.

Table 6-20: Total cost of information option in combination with CSA option relative to baseline (current requirements) - € millions						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Cost relative to baseline LOW scenario	-€ 3.1	€ 20.9	€ 111.7	€ 530.6	€ 493.8	€ 1,232.5
Cost relative to baseline MEDIUM scenario	-€ 17.7	€ 6.3	€ 98.5	€ 522.7	€ 486.1	€ 1,230.8
Cost relative to baseline HIGH scenario	-€ 82.6	-€ 58.7	€ 36.6	€ 466.1	€ 433.9	€ 1,190.9

The costs provided in these tables are discussed further in Section 8 which compares costs and benefits of the options.

Table 6-21: Total cost of information option in isolation and in combination with CSA option - LOW SCENARIO (€ millions)						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
No CSA/CSR Obligation						
Total costs of revising/upgrading dossiers (MIs and DUs)	€ 0.0	€ 24.1	€ 93.4	€ 398.7	€ 366.6	€ 892.4
MI costs of withdrawal	€ 0.0	€ 0.0	€ 7.0	€ 44.2	€ 42.6	€ 112.6
DU costs of Withdrawal	€ 0.0	€ 0.0	€ 14.0	€ 88.4	€ 85.2	€ 225.2
Total REACH	**€ 0.0**	**€ 24.1**	**€ 114.5**	**€ 531.2**	**€ 494.5**	**€ 1,230.1**
DU cost of complying with parallel regulation on CMRs	€ 6.3	€ 6.3	€ 7.3	€ 11.6	€ 11.6	€ 17.5
Total cost of compliance with legislation	**€ 6.3**	**€ 30.3**	**€ 121.8**	**€ 542.8**	**€ 506.0**	**€ 1,247.6**
With CSA/CSR Obligation						
Total costs of revising/upgrading dossiers (MIs and DUs) and completing CSA/CSR (MIs)	€ 1.1	€ 25.0	€ 94.5	€ 400.2	€ 367.8	€ 893.4
MI costs of withdrawal	€ 0.0	€ 0.0	€ 7.01	€ 44.36	€ 42.91	€ 113.47
DU costs of withdrawal	€ 0.0	€ 0.0	€ 14.0	€ 88.7	€ 85.8	€ 226.9
DU costs of CSA	€ 2.1	€ 2.1	€ 2.4	€ 3.5	€ 3.5	€ 5.0
DU cost of complying with parallel regulation on CMRs	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Total cost of compliance with legislation	**€ 3.2**	**€ 27.2**	**€ 118.0**	**€ 536.8**	**€ 500.1**	**€ 1,238.7**
Cost relative to baseline	**-€ 3.1**	**€ 20.9**	**€ 111.7**	**€ 530.6**	**€ 493.8**	**€ 1,232.5**

Table 6-22: Total cost of information option in isolation and in combination with CSA option - MEDIUM SCENARIO (€ millions)						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
No CSA/CSR Obligation						
Total costs of revising/upgrading dossiers (MIs and DUs)	€ 0.0	€ 24.1	€ 93.4	€ 398.7	€ 366.6	€ 892.4
MI costs of withdrawal	€ 0.0	€ 0.0	€ 7.0	€ 44.2	€ 42.6	€ 112.6
DU costs of Withdrawal	€ 0.0	€ 0.0	€ 14.0	€ 88.4	€ 85.2	€ 225.2
Total REACH	**€ 0.0**	**€ 24.1**	**€ 114.5**	**€ 531.2**	**€ 494.5**	**€ 1,230.1**
DU cost of complying with parallel regulation on CMRs	€ 31.4	€ 31.4	€ 36.5	€ 57.9	€ 57.8	€ 87.5
Total cost of compliance with legislation	**€ 31.4**	**€ 55.4**	**€ 150.9**	**€ 589.1**	**€ 552.2**	**€ 1,317.6**
With CSA/CSR Obligation						
Total costs of revising/upgrading dossiers (MIs and DUs) and completing CSA/CSR (MIs)	€ 2.5	€ 26.5	€ 95.9	€ 402.0	€ 367.4	€ 891.8
MI costs of withdrawal	€ 0.0	€ 0.0	€ 7.14	€ 44.65	€ 44.36	€ 115.67
DU costs of withdrawal	€ 0.0	€ 0.0	€ 14.3	€ 89.3	€ 88.8	€ 231.3
DU costs of CSA	€ 11.2	€ 11.2	€ 12.5	€ 18.1	€ 16.9	€ 23.3
DU cost of complying with parallel regulation on CMRs	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Total cost of compliance with legislation	**€ 13.7**	**€ 37.6**	**€ 129.8**	**€ 554.0**	**€ 517.5**	**€ 1,262.1**
Cost relative to baseline	**-€ 17.7**	**€ 6.3**	**€ 98.5**	**€ 522.7**	**€ 486.1**	**€ 1,230.8**

Table 6-23: Total cost of information option in isolation and in combination with CSA option - HIGH SCENARIO (€ millions)						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
No CSA/CSR Obligation						
Total costs of revising/upgrading dossiers (MIs and DUs)	€ 0.0	€ 24.1	€ 93.4	€ 398.7	€ 366.6	€ 892.4
MI costs of withdrawal	€ 0.0	€ 0.0	€ 7.0	€ 44.2	€ 42.6	€ 112.6
DU costs of Withdrawal	€ 0.0	€ 0.0	€ 14.0	€ 88.4	€ 85.2	€ 225.2
Total REACH	**€ 0.0**	**€ 24.1**	**€ 114.5**	**€ 531.2**	**€ 494.5**	**€ 1,230.1**
DU cost of complying with parallel regulation on CMRs	€ 146.3	€ 146.3	€ 170.1	€ 270.2	€ 269.5	€ 408.1
Total cost of compliance with legislation	**€ 146.3**	**€ 170.4**	**€ 284.6**	**€ 801.4**	**€ 764.0**	**€ 1,638.2**
With CSA/CSR Obligation						
Total costs of revising/upgrading dossiers (MIs and DUs) and completing CSA/CSR (MIs)	€ 10.6	€ 34.6	€ 103.4	€ 403.7	€ 372.3	€ 893.1
MI costs of withdrawal	€ 0.0	€ 0.0	€ 7.76	€ 49.10	€ 47.34	€ 121.70
DU costs of withdrawal	€ 0.0	€ 0.0	€ 15.6	€ 98.1	€ 94.9	€ 243.4
DU costs of CSA	€ 53.1	€ 53.1	€ 56.1	€ 61.5	€ 65.7	€ 79.1
DU cost of complying with parallel regulation on CMRs	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0	€ 0.0
Total cost of compliance with legislation	**€ 63.7**	**€ 87.6**	**€ 182.9**	**€ 612.4**	**€ 580.2**	**€ 1,337.2**
Cost relative to baseline	**-€ 82.6**	**-€ 58.7**	**€ 36.6**	**€ 466.1**	**€ 433.9**	**€ 1,190.9**

7 Benefits under the information and CSA/CSR options

7.1 Approach to estimation

As described in Section 3.1.3, the main environmental and human health benefits of the options to extend the requirements for 1-10t substances are associated with the identification of more substances with the following hazardous properties:

- Mutagenicity (and via this route, genotoxic carcinogens)[26];
- Dermal, inhalation and/or oral toxicity;
- Aquatic toxicity; and
- Persistence, bioaccumulation and toxicity.

In addition, the options also provide better, more useful information substances and their hazardous properties, specifically:

- better information on dermal/inhalation exposure limits for the substances with the relevant classifications;
- identification of substances with properties meeting classification for Single Target Organ Toxicity – repeated exposure (STOT RE 1 or 2); and
- sufficient information to derive a Predicted No Effect Concentration (PNEC) for substances meeting classification for aquatic toxicity and so provide a more robust basis for pollution prevention.

When combined, all of these changes are expected to produce impacts on:

- the incidence of diseases, disorders and impacts (occupational and wider public) associated with each of the classifications for hazardous properties; and
- environmental pollution and impacts on the ecological status of the environment.

The approach taken to estimating the benefits associated with each of the options involves:

1. estimating how many substances are identified as having previously unknown hazardous properties for classification under each option;

2. identifying the disorders, diseases and impacts that are associated with each of those hazardous properties;

3. applying appropriate economic metrics for the single cases of disorders and diseases avoided or units of reduction in environmental impact (in €s);

4. estimating the number of cases of these diseases, disorders and impacts that would be

[26] Note that no testing for carcinogenicity or reproductive toxicity is required in Annex VII of REACH or under any of the options. Thus non-genotoxic carcinogens/reproductive toxins will not be identified for any 1-10t substances.

avoided by identifying substances with each hazardous property and taking action to reduce risks;

5. combining 3 and 4 above, calculating total present value (PV) benefits (in €s) of identifying a substance with each hazardous property; and

6. combining the numbers of hazardous substances identified under each option in step 1 with the PV benefits in step 5 to provide estimated environmental and human health benefits under each of the options.

As the methods employed in the steps above are highly technical (in particular steps 3 to 6), a full description of the approaches used in each is provided in Section 7 of the Technical Annex Report. Section 7 of this (main) report limits itself to a summary of the steps and the outcome.

7.2 Number of substances identified with previously unknown hazardous properties

Depending on the option, the following classifications are possible using the toxicological and ecotoxicological information generated:

- classification for skin/eye damage and irritation;
- classification for skin sensitisation;
- classification as CMR 1A/1B;
- availability of sufficient information to establish dermal/inhalation exposure limits;
- classification for long term toxicity;
- classification for STOT RE 1 or 2;
- classification for acute aquatic toxicity;
- availability of sufficient information to establish a PNEC for aquatic toxicity; and
- identification of PBT properties.

Table 7-1 overleaf provides the number of substances identified with each of the above hazardous properties/additional information under the baseline and the **additional numbers** of substances that would be identified under each of the information options. Also provided in the last column of the table is the total number of substances with hazardous properties that are not identified under the baseline. This is simply the total number of substances predicted to have hazardous properties less the number predicted to be identified in 2018 by application of the current information requirements; in other words, the number of substances with hazardous properties that would remain undetected after 2018 under the current requirements. As can be seen from the table, some of the options are more successful than others at identifying these hazardous substances (and so there is variation between options in terms of residual damages from unidentified substances). In addition, none of the options is 100% successful at identifying CMRs because all options rely on one or more *in* vitro screening tests (which are not able to correctly predict a positive result for all mutagenic substances).

Table 7-1: Number of substances with identified with previously unknown hazardous properties							
	Substances identified under the Baseline	Additional substances identified under the options					
		Option A	Option D	Option B	Option C	Option E	Total substances with hazardous properties not identified under the baseline
Annex III option	Current Annex III	Current Annex III	No diffuse/ dispersive use criterion in Annex III	No diffuse/ dispersive use criterion in Annex III	No Annex III	No Annex III	
Information Option	Current Annex VII	Annex VII+	Annex VII+	Annex VII++	Annex VII+	Annex VII++	
Substances classified for skin/eye damage and irritation	2,757	0	899	899	4,330	4,330	4,330
Substances classified for skin sensitisation	1,534	0	640	640	2,351	2,351	2,351
CM(R) 1A/1B	209	0	34	217	176	465	531*
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	0	0	0	3,344	0	5,356	5,356
Substances with long-term toxicity information	0	0	0	903	0	1,446	1,446
Substances that would have classification for STOT RE 1 or 2	0	0	0	131	0	210	210
Substances classified for acute aquatic toxicity	1,515	0	495	495	2,089	2,089	2,089
Substances classified for acute aquatic toxicity with enough information for PNECs	0	1,709	2,411	2,411	4,005	4,005	4,005
PBTs/vPvB substances non diffuse use	0	22	25	25	55	55	55
PBTs/vPvB substances diffuse use	0	8	9	9	19	19	19
* 740 mutagens would be identified if *in vivo* testing were carried out on all 1-10t substances. Of these 209 would be identified under the baseline leaving 531 (740-209) mutagenic substances unidentified and unclassified under the current requirements for 1-10t substances. Not all of these are detected under the options because all options employ *in vitro* screening tests to trigger any *in vivo* testing and this is not 100% successful at identifying all mutagenic substances.							

7.3 Outcomes and damage costs associated with different classifications

7.3.1 Outcomes

A range of disorders, diseases and impacts can be associated with each of the hazardous properties listed in Section to which can be applied appropriate economic metrics to provide a monetary value for the associated damages. Valuing damages in this way provides a means of estimating the benefits of each option in terms of the damage costs avoided through identification of hazardous properties and appropriate risk control. At the same time, the range of possible outcomes from exposure and environmental releases is much larger than the range of available metrics. As such, valuation must rely on selected 'representative' outcomes.

For human health outcomes the analysis is limited to the consideration of occupational (worker) exposure because this group is the only group for which expected levels of exposure can be estimated. For the environmental component very few metrics are available and this limits the ability of the analysis to assess the full breadth and depth of possible impacts. The human health and environmental outcomes linked to each hazardous property used in the analysis are summarised in Table 7-2 below.

Table 7-2: Classifications and 'representative' outcomes

Groups of substances	Classification/identification under Options	Representative outcomes for valuation
Skin Sensitizers and irritants	Skin/eye damage and irritation	Cases of skin damage and disorders of varying severity
	Skin Sensitisation	
Substances classified as Toxic	Substances identified with a classification for dermal or inhalation toxicity as well as oral	Cases of poisoning
	Substances for which there is better information on dermal/inhalation exposure limits	
	Substances for which there is better long term toxicity information	Cases of kidney disease of varying severity
	Substances identified with classification for STOT RE 1/2	
Carcinogens and mutagens	Mutagenicity 1A/1B	Fatal and non-fatal cancers
Environmental hazards	Number of substances identified with acute aquatic toxicity classification	Levels of improvement to chemical status of waterbodies. Implied willingness to pay to eliminate PBT substances.
	Number of substances identified as toxic to the aquatic environment with enough information for PNEC where applicable	
	number of PBTs/vPvBs identified	

7.3.2 Valuation of individual human health outcomes

Overview

In order to estimate the economic value of the associated human health benefits, a cost-of-illness approach has been adopted. This considers medical treatment costs, productivity losses and, where available, individual's willingness to pay (WTP) to avoid the disease/discomfort in question.

Skin sensitizers and irritants

Skin sensitizers and irritants are present in a wide range of products and can cause skin disorders. According to EU-OSHA "*occupational skin diseases are estimated to cost the EU €600 million each year, resulting in around 3 million lost working days. They affect virtually all industry and business sectors and force many workers to change jobs*"[27].

A cost-of-illness approach has been adopted to value outcomes. This considers medical treatment costs, productivity losses and, where available, individual's willingness to pay (WTP) values to avoid the occupational disease in question. The outcomes and values used for skin sensitizers and irritants are summarised in Table 7-3 below. The derivation of these is described in detail in Section 7.3 of the Technical Annex Report.

Table 7-3: Metrics applied to hazardous property endpoints and associated monetary value of avoiding a single occurrence of each

Substance properties	Valuation metric used	Monetary Value applied to metric
Substances classified for skin/eye damage and irritation	Medical treatment cost + Productivity loss + WTP to avoid a single episode of mild acute dermatitis = **Cost of a case of mild acute dermatitis**	€ 0 + € 390 + € 277 **€ 667**
Substances classified for skin sensitisation	Medical treatment cost + Productivity loss + WTP to avoid a single episode of case of chronic dermatitis = **Cost of a case of severe chronic dermatitis**	€ 2,100 + € 2,100 + € 1,055 **€ 5,255**

Substances classified as Toxic

As with skin diseases, the cost of poisoning can be estimated with reference to medical treatment costs and lost productivity as follows:

- With regard to substances identified with dermal, inhalation and/or oral toxicity classifications, the medical treatment cost for a 'non-fatal poisoning incident' has been added to lost productivity;
- With regard to substances identified with long term toxicity classifications, kidney disease 'kidney disease of short-term duration' has been considered as an end-point with medical

[27] EU-OSHA Factsheet 40. Available at: https://osha.europa.eu/en/tools-and-publications/publications/factsheets/40

treatment cost added to lost productivity to give a total cost for a case of 'kidney disease of short-term duration';

- For substances with long term toxicity classifications and substances with classification for STOT RE 1 or 2, non-fatal chronic kidney disease has been considered as an outcome. To medical treatment costs have been added productivity loss.

The values calculated for each of these outcomes are summarised in Table 7-4 below. The derivation of these is described in detail in Section 7.3 of the Technical Annex Report.

Table 7-4: Metrics applied to hazardous property endpoints and associated monetary value of avoiding a single occurrence of each

Substance properties	Valuation metric used	Monetary Value applied to metric
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	Medical treatment cost + Productivity loss **Cost of a 'poisoning event'**	€ 1,370 + € 1,500 + = **€ 2,870**
Substances with long-term toxicity information	Medical treatment cost + Productivity loss **Kidney disease of short-term duration**	**€ 4,500+** **€ 6,000** **=** **€ 10,500**
Substances with a classification for STOT RE 1 or 2	Medical treatment cost per year+ Productivity loss per year Annual cost of a case of chronic kidney disease **Total cost of a case of chronic kidney disease assuming 10 years of treatment**	€ 40,300+ €6,000 = € 46,300 per year **€ 380,400**

Carcinogens and mutagens

In terms of the valuation of cancer cases, a number of different potential economic impacts can be identified from the health economics literature, and these can be categorised in terms of those who may bear the impacts:

- **individuals/workers and their families**: financial costs, which consist of loss of earnings as a result of absence from work or the loss of a job and any extra expenditure required, for example on drugs or the need to attend hospitals; 'human costs' which relate to the loss of quality of life or of general welfare, and may include pain and suffering to the affected individual, and worry and grief caused to family and friends;

- **employers**: loss of output; payments related to sick leave; administrative costs related to a worker's absence[28] including additional recruitment costs; loss of experience/expertise; overtime working; compensation payments (although this is usually covered by some form of employer's liability insurance); and insurance premiums; and

[28] Clerical and management related costs. Legal costs may also be relevant where compensation payments are required in the case of disablement, for example.

- **taxpayers**: costs borne by taxpayers for national health care provision, disability and other social security benefits.

The total social costs of occupational cancers are measured by the costs born for health care provision, together with lost output (including productivity losses), the non-wage labour costs of absent workers (such as loss of experience), administrative costs and human costs. These represent the direct and indirect resource costs and the non-market 'external' costs of illness. The other costs listed above (e.g. insurance premiums) relate to what are commonly referred to as 'transfer payments', which do not give rise to net welfare effects. As a result, they are not considered in economic analyses, even though they may be important in financial terms to an individual worker or an employer.

When deriving a single value for a cancer case several factors need to be considered within the same expression. These are as follows:

- fatality rate – not all cases of cancer result in a fatality. For fatal cancers the value of a statistical life (VSL) applies and for non-fatal cases the value of cancer morbidity (VCM) applies.
- latency period – every case of cancer (fatal or non-fatal) is preceded by a period of latency before diagnosis and treatment. As such, the benefit of any action taken to reduce exposure to a carcinogen in the present day will not manifest itself until a time in the future that is equal to the latency period of the cancer ;
- costs of healthcare, productivity and lost working days vary from one cancer to another.

For the costs of each treatment year, data from Luengo-Fernandez, et al (2013[29]) have been applied. The value of a statistical life (VSL) is taken as €4 million to be consistent with advice from DG Employment (pers. comm.) and the figure set out in the Better Regulation Guidelines. The value of a cancer morbidity (VCM) is applied to non-fatal cases of cancer. This is taken as €410,000 to be consistent with recent WTP studies undertaken for ECHA (where this is also consistent with the value of €400,000 in 2003 prices which appears in ECHA SEA guidance).

The latency period between exposure and development of cancer means that any action taken to reduce exposure to a carcinogen in the present day will not manifest itself until a time in the future that is equal to the latency period of the cancer. Thus, when calculating the benefits of taking action in the present one must consider the benefits in the future and discount them as appropriate to arrive at Present value (PV) benefits.

To accomplish this, the value of cancer prevention has been calculated on the basis of the aggregated cost of one cancer exposure a year over a period of 40 years of exposures. Total costs in each year are calculated and to these has been applied the 4% standard discounting rate applied in EC impact assessments to give costs as NPV. The sum of these NPV costs provides the cost of one cancer exposure per year for 40 years (and thus the total PV benefits associated with prevention of one exposure per year).

[29] Luengo-Fernandez, R. et al (2013): Economic burden of cancer across the European Union: a population-based cost analysis; Lancet Oncology; 14: 1165–74, published online October 14: http://dx.doi.org/10.1016/S1470-2045(13)70442-X

When calculating this, average 'all cancer' values have been applied as follows:

- Latency = 15 years
- Survival/treatment period (years) = 5 years
- Fatality rate at end of period = 47%[30]
- Annual cost per patient (€) = € 14,966
- VSL (€) = € 4,000,000
- VCM (€) = € 410,000

This provides an aggregated NPV of €22,673,090 for the prevention of one cancer exposure per year over a period of 40 years.

7.3.3 Valuing individual environmental outcomes

Aquatic toxicity

Willingness to pay of UK households for improving the quality of water bodies to different Water Framework Directive Status levels ('bad', 'poor', 'moderate' and 'good') has been used to provide indicative values[31] for water quality improvements. The so called NWEBS (National Water Environment Benefit Survey values) are used in the UK as part of the assessment of the costs and benefits of catchment level projects to increase the status of water bodies.

To estimate the benefits of identifying substances which are toxic to aquatic life, it has been assumed that three components will be affected (fish; other animals such as invertebrates; plant communities) and that:

- The identification of acute aquatic toxic substances but without an associated PNEC would result in the quality of water bodies improving from "bad" to "poor" at a value of €12,250 per km^2 river per year;
- The definition of PNECs would result in the setting of more stringent environmental risk management measures, with the effect of improving the quality of water bodies from "bad" to "moderate" at a value of €26,380 per km^2 river per year.

PBTs and vPvBs

Estimation of the benefits of preventing emissions and losses of PBTs and vPvBs is a difficult, topical and ongoing issue. In its document *Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances*[32], ECHA's Committee for Socio-Economic Analysis (SEAC)

[30] Based on data for the EU from International Association of Cancer Registries http://www.iacr.com.fr/

[31] Environment Agency (2013): Updating the National Water Environment Benefit Survey values: summary of the peer review. All benefit values are in 2012 prices. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/291464/LIT_8348_42b259.pdf

[32] See Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC - SEAC/24/2014/04 https://echa.europa.eu/documents/10162/13580/approach_for_evaluation_pbt_vpvb_substances_seac_en.pdf

identifies that "*data on P, B and T properties does not often allow for quantitative assessment of the human health or environmental impacts. The valuation of benefits via the assessment of the impacts on the environment and human health – the standard 'impact pathways' approach to benefits assessment for chemicals – is therefore not possible, and other options for benefits assessment need to be considered*". Accordingly, SEAC has pursued the approach of establishing a benchmark for the proportionality/disproportionality of action to reduce emissions of PBTs considering the cost of past action.

In 2015, IVM conducted a study (IVM, 2015[33]) to provide SEAC with information that could be used in the development of such a benchmark. The study gathered information on the past (and current) cost of PBT emission reduction or on reductions in the use of, or exposure to PBTs/vPvBs. In turn, the study identifies that this information provides an indication of "public willingness to pay" for such reductions through a revealed preferences.

Taking all of the available evidence into account and also differences between PBTs/vPvBs and their effects, the study identifies a very wide 'grey zone' of somewhere between €1,000 and €50,000 per kg PBT substituted, remediated or emission reduced. Within this 'grey' zone, measures may be either proportionate or disproportionate from a cost-effectiveness perspective (depending on factors including the nature of the PBT/vPvB).

These lower and higher bound WTP estimates have been used to develop the following scenarios for this benefit assessment.

- Low WTP = €1,000 per kg PBT substituted, remediated or emission reduced;
- Medium WTP = €25,500 per kg PBT substituted, remediated or emission reduced; and
- High WTP = €50,000 per kg PBT substituted, remediated or emission reduced.

[33] IVM Institute for Environmental Studies (2015): Benchmark development for the proportionality assessment of PBT and vPvB substances - a report for the Dutch Ministry of Infrastructure and the Environment; by Oosterhuis, F & Brouwer, R - Report R-15/11, 21 September 2015. http://echa.europa.eu/documents/10162/13647/R15_11_pbt_benchmark_report_en.pdf

7.3.4 Summary of values applied to human health and environmental outcomes

Table 7-5 summarises the monetary values discussed above and applied within the assessment of benefits.

Table 7-5: Metrics applied to hazardous property endpoints and associated monetary value of avoiding a single occurrence of each

Substance properties	Valuation metric	Monetary value calculated using cost of illness
Substances classified for skin/eye damage and irritation	Case of mild acute dermatitis	€667 per case
Substances classified for skin sensitisation	Case of severe chronic dermatitis	€5,255 per case
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	'Poisoning event'	€2,870 per case
Substances with long-term toxicity	Case of kidney disease of short-term duration	€10,500 per case
Substances that would have classification for STOT RE 1 or 2	Case of chronic kidney disease requiring 10 years of treatment	€380,400 per case
Number of CM(R) 1A/1B substances identified	NPV cost of one cancer exposure per year over 40 years	€22,673,090 (NPV over 40 years)
Substances classified for acute aquatic toxicity	Improvement of 1km^2 WFD water body status from 'Bad' to 'poor'	€ 12,250 per year
Substances classified for acute aquatic toxicity with enough information for PNECs	Improvement of 1km^2 WFD water body status from 'Bad' to 'moderate'	€ 26,380 per year
PBTs/vPvB substances	Low WTP to eliminate	€ 1,000 per kg
	Medium WTP to eliminate	€ 25,500 per kg
	High WTP to eliminate	€ 50,000 per kg

7.4 Health cases avoided/unit environmental impacts avoided per substance identified

7.4.1 Overview

The final piece of information for assessment of the benefits is estimation of the number of human health cases avoided and environmental impacts avoided for every substance identified.

Taking a similar approach to that described so far, the Phase 2 analysis simply assumed that, for every substance identified one case per year of the corresponding representative disease/disorder or environmental impact outcome would be prevented. Although this was considered to be an extremely conservative estimate, as it applied equally across all options, it was sufficient for the purpose of comparing the options to see which was likely to provide the greatest benefit relative to the cost.

For this Phase 3 analysis, however, we have been requested to provide an analysis which better describes the likely actual benefits of each option rather than one that simply provides the likely relative benefits of the options.

7.4.2 Number of individual health cases avoided

The starting point for estimating the number of human health cases avoided has been the ECHA guidance on socioeconomic analysis (SEA) for Authorisation[34]. In relation to quantitative analyses of health impacts from individual chemicals, ECHA's SEA guidance identifies that a number of types of data are likely to be needed:

- an estimate of the total population exposed (and if possible the distribution of exposure within that population);
- an assessment of exposure, including, for example, the frequency and duration of exposure, the rate of uptake of the substance by the relevant route (e.g. inhalation, oral, dermal) in order to be able to estimate and average dose or a range of doses;
- quantitative estimates of the relationship between individual exposure and the incidence of a defined health effect (for example skin irritation, respiratory illnesses, cancer) and derivation of a probability of that effect being manifested (such as a dose-response relationship); and
- A measure of actual impact of the health effect (such as numbers of life years lost due to contracting cancer).

Regarding the application of such an approach to the options, analysis for SEA and Authorisation is carried out on individual, identified substances using real data on toxicity, doses and response as well as exposed populations. The analysis that is being attempted here, however, is on multiple substances for which no such substance specific data are available other than that predicted for:

- hazardous properties not previously known;
- average quantity likely to be manufactured;
- average number of downstream users; and
- number of substances with one or more dispersive/diffuse uses.

Whilst it is clearly not possible to apply the approach set out in ECHA's SEA guidance 'to the letter', it is possible to apply the stages and attempt estimation of the likely outcomes using conservative risk characterisations of an 'average substance'. When combined with the different scenarios and assumptions used in the assessment of costs, this adapted approach allows assessment of:

- Exposed population;
- Frequency of exposure;
- Incidence of ill effects from acute exposure; and
- Incidence of ill effects from repeated exposure.

A low, medium high scenario approach has been applied to deliver these estimates.

[34] http://echa.europa.eu/support/socio-economic-analysis-in-reach

The three scenarios draw directly from the scenarios used in the cost assessment with regard to different numbers of downstream uses and downstream users. These numbers of downstream users provide estimates of the potentially exposed population and, in turn, numbers exposed.

Owing to this link with the cost assessment scenarios, it should be noted that the estimates of the benefits can be compared only with the matching scenario estimate for costs. The approach applied is highly technical in nature and so is described in detail in Section 7.4 of the Technical Annex Report with this report summarising and describing the outcomes.

Estimation of ill effects from acute exposures

From the analysis described in the Technical Annex Report, the total number of cases of acute ill health associated with exposure to individual 1-10t substances with as yet unidentified acute hazardous properties is estimated to be 23, 63 and 126 cases per year per substance for low, medium and high downstream user scenarios respectively. These values are summarised in Table 7-6 below along with the same expressed as the percentage of the exposed population suffering from an acute disease/disorder per year. This same value also expresses the individual probability of receiving an exposure that leads to an acute disease/disorder. It will be observed that the individual probability is lower under the high scenarios for numbers of DUs and *vice versa*. This is because, with higher numbers of DUs the greater the number of people exposed but the lower the level of exposure (because of the smaller quantities being used).

Table 7-6: Total disease cases from acute exposure (all users per substance)

	Number of cases per year	Percentage of total exposed population suffering from an acute disease/disorder per year
Low	23	1.8%
Medium	63	0.2%
High	126	0.03%

Estimation of ill effects from repeated exposures

As described in the analysis described in Section 7.4 of the Technical Annex Report, estimation of incidence of ill effects from repeated exposures to substances involves:

- Calculating the likelihood of exposed individuals receiving n exposures per year (where n is between 1 and 1,000) for each use; and
- Estimating the probability that n repeat exposures will trigger an ill health outcome in an exposed individual.

The combination of these two sets of probabilities provides the cumulative probability that a disease outcome may be triggered per individual per year for application to the exposed population and, therein, the number of expected cases triggered per substance per year. These totals and annual averages are provided in Table 7-7 below as numbers of cases. As with the acute exposures, the table also shows the number of cases expressed as the percentage of the exposed population. This same value also expresses the individual probability of receiving sufficient repeated exposures to trigger a disease/disorder. As with the acute cases, it will be observed that the individual probability is lower under the high scenarios for numbers of DUs and vice versa. This is because, with higher

numbers of DUs the greater the number of people exposed but the lower the level of exposure (because of the smaller quantities being used).

Table 7-7: Total number of disease cases (over a 40-year period) and average cases per year from chronic exposure - all uses and users			
Scenario	**Total number of chronic cases over 40 years per substance**	**Number of cases per year per substance**	**Percentage of total exposed population suffering from an chronic disease/disorder per year**
Low	29	0.7	0.06%
Medium	88	2.2	0.008%
High	573	14.3	0.004%

7.4.3 Environmental impacts

Aquatic toxicity

The metric for estimating the environmental benefits of identifying substances that are toxic to the aquatic environment is expressed in € per km^2 waterbody improved. Consistent with the low/ medium/high scenario approach used elsewhere in the analysis the following three different values have been applied to cover a range of possibilities:

- **Low:** 2 km^2 'improved' per substance;
- **Medium:** 5 km^2 'improved' per substance; and
- **High:** 10 km^2 'improved' per substance.

PBTs and vPvBs

The metrics for valuing the benefits of identifying and controlling PBTs/vPvBs are based on low, medium and high estimates of the value (in €s) per kg PBT/vPvB substituted, remediated or emission reduced. To these three scenario values have been applied estimates of releases to the environment.

Based on the cost assessment and the Monte Carlo model, the average total annual production of 1-10t substances by all MIs is 19,550 kg/year.[35] However, only a percentage of that annual production may ultimately be released to the environment and this will differ between substances with and without diffuse/dispersive uses.

Table R.16-7: Default parameters to derive the environmental release rate in ECHA's Guidance on information requirements and Chemical Safety Assessment[36] suggests that:

[35] Average of 2.3 MIs each manufacturing/importing 8,500kg/year = 19,550 kg/year total production and use on average.

[36] ECHA (2016): Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment, Version 3.0, February 2016 - http://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf

- **For non-diffuse/dispersive uses:** around 10% by weight of the substance may ultimately be released to air, water and soil considering manufacture and all non-dispersive/diffuse downstream uses; and
- **For diffuse/dispersive uses (perhaps conservatively):** around 50% by weight of the substance may ultimately be released to air, water and soil considering manufacture and all diffuse/dispersive downstream uses.

Applying these values to the factors used in the cost assessment for substances with different uses provides the estimates of the environmental releases eliminated in Table 7-8.

Table 7-8: Environmental releases of 1-10t substances

		Quantity used (kg/year)	Percent released to the environment	Environmental release eliminated (kg/year)
Substance with no diffuse use		19,550	10%	**1,955**
Substance with one or more diffuse uses	Non-diffuse use	11,730	10%	1,173
	Diffuse use	7,820	50%	3,910
	Total			**5,083**

7.4.4 Final scenarios for human health and environmental impacts avoided

Table 7-9 provides the resulting human health disease/disorders cases avoided per year per substance for the low, medium and high scenarios and the environmental impacts avoided.

Table 7-9: Scenarios for human health and environmental impacts avoided

Classification/identification under Options	Representative outcome	Cases avoided per year per substance identified with property		
		Low	Medium	High
Human health impacts avoided				
Substances classified for skin/eye damage and irritation	Cases of mild acute dermatitis	23	63	126
Substances classified for skin sensitisation	Cases of severe chronic dermatitis	0.7	2.2	14.3
CM(R) 1A/1B	Cancer exposures	0.7	2.2	14.3
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	'Poisoning events'	23	63	126
Substances with long-term toxicity information	Cases of kidney disease of short-term duration	0.7	2.2	14.3
Substances that would have classification for STOT RE 1 or 2	Cases of chronic kidney disease of longer-term duration	0.7	2.2	14.3

Environmental impacts avoided				
Classification/identification under Options	Representative outcome	Area waterbody improved/ emissions eliminated		
		Low	Medium	High
Substances classified for acute aquatic toxicity	Improvement of water status from 'bad' to 'poor' per km^2	2 km^2	5 km^2	10 km^2
Substances classified for acute aquatic toxicity with enough information for PNECs	Improvement of water status from 'bad' to 'moderate' per km^2	2 km^2	5 km^2	10 km^2
PBTs/vPvBs non-diffuse	kg PBT/vPvB substituted, remediated or emission reduced	1,955 kg		
PBTs/vPvBs diffuse		5,083 kg		

7.5 Estimated benefits

7.5.1 Annual damage costs avoided for substances newly identified with hazardous properties

The total annual damage costs avoided for each representative outcome/metric is the product of:

- the monetary value applicable to the representative outcome (provided in Table 7-5); and
- the number of cases of the representative outcome that are avoided per substance newly identified with each type of classification/property (provided in Table 7-9).

Table 7-10 provides the estimated damage costs avoided per year from controlling a substance that is newly identified with the corresponding classification. Values for all three scenarios are provided.

With regard to the values for avoiding cancer triggering exposures, as discussed in Section 7.3.2, these are calculated on the basis of the aggregated cost of one cancer exposure a year over a period of 40 years of exposure to provide an aggregated NPV of €22,673,090 over the 40 year period per case. Multiplied by the number of cancer exposures avoided per year, this provides the NPV of cases avoided over 40 years. This is presented in the table in spite of it not being an annual value. For comparison with the other damage costs avoided, the NPVs for each scenarios have been converted to equivalent Annual costs (EAC) using a discount rate of 4%.

Table 7-10: Estimated annual damage cost avoided by the identification of a substance with the corresponding classification										
Damage Metrics/representative outcomes		Monetary value per unit incidence of representative outcome (from Table 7-5)			Cases/outcomes avoided per year (from Table 7-9)			Calculated annual damage cost avoided by the identification of one substance with corresponding classification		
		Low	Med	High	Low	Med	High	Low	Med	High
Substances classified for skin/eye damage and irritation	**Cases of mild acute dermatitis**	€ 667	€ 667	€ 667	23	63	126	€ 15,448	€ 41,941	€ 83,882
Substances classified for skin sensitisation	**Cases of severe chronic dermatitis**	€ 5,255	€ 5,255	€ 5,255	0.7	2.2	14.3	€ 3,755	€ 11,510	€ 75,260
CM(R)s 1A/1B	**NPV cancer over 40 years**	*€ 22,673,090**	*€ 22,673,090**	*€ 22,673,090**	*0.7*	*2.2*	*14.3*	*€ 16,200,952**	*€ 49,659,849**	*€ 324,713,183**
	Equivalent Annual Cost (EAC) cancer	Note that the EAC is calculated from the NPV over 40 years (in italics above)						€ 818,529	€ 2,508,989	€ 16,405,643
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	**'Poisoning events'**	€ 2,870	€ 2,870	€ 2,870	23	63	126	€ 66,469	€ 180,466	€ 360,931
Substances with long-term toxicity information	**Cases of kidney disease of short-term duration**	€ 10,500	€ 10,500	€ 10,500	0.7	2.2	14.3	€ 7,503	€ 22,998	€ 150,376
Substances that would have classification for STOT RE 1 or 2	**Cases of chronic kidney disease of longer-term duration**	€ 380,400	€ 380,400	€ 380,400	0.7	2.2	14.3	€ 271,813	€ 833,173	€ 5,447,907
Substances classified for acute aquatic toxicity	**Improvement of WFD water body status from 'Bad' to 'poor'**	€ 12,250 per km^2	€ 12,250 per km^2	€ 12,250 per km^2	2 km^2	5 km^2	10 km^2	€ 24,500	€ 61,250	€ 122,500
Substances classified for acute aquatic toxicity with enough information for PNECs	**Improvement of WFD water body status from 'Bad' to 'moderate'**	€ 26,380 per km^2	€ 26,380 per km^2	€ 26,380 per km^2	2 km^2	5 km^2	10 km^2	€ 52,760	€ 131,900	€ 263,800
PBTs/vPvBs non-diffuse	**WTP to eliminate emissions of 1-10t PBTs**	€ 1,000 per kg eliminated	€ 25,500 per kg eliminated	€ 50,000 per kg eliminated	1,955 kg eliminated			€ 1,955,000	€ 49,852,500	€ 97,750,000
PBTs/vPvBs diffuse					5,083 kg eliminated			€ 5,083,000	€ 129,616,500	€ 254,150,000
* values reflect NPV damage costs avoided over a 40 year time period. These have been converted to an Equivalent Annual Cost using the standard approach and a discount rate of 4%.										

7.5.2 Aggregated benefits under the options

The annual human health and environmental benefits under each option are a function of the numbers of substances newly identified with different hazardous classifications (in Table 7-1) and the damage cost avoided by the identification of a substance each classification (in Table 7-10). The resulting estimates of annual damage costs avoided under the options are provided in Table 7-12, Table 7-13 and Table 7-14 for the low, medium and high scenarios respectively.

In the same tables are the damage costs avoided over a 40 year period expressed as Net Present Values (NPVs) using the discount rate of 4%,. When aggregating over this period it is assumed that there is some lead in time before human health and environmental controls take full effect. Human health benefits are assumed to begin in 2022 and are calculated over the remaining period (discounting at 4%). Environmental benefits are assumed to take longer to be established and are assumed to be accrued in the period after 2026 (discounting at 4%).

The total PV benefits under each option for each scenario are summarised in Table 7-11 below. It should be noted (again) that the three scenarios draw directly from the scenarios used in the cost assessment with regard to different numbers of downstream uses and downstream users. As such, **estimates of the benefits should only be compared with the matching scenario estimate for costs**.

The benefits of the options are compared with the costs in Section 8.

Table 7-11: Total Present Value (PV) Benefits (discounted at 4%) – (€ millions)

Scenario	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Low	€ 2,465.7	€ 8,588.5	€ 7,980.2	€ 9,026.9	€ 22,124.7
Medium	€ 33,460.5	€ 53,975.3	€ 53,142.7	€ 90,837.3	€ 128,491.1
High	€ 65,734.2	€ 125,119.8	€ 155,991.9	€ 219,031.0	€ 377,487.8

Table 7-12: Estimated damage cost avoided by the identification of a substance with the corresponding classification – Low Scenario					
Damage Metrics: representative outcomes	Damage costs avoided (€ millions)				
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Annual damage costs avoided					
Substances classified for skin/eye damage and irritation: Cases of mild acute dermatitis	€ 0.0	€ 13.9	€ 13.9	€ 66.9	€ 66.9
Substances classified for skin sensitisation: Cases of severe chronic dermatitis	€ 0.0	€ 2.4	€ 2.4	€ 8.8	€ 8.8
Substances with better information on exposure limits for oral and dermal/inhalation toxicity: 'Poisoning events'	€ 0.0	€ 0.0	€ 222.3	€ 0.0	€ 356.0
Substances with long-term toxicity information: Cases of kidney disease of short-term duration	€ 0.0	€ 0.0	€ 6.8	€ 0.0	€ 10.8
Substances that would have classification for STOT RE 1 or 2: Cases of chronic kidney disease of longer-term duration	€ 0.0	€ 0.0	€ 35.6	€ 0.0	€ 57.1
Substances classified for acute aquatic toxicity: Improvement of WFD water body status	€ 90.2	€ 127.2	€ 127.2	€ 211.3	€ 211.3
PBTs/vPvBs: WTP to eliminate emissions of PBTs	€ 83.7	€ 94.6	€ 94.6	€ 204.1	€ 204.1
Non cancer human health damage costs avoided (Benefits) - € millions per year	€ 0.0	€ 16.3	€ 280.9	€ 75.7	€ 499.7
Environmental damage costs avoided (Benefits) - € millions per year	€ 173.8	€ 221.8	€ 221.8	€ 415.4	€ 415.4
Present Values Over 40 year Period (@4% discount rate)					
CMRs 1A/1B: PV cancers avoided over 40 years	€ 0.0	€ 550.8	€ 3,515.6	€ 2,851.4	€ 7,533.4
Total PV non-cancer human health damage costs avoided over the benefit period (between 2022 and 2061 inclusive) - € millions total	€ 0.0	€ 4,891.4	€ 1,318.3	€ 283.6	€ 8,699.3
Total PV environmental damage costs avoided over the benefit period (between 2026 and 2061 inclusive) - € millions total	€ 2,465.7	€ 3,146.3	€ 3,146.3	€ 5,891.9	€ 5,891.9
Total Present Value (PV) Benefits (discounted at 4%)	**€ 2,465.7**	**€ 8,588.5**	**€ 7,980.2**	**€ 9,026.9**	**€ 22,124.7**

Table 7-13: Estimated damage cost avoided by the identification of a substance with the corresponding classification – Medium Scenario					
Damage Metrics: representative outcomes	Damage costs avoided (€ millions)				
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Annual damage costs avoided					
Substances classified for skin/eye damage and irritation: Cases of mild acute dermatitis	€ 0.0	€ 37.7	€ 37.7	€ 181.6	€ 181.6
Substances classified for skin sensitisation: Cases of severe chronic dermatitis	€ 0.0	€ 7.4	€ 7.4	€ 27.1	€ 27.1
Substances with better information on exposure limits for oral and dermal/inhalation toxicity: 'Poisoning events'	€ 0.0	€ 0.0	€ 603.5	€ 0.0	€ 966.6
Substances with long-term toxicity information: Cases of kidney disease of short-term duration	€ 0.0	€ 0.0	€ 20.8	€ 0.0	€ 33.3
Substances that would have classification for STOT RE 1 or 2: Cases of chronic kidney disease of longer-term duration	€ 0.0	€ 0.0	€ 109.1	€ 0.0	€ 175.0
Substances classified for acute aquatic toxicity: Improvement of WFD water body status	€ 225.4	€ 318.0	€ 318.0	€ 528.3	€ 528.3
PBTs/vPvBs: WTP to eliminate emissions of PBTs	€ 2,133.7	€ 2,412.9	€ 2,412.9	€ 5,204.6	€ 5,204.6
Non cancer human health damage costs avoided (Benefits) - € millions per year	€ 0.0	€ 45.1	€ 778.5	€ 208.7	€ 1,383.5
Environmental damage costs avoided (Benefits) - € millions per year	€ 2,359.1	€ 2,730.9	€ 2,730.9	€ 5,732.9	€ 5,732.9
Present Values Over 40 year Period (@4% discount rate)					
CMRs 1A/1B: PV cancers avoided over 40 years	€ 0.0	€ 1,688.4	€ 10,776.2	€ 8,740.1	€ 23,091.8
Total PV non-cancer human health damage costs avoided over the benefit period (between 2022 and 2061 inclusive) - € millions total	€ 0.0	€ 13,553.4	€ 3,632.9	€ 784.7	€ 24,086.8
Total PV environmental damage costs avoided over the benefit period (between 2026 and 2061 inclusive) - € millions total	€ 33,460.5	€ 38,733.5	€ 38,733.5	€ 81,312.4	€ 81,312.4
Total Present Value (PV) Benefits (discounted at 4%)	**€ 33,460.5**	**€ 53,975.3**	**€ 53,142.7**	**€ 90,837.3**	**€ 128,491.1**

Table 7-14: Estimated damage cost avoided by the identification of a substance with the corresponding classification – High Scenario					
Damage Metrics: representative outcomes	Damage costs avoided (€ millions)				
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Annual damage costs avoided					
Substances classified for skin/eye damage and irritation: Cases of mild acute dermatitis	€ 0.0	€ 75.4	€ 75.4	€ 363.2	€ 363.2
Substances classified for skin sensitisation: Cases of severe chronic dermatitis	€ 0.0	€ 48.2	€ 48.2	€ 176.9	€ 176.9
Substances with better information on exposure limits for oral and dermal/inhalation toxicity: 'Poisoning events'	€ 0.0	€ 0.0	€ 1,207.0	€ 0.0	€ 1,933.1
Substances with long-term toxicity information: Cases of kidney disease of short-term duration	€ 0.0	€ 0.0	€ 135.8	€ 0.0	€ 217.5
Substances that would have classification for STOT RE 1 or 2: Cases of chronic kidney disease of longer-term duration	€ 0.0	€ 0.0	€ 713.7	€ 0.0	€ 1,144.1
Substances classified for acute aquatic toxicity: Improvement of WFD water body status	€ 450.8	€ 636.0	€ 636.0	€ 1,056.5	€ 1,056.5
PBTs/vPvBs: WTP to eliminate emissions of PBTs	€ 4,183.7	€ 4,731.1	€ 4,731.1	€ 10,205.1	€ 10,205.1
Non cancer human health damage costs avoided (Benefits) - € millions per year	€ 0.0	€ 123.6	€ 2,180.0	€ 540.1	€ 3,834.8
Present Values Over 40 year Period (@4% discount rate)					
Environmental damage costs avoided (Benefits) - € millions per year	€ 4,634.5	€ 5,367.1	€ 5,367.1	€ 11,261.6	€ 11,261.6
CMRs 1A/1B: PV cancers avoided over 40 years	€ 0.0	€ 11,040.2	€ 70,462.8	€ 57,149.5	€ 150,991.6
Total PV non-cancer human health damage costs avoided over the benefit period (between 2022 and 2061 inclusive) - € millions total	€ 0.0	€ 37,954.6	€ 9,404.2	€ 2,151.5	€ 66,766.2
Total PV environmental damage costs avoided over the benefit period (between 2026 and 2061 inclusive) - € millions total	€ 65,734.2	€ 76,125.0	€ 76,125.0	€ 159,730.0	€ 159,730.0
Total Present Value (PV) Benefits (discounted at 4%)	**€ 65,734.2**	**€ 125,119.8**	**€ 155,991.9**	**€ 219,031.0**	**€ 377,487.8**

7.6 Benefits that have not been quantified

7.6.1 Overview

A number of benefits cannot be adequately/meaningfully assessed in monetary or other terms. These mainly relate to benefits of the CSA/CSR option (as opposed to the information options) and are described in the following subsections.

7.6.2 Implementation of consistent and adequate risk management measures in relation to worker exposure

The extension of the CSA/CSR obligation to 1-10t CMRs 1A/1B would for each substance, result in the identification of consistent and robust risk management measures for implementation by downstream users and manufacturers alike and communication of these, and other important information, to all downstream users of the substances.

Under the current regulatory regime that applies, each individual manufacturer and downstream user is required to assess their own situation individually with the aid of only the general information provided in the SDS (as opposed to that of an extended SDS including DNELs where they have been or can be established for substances where there may or may not be a threshold effect). In the course of duplicating effort in this way, and with the more limited information available to conduct assessments, the result may be the implementation of a range of different risk management measures by different manufacturers and different downstream users. Some of these may provide adequate control and some may not. The current regulatory regime does not provide a means of establishing this either way.

Substances also registered in higher tonnage bands would also be required to communicate information in the supply chain. At present, whilst it has been assumed in this analysis that uses of these substances would be covered in the CSAs required for the higher tonnage substances (and, as such, the costs of the obligation for these substances is zero), there is no requirement for manufacturers and importers to provide an eSDS to downstream users including the relevant exposure scenarios for those uses. Thus, at present, there is a risk that information supplied to downstream users may be differ depending on whether the supplier manufacturers or imports the substance in quantities of 1-10t or >10t per year. **Extending the obligation would result in the communication of consistent and robust risk management information to all downstream users regardless of the volumes imported or produced by the registrants.**

7.6.3 Adequate risk management measures in relation to articles

In relation to substances used in articles, where the substance is used in quantities of 1 tonne or more and the substance is intended to be released under normal or reasonably foreseeable conditions of use that use must be registered as an identified use either in the registration for the substance or mixture or as a substance used in an article in its own right.

Here, under Article 7 of REACH, manufacturers and importers of such articles would have to complete a registration for the substance and its use if the use in the articles is not already registered.

In the case of 1-10t CMRs 1A/1B used in such articles there is no obligation to perform a CSA/CSR at present and the safety of the article is only a consideration under general product safety regulations (or specific product regulations where they are applicable to the article and its use).

If the CSA obligation were to be extended, the use of a substance in such an article would have to be included in the CSA/CSR (and an extended SDS provided to downstream users producing those articles). This would identify consistent and robust recommended risk management measures where these can be identified.

If risk management measures cannot be identified, under Article 37, '*where the manufacturer, importer or downstream user, having assessed the use in accordance with Article 14* [CSA/CSR], *is unable to include it as an identified use for reasons of protection of human health or the environment, he shall provide the Agency and the downstream user with the reason(s) for that decision in writing without delay and shall not supply downstream user(s) with the substance without including these reason(s) in the information referred to under Articles 31 or 32. The manufacturer or importer shall include this use in Section 3.7 of Annex VI in his update of the registration in accordance with Article 22(1)(d)*'.

As such, where a CSA identifies that use in the article cannot be supported '*for reasons of protection of human health or the environment*' ECHA is alerted of this fact and action concerning these articles on the market or to be put onto the market can be implemented. This is not possible under current regulation where the safety of the article is only a consideration under general product safety regulations (or specific product regulations where they are applicable to the article and its use).

7.6.4 Control of environmental risks under the baseline

Extending the CSA obligation to 1-10t CMRs 1A/1B would require consideration of environmental exposure, its likely effects, and appropriate risk management for identified uses. Under the current requirements this would not otherwise be considered for these substances other than when action was identified as being required by Member States or the Commission under community regulation.

For PBT/vPvB substances it would have to be demonstrated through exposure assessment that there are no emissions or losses to environmental compartments. For non PBTs, under the current Annex VII information requirements quantitative comparison between environmental exposures and an established PNEC is unlikely to be possible because the two Annex VII tests are not sufficient to develop a PNEC and a third species would be needed to establish an acute PNEC for the aquatic compartment. There is no requirement to undertake a third test in the current Annex VII or Annex I and, as such, the environmental exposure assessment and risk characterisation in the CSAs of CMRs 1A/1B would remain incomplete.

This is a situation that is resolved when combining the CSA/CSR option with any of the information options A to E because all of these options include the third test necessary to establish a PNEC. However, it has not been possible to measure the benefits of this in a meaningful way.

7.6.5 Benefits for Member States and the Commission

Extending the CSA/CSR obligation to 1-10t CMRs 1A/1B and the subsequent consistent documentation of appropriate risk management measures for the concerned substances would simplify and improve the control on safe handling of substances in the workplace under all

applicable regulation by enforced by all relevant authorities. It would also facilitate the identification of cases for which the Commission or Member States could consider that the manufacture, placing on the market or use of a substance, on its own, in a mixture or in an article poses a risk to human health and for which a restriction procedure could be initiated.

In addition, the extended CSA/CSR obligation would further ensure the generation of robust study summaries on selected human and environmental health endpoints. Currently these robust study summaries must be generated by Member States during the development of a harmonised classification and not by manufacturers and importers (as they would were the CSA obligation to be extended).

It has not been possible to measure these benefits in a meaningful way.

8 Comparison of all options

8.1 Overview of total costs and benefits

Prior to the adoption of REACH, information on the inherent hazardous properties of chemicals needed to manage them safely was not available or was incomplete for a significant percentage of the substances on European market. More than half of these substances (around 20,000) were estimated to be on the market at quantities of 1-10t per MI per year.

The REACH regulation sought to address these information deficits by requiring MIs to generate toxicological and ecotoxicological information on substances placed on the market in quantities of >1t per MI per year. In so doing, REACH aims to provide a high level of protection of human health and the environment, while at the same time enhancing the competitiveness and innovative capability of the EU industry.

In the light of the latter aim and the need to keep the economic and business impacts of the regulation proportional to the likely risks of chemicals, requirements under REACH were tailored according to tonnage band, with higher volume substances required to produce more information on more toxicological and ecotoxiciological endpoints and *vice versa*. In the case of the 1-10t substances that are the subject of this Phase 3 study, by defining '*priority substances*' on the basis of (Q)SARs or other evidence[37], Article 12 and Annex III of the regulation exclude a proportion of the 1-10t substances from requirements to provide toxicological and ecotoxicological information. In addition, all 1-10t substances were excluded from the requirement to undertake Chemical Safety Assessment (CSA), provide a Chemical Safety Report (CSR) and supply extended Safety Data Sheets (eSDS) to downstream users. Partly owing to the fact that some toxicological and ecotoxicological information was present for use in CSA/CSR, but also to reduce costs and impacts, the information required for 1-10t substances was also reduced.

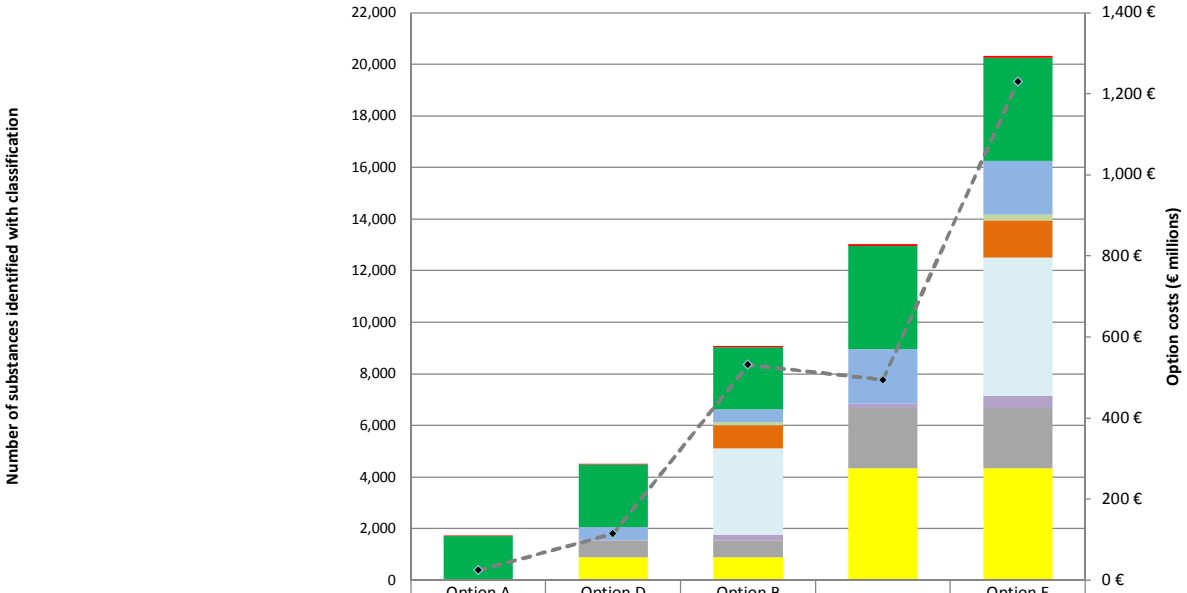
This Phase 3 study has examined five alternative options for information requirements for 1-10t substances each of which extends the numbers of substances required to generate information and/or the nature of the information generated. Figure 8-1 provides a plot and a table of the number of additional substance classifications that modelling suggests would be identified under these alternative options. All of the substance classifications in the figure are additional to those identified under the baseline (current requirements) and, as such, can be regarded as hazardous substance classifications that are missed (not detected) under the current requirements.

[37] '*Priority substances*' are "*substances for which it is predicted (i.e. by the application of (Q)SARs or other evidence) that they are likely to meet the criteria for*" classification as C, M or R 1A/1B or PBT/vPvB or any health or environmental hazard classes or differentiations under CLP and also have a dispersive or diffuse use.

Also provided in the figure are the additional costs associated with each of these five alternative options (plotted against the secondary axis), where these have been assessed using a Monte Carlo simulation and comprise the total of:

- the costs of withdrawing substances to MIs and DUs;
- the costs of revising/updating the registration dossiers of '*priority substances*' for which some toxicological and ecotoxicological information will have been supplied in 2018 (to MIs and DUs); and
- the costs of upgrading registrations for substances only submitting physicochemical information in their 2018 registration dossiers (to MIs and DUs).

Figure 8-1: Additional hazardous substance classifications identified under options and associated costs



	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
PBTs/vPvB substances	30	34	34	74	74
Substances classified for acute aquatic toxicity with enough information for PNECs	1,709	2,411	2,411	4,005	4,005
Substances classified for acute aquatic toxicity	0	495	495	2,089	2,089
Substances that would have classification for STOT RE 1 or 2	0	0	131	0	210
Substances with long-term toxicity information	0	0	903	0	1,446
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	0	0	3,344	0	5,356
CM(R) 1A/1B	0	34	217	176	465
Substances classified for skin sensitisation	0	640	640	2,351	2,351
Substances classified for skin/eye damage and irritation	0	899	899	4,330	4,330
Option costs (without CSA - € millions)	€ 24.1	€ 114.5	€ 531.2	€ 494.5	€ 1,230.1

As can be seen from the figure, the analysis suggests that a large number of hazardous substance classifications not detected under the baseline (current requirements) would be identified under these alternative options. The scale and significance of this non-detection from the perspective of providing *a high level of protection of human health and the environment* is discussed Section 8.2.2.

The more extensive the alternative information option in terms of level of information required and substances considered, the more hazardous property classifications are identified and the greater the cost to MIs and DUs.

This Phase 3 study has also considered the option of extending CSA/CSR requirements to substances known or newly identified as CMR 1A/1B. The costs and benefits of this option have been assessed for both application to the current information requirements (the baseline) and also for each information option described above. Modelling of costs in relation to all has considered withdrawal of substances (and associated costs to MIs and DUs) as well the costs of undertaking CSA/CSR and providing eSDS (to DUs and MIs). As discussed in detail in Section 6, whilst there are costs to DUs for a number of elements including supplying MIs with information on uses, there is a net saving for DUs when this is compared with the costs of complying with current requirements under parallel product and worker health and safety regulation. Here it has been identified that the CSAs/CSRs provided under this would provide compliance with this parallel regulation or greatly facilitate that compliance. Moving responsibilities from the DUs to the MIs in this way is likely to benefit multiple downstream users of each substance and reduce duplication of effort significantly.

As there are few statistics on the numbers of DUs for substances, estimation of the costs of the CSA/CSR options has taken a scenario based approach to cover low, medium and high numbers of DUs and associated costs of compliance with CSA/CSR requirements as well as parallel regulation. These same scenarios for numbers of DUs have been carried through to the estimation of the human health damage costs avoided by the identification of hazardous substance classifications - with each scenario dictating the potentially exposed population. This, along with other low, medium, high estimates for other factors (such as environmental benefits) has been used to define three scenarios for human health and environmental benefits expressed in monetary terms, with each of these matching the assessment of costs.

For each of these scenarios, Table 8-1 provides the costs of the information options with and without the addition of CSA/CSR requirements for CMRs 1A/1B and estimates of the human health and environmental damage costs avoided (i.e. benefits).

As can be seen from the table, for almost all information options, costs are reduced by combination with CSA/CSR for CMRs 1A/1B owing to the aforementioned reduction in the costs of compliance with requirements under parallel legislation. Regardless of scenario or option, human health and environmental benefits are estimated to be (significantly) larger than the costs. Consistent with the data and discussion presented around Figure 8-1, the more extensive and expensive the option, the more additional hazardous substance classifications are identified for risk control and larger the human health and environmental damage costs avoided.

Table 8-1: Additional costs and benefits of options under the three scenarios (€ millions)						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Low scenario						
Increase in costs with information options (without CSA) relative to baseline	€ 0.0	€ 24.1	€ 114	€ 531	€ 494	€ 1,230
Increase in costs with information options (with CSA) relative to baseline	-€ 3.1	€ 20.9	€ 112	€ 531	€ 494	€ 1,232
Total additional health and environmental benefits (€ million)	€ 0.0	€ 2,466	€ 8,589	€ 7,980	€ 9,027	€ 22,125
Medium scenario						
Increase in costs with information options (without CSA) relative to baseline	€ 0.0	€ 24.1	€ 114	€ 531	€ 494	€ 1,230
Increase in costs with information options (with CSA) relative to baseline	-€ 17.7	€ 6.3	€ 98.5	€ 523	€ 486	€ 1,231
Total additional health and environmental benefits (€ million)	€ 0.0	€ 33,461	€ 53,975	€ 53,143	€ 90,837	€ 128,491
High scenario						
Increase in costs with information options (without CSA) relative to baseline	€ 0.0	€ 24.1	€ 114	€ 531	€ 494	€ 1,230
Increase in costs with information options (with CSA) relative to baseline	-€ 82.6	-€ 58.7	€ 36.6	€ 466	€ 434	€ 1,191
Total additional health and environmental benefits (€ million)	€ 0.0	€ 65,734	€ 125,120	€ 155,992	€ 219,031	€ 377,488

8.2 Comparing the options

8.2.1 Overview

It is clear from this Phase 3 analysis that the alternative options are likely to identify more substances with a larger number of classifications than are identified under the current requirements, that some options perform better in this respect than others (and so the benefits in terms of environmental and human health benefits are larger), and that those same higher performing options also come at greater cost to industry (MIs and DUs).

Given the interplay between generating information suitable for making classifications and the cost of that information, this is not a surprising finding. Throughout the development of REACH from the White Paper though to the final text there was an awareness of the need to strike a balance between the level of information required to "*ensure a high level of protection of human health and the environment*"[38] and the need to keep costs at a level commensurate with "*enhancing competitiveness and innovation*"[38].

The purpose of this Phase 3 study is not to make a judgement on which would be the best option considering these often competing objectives but rather provide the Commission with the information required to consider, in the light of new information on substance classifications generated by the 2010 and 2013 registration deadlines, which of the options (including do nothing) is likely to strike the 'best' balance.

The following sub-sections provide a broad comparison of options in terms of:

- the level of protection of human health and environment;
- cost-effectiveness;
- benefit-cost ratios; and
- other metrics including substance withdrawal and vertebrates used in testing.

8.2.2 Level of protection

As noted above, REACH aims to "*ensure a high level of protection of human health and the environment*"[38]. Where in 2003 and 2006 (when the text of REACH was being finalised) it was difficult to predict how many substances would be identified with different hazardous properties, new statistical information on the hazardous properties of substances fully registered in 2010/13 makes such prediction more robust and more detailed (in terms of the number of endpoints).

As has been described in previous sections (and is further discussed in great detail in the Technical Annex), statistics on fully registered substances have been used in the Monte Carlo model to predict the numbers of substances that would be identified with hazardous properties if full *in vitro* and *in vivo* testing were applied to all 20,000 substances. Based on this information (in simple terms) the Monte Carlo model calculates how many of these hazardous substances would be identified under each of the options (and the cost of doing so). Using the same scenario based approaches to monetary valuation of damage costs applied to the options (described in Section 7), it is also possible to calculate the accompanying estimates of:

- the human health and environmental damage costs that would result if there were no requirements at all for 1-10t substances (as a PV over 40 years);
- the human health and environmental damage costs avoided under the baseline (current requirements) as a PV over 40 years;
- the percentage of total damage costs avoided under the baseline (current requirements); and
- the damage costs remaining after 2018 as a PV over 40 years.

[38] Article 1 (1) of REACH

These are provided in Table 8-2 for each of the three scenarios. As can be seen from these data, it is estimated that the current requirements will reduce human health and environmental damage costs by 10% to 17% depending on the downstream user/benefit scenario. Table 8-3 provides accompanying estimates of the impact of each option on total damage costs and also damage costs remaining after 2018.

Table 8-2: Estimated total human health and environmental damage costs (€ millions)			
	Baseline (Annex VII and Current Annex III)		
	Low	Medium	High
Damage costs in the absence of any REACH requirements on 1-10t substances	€ 27,948.2	€ 145,784.3	€ 475,452.6
Damage costs avoided under current requirements (the baseline)	€ 4,754.2	€ 14,015.7	€ 76,533.8
Percentage of total damage costs avoided under current requirements	17%	10%	16%
Remaining damage costs after 2018	€ 23,193.9	€ 131,768.6	€ 398,918.8

Table 8-3: Percentage impact of options on damage costs						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Low scenario						
Percentage impact on total estimated damage costs (in the absence of REACH requirements)	17%	26%	48%	46%	49%	96%
Percentage impact on damage costs remaining after registration 2018	n/a	11%	37%	34%	39%	95%
Rank level of protection	n/a	5	3	4	2	1
Medium scenario						
Percentage impact on total estimated damage costs (in the absence of REACH requirements)	10%	33%	47%	46%	72%	98%
Percentage impact on damage costs remaining after registration 2018	n/a	25%	41%	40%	69%	98%
Rank level of protection	n/a	5	3	4	2	1
High scenario						
Percentage impact on total estimated damage costs (in the absence of REACH requirements)	16%	30%	42%	49%	62%	95%
Percentage impact on damage costs remaining after registration 2018	n/a	16%	31%	39%	55%	95%
Rank level of protection	n/a	5	4	3	2	1

Whilst REACH does not define what a "*high level of protection of human health and the environment*"[38] constitutes in numerical terms, as the current requirements may only address 10-17% of the human health and environmental damage costs it is difficult to conclude that REACH will offer a high level of protection in the case of the 1-10t substances. All of the alternative options offer higher levels of protection than the current requirements but it is only the more demanding, higher cost options that appear to offer what a might be more commonly understood as a 'high level of protection'.

8.2.3 Cost-effectiveness

The cost-effectiveness of the options can be expressed as the ratio of cost:benefit providing the cost (in €s) of purchasing €1 of human health and environmental benefits. The results of this comparison are provided in Table 8-4 below. As the estimated benefits significantly outweigh the estimated costs under all options and under all scenarios, the cost of purchasing €1 of human health and environmental benefit are all well below €1 and mostly at or below one euro cent. Placed in rank order the options are generally ordered as below (with 4 and 5 being reversed under the high scenario with CSA). When considering the rank order it should be borne in mind that all options perform well by these measures and that options B, C and E perform almost equally well[39] and so the 3, 4 and 5 rank order is somewhat artificial. The performance of the options against cost-effectiveness criteria must be set against the level of protection offered. Here, from Table 8-2, the level of protection provided is lower for the options ranking higher for benefit-cost ratio and cost-effectiveness (with Option A providing only a modest increase in levels of protection from the baseline).

Table 8-4: Cost-effectiveness of options (€/€ human health and environmental benefit)

	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Low scenario					
Cost effectiveness (C/B) - No CSA	€ 0.010	€ 0.01	€ 0.07	€ 0.05	€ 0.06
Cost effectiveness (C/B) - with CSA	€ 0.01	€ 0.01	€ 0.07	€ 0.05	€ 0.06
Rank cost-effectiveness - No CSA	1	2	5	3	4
Rank cost-effectiveness - with CSA	1	2	5	3	4
Medium scenario					
Cost effectiveness (C/B) - No CSA	€ 0.001	€ 0.002	€ 0.01	€ 0.01	€ 0.01
Cost effectiveness (C/B) - with CSA	€ 0.0002	€ 0.002	€ 0.01	€ 0.01	€ 0.01
Rank cost-effectiveness - No CSA	1	2	5	3	4
Rank cost-effectiveness - with CSA	1	2	5	3	4
High scenario					
Cost effectiveness (C/B) - No CSA	€ 0.0004	€ 0.001	€ 0.003	€ 0.002	€ 0.003
Cost effectiveness (C/B) - with CSA	-€ 0.001	€ 0.0003	€ 0.003	€ 0.002	€ 0.003
Rank cost-effectiveness - No CSA	1	2	5	3	4
Rank cost-effectiveness - with CSA	1	2	4	3	5

[39] With the 'distance' between the third and fifth options being less than €0.01 of cost per € of benefit on the cost-effectiveness scale.

When considering the cost-effectiveness of the options it may be useful make a comparison with the estimated cost-effectiveness of the measures in place at present. Here, Table 8-5 provides the costs, benefits and cost-effectiveness of the measures in place for registration of 1-10t substances in 2018. As can be seen from this, all of the options, if introduced, would provide levels of cost-effectiveness higher than those expected from registration under current requirements only in 2018. This is not to say that the current requirements are not cost-effective, merely that taking up any of the options in addition to these requirements would offer similarly high levels of cost-effectiveness.

Table 8-5: Cost-effectiveness of current requirements for 2018 (€/€ human health and environmental benefit)			
	Baseline (Annex VII and Current Annex III)		
	Low	Medium	High
Total costs for 2018 requirements	€ 410.9	€ 410.9	€ 410.9
Total benefits of 2018 requirements	€ 4,754.2	€ 14,015.7	€ 76,533.8
Cost effectiveness (C/B)	€ 0.09	€ 0.03	€ 0.005

8.2.4 Benefit-cost ratios

Benefit-cost ratios effectively express the level of benefit gained (in €s) for every €1 of investment. They are often used to identify/screen out options for which the cost exceeds the benefits (i.e B/C<1) and/or identify those options that perform best. As discussed previously, the human health and environmental benefits of all of the options (and the current requirements) are estimated to greatly exceed the costs so the benefit-cost ratios are useful only to indicate the relative performance of options. Being based on the same values as cost-effectiveness, the conclusions are the same but, for completeness, benefit-cost ratios for the options are nonetheless provided in Table 8-6 and, for comparison, those for the current requirements under the three benefit and cost scenarios are provided in Table 8-7.

Table 8-6: Benefit:cost ratios for options					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Low scenario					
Benefit-cost ratio (B/C) - No CSA	102	75	15	18	18
Benefit-cost ratio (B/C) - with CSA	118	77	15	18	18
Rank Benefit-cost - No CSA	1	2	5	3	4
Rank Benefit-cost - with CSA	1	2	5	3	4
Medium scenario					
Benefit-cost ratio (B/C) - No CSA	1,390	472	100	184	104
Benefit-cost ratio (B/C) - with CSA	5,317	548	102	187	104
Rank Benefit-cost - No CSA	1	2	5	3	4
Rank Benefit-cost - with CSA	1	2	5	3	4
High scenario					
Benefit-cost ratio (B/C) - No CSA	2,730	1,093	294	443	307
Benefit-cost ratio (B/C) - with CSA	-1,121*	3,422	335	505	317
Rank Benefit-cost - No CSA	1	2	5	3	4
Rank Benefit-cost - with CSA	1	2	4	3	5
* this value is negative because the costs of this option are negative					

Table 8-7: Benefit:cost ratios for current requirements for 2018			
	Baseline (Annex VII and Current Annex III)		
	Low	Medium	High
Total costs for 2018 requirements	€ 410.9	€ 410.9	€ 410.9
Total benefits of 2018 requirements	€ 4,754.2	€ 14,015.7	€ 76,533.8
Benefit:cost (B/C)	12	34	186

8.2.5 Other metrics

Withdrawal of substances

As noted in the discussion on the summary metrics of level of protection, costs, benefits and costs versus benefits it seems clear that:

- Levels of protection afforded by the current requirements are relatively low (at 10-17% of total damages in the absence of any requirements) and are unlikely to satisfy the REACH objective of ensuring "a *high level of protection of human health and the environment*";
- The lower cost options (such as Option A) produce a slight improvement in this (bringing overall level of protection to 26%-33%) but this may still not be regarded as ensuring '*a high level of protection of human health and the environment*' even though these lower cost options are, numerically, the more cost-effective of the alternatives;
- The highest cost option (Option E) would provide a high level of protection by any definition (95-98% of total damages in the absence of any requirements) but, even though very cost effective, the costs are relatively high and may or may not be commensurate with the REACH objective of "*enhancing competitiveness and innovation*"; and
- The (three) options in the middle of the two extremes provide something in the middle ground in terms of costs, benefits and levels of protection but, depending on the benefit scenario, provide anything between a 46% and 72% reduction in total damage costs which may or may not constitute '*a high level of protection*'.

The business impacts of the options have been estimated and considered in detail in Section 5. This analysis found no evidence that costs (withdrawal or updating/upgrading) were likely to have disproportional impacts on SMEs/large companies. However, as discussed in Sections 4.2, 5.2 and 5.3, there are differences between the options in terms of the numbers of substances likely to be withdrawn because the costs of updating/revising registration dossiers are likely to be unsupportable. Whilst the costs of these withdrawals are included with the total costs of the options presented in all of the tables in this section, they are also an outcome and can be viewed as providing an indicator of the impact of options on competition and innovation.

Table 8-8 and Table 8-9 provide the estimates of the numbers of substances and numbers of MIs affected by withdrawal respectively. Data are provided as both numbers (substances/MIs) and as percentages (of substances/MIs). As it is the cost of the information elements that largely drives both the total costs of the options and the withdrawals, the trends are the same in terms of which options have the highest impact/costs. The data do, however, provide information that may be of use to deliberations on which of the options (if any) provide the better balance between the competing demands.

Table 8-8: Number of substances likely to be withdrawn					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Low scenario					
Substances withdrawn - No CSA	0	187	956	1,132	2,525
Substances withdrawn - with CSA	0	187	961	1,138	2,550
Percent substances withdrawn - No CSA	0.0%	1.0%	4.9%	5.8%	12.9%
Percent substances withdrawn - with CSA	0.0%	1.0%	4.9%	5.8%	13.0%
Medium scenario					
Substances withdrawn - No CSA	0	187	956	1,132	2,525
Substances withdrawn - with CSA	0	190	969	1,173	2,612
Percent substances withdrawn - No CSA	0.0%	1.0%	4.9%	5.8%	12.9%
Percent substances withdrawn - with CSA	0.0%	1.0%	4.9%	6.0%	13.3%
High scenario					
Substances withdrawn - No CSA	0	187	956	1,132	2,525
Substances withdrawn - with CSA	0	206	1,091	1,245	2,769
Percent substances withdrawn - No CSA	0.0%	1.0%	4.9%	5.8%	12.9%
Percent substances withdrawn - with CSA	0.0%	1.1%	5.6%	6.4%	14.1%

Table 8-9: Number of MIs affected by withdrawal					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Low scenario					
Number of MIs affected by withdrawal - No CSA	0	187	898	1,062	2,160
Number of MIs affected by withdrawal - with CSA	0	187	903	1,068	2,185
Percentage of MIs affected by withdrawal - No CSA	0.0%	2.2%	10.7%	12.7%	25.8%
Percentage of MIs affected by withdrawal - with CSA	0.0%	2.2%	10.8%	12.8%	26.1%
Medium scenario					
Number of MIs affected by withdrawal - No CSA	0	187	898	1,062	2,160
Number of MIs affected by withdrawal - with CSA	0	190	911	1,103	2,247
Percentage of MIs affected by withdrawal - No CSA	0.0%	2.2%	10.7%	12.7%	25.8%
Percentage of MIs affected by withdrawal - with CSA	0.0%	2.3%	10.9%	13.2%	26.9%
High scenario					
Number of MIs affected by withdrawal - No CSA	0	187	898	1,062	2,160
Number of MIs affected by withdrawal - with CSA	0	206	1,036	1,175	2,419
Percentage of MIs affected by withdrawal - No CSA	0.0%	2.2%	10.7%	12.7%	25.8%
Percentage of MIs affected by withdrawal - with CSA	0.0%	2.5%	12.4%	14.0%	28.9%

Vertebrate testing

A further consideration for decision making on the options is the number of vertebrates that would be needed for testing (assuming that all testing proposals were granted by ECHA). These were a programmed output of the Monte Carlo model and are provided in Table 8-10. These should be compared with the 252,677 vertebrates estimated in the Monte Carlo simulation for current requirements for 2018.

Table 8-10: Additional number of vertebrates used in tests under the options					
	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Vertebrate animals used in tests	46,374	120,428	416,995	419,410	929,618

8.3 Summary Tables

Summary tables of costs, benefits and impact metrics are provided in the tables below for each scenario.

Table 8-11: Summary table of key metrics and indicators – Low scenario						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Increase in costs with information options (without CSA) relative to baseline (€ millions)	€ 0.0	€ 24.1	€ 114	€ 531	€ 494	€ 1,230
Increase in costs with information options (with CSA) relative to baseline (€ millions)	-€ 3.1	€ 20.9	€ 112	€ 531	€ 494	€ 1,232
Total additional health and environmental benefits (€ million)	€ 0.0	€ 2,466	€ 8,589	€ 7,980	€ 9,027	€ 22,125
Percentage impact on total estimated damage costs (in the absence of REACH requirements)	17%	26%	48%	46%	49%	96%
Percentage impact on damage costs remaining after registration 2018	-	11%	37%	34%	39%	95%
Number of substances withdrawn under information options (No CSA)	-	0	187	956	1,132	2,525
Number of CMRs withdrawn (under CSA)	0	0	0	5	6	25
Number of substances withdrawn options plus CSA	0	0	187	961	1138	2550
Percentage of substances withdrawn (no CSA)	-	0.0%	1.0%	4.9%	5.8%	12.9%
Percentage of substances withdrawn options plus CSA	0.0%	0.0%	1.0%	4.9%	5.8%	13.0%
Number of MIs withdrawing one or more substances (no CSA)	-	0	187	898	1,062	2,160
Number of MIs withdrawing a CMR under CSA	0	0	0	5	6	25
Total MIs withdrawing one or more substances with CSA	-	0	187	903	1,068	2,185
Percentage of MIs withdrawing one or more substances (no CSA)	-	0.0%	2.2%	10.7%	12.7%	25.8%
Percentage of MIs withdrawing a CMR under CSA	-	0.0%	0.0%	0.1%	0.1%	0.3%
Percentage of MIs withdrawing one or more substances (with CSA)	-	0.0%	2.2%	10.8%	12.8%	26.1%
Total number of vertebrates used in testing	252,677	46,374	120,428	416,995	419,410	929,618

Table 8-12: Summary table of key metrics and indicators – Medium scenario						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Increase in costs with information options (without CSA) relative to baseline (€ millions)	€ 0.0	€ 24.1	€ 114	€ 531	€ 494	€ 1,230
Increase in costs with information options (with CSA) relative to baseline (€ millions)	-€ 17.7	€ 6.3	€ 98.5	€ 523	€ 486	€ 1,231
Total additional health and environmental benefits (€ million)	€ 0.0	€ 33,461	€ 53,975	€ 53,143	€ 90,837	€ 128,491
Percentage impact on total estimated damage costs (in the absence of REACH requirements)	10%	33%	47%	46%	72%	98%
Percentage impact on damage costs remaining after registration 2018	-	25%	41%	40%	69%	98%
Number of substances withdrawn under information options (No CSA)	-	0	187	956	1,132	2,525
Number of CMRs withdrawn (under CSA)	0	0	3	13	41	86
Number of substances withdrawn options plus CSA	0	0	190	969	1,173	2,611
Percentage of substances withdrawn (no CSA)	-	0.0%	1.0%	4.9%	5.8%	12.9%
Percentage of substances withdrawn options plus CSA	0.0%	0.0%	1.0%	4.9%	6.0%	13.3%
Number of MIs withdrawing one or more substances (no CSA)	-	0	187	898	1,062	2,160
Number of MIs withdrawing a CMR under CSA	0	0	3	13	41	87
Total MIs withdrawing one or more substances with CSA	-	0	190	911	1,103	2,247
Percentage of MIs withdrawing one or more substances (no CSA)	-	0.0%	2.2%	10.7%	12.7%	25.8%
Percentage of MIs withdrawing a CMR under CSA	-	0.0%	0.0%	0.2%	0.5%	1.0%
Percentage of MIs withdrawing one or more substances (with CSA)	-	0.0%	2.3%	10.9%	13.2%	26.9%
Total number of vertebrates used in testing	252,677	46,374	120,428	416,995	419,410	929,618

Table 8-13: Summary table of key metrics and indicators – High scenario						
	Baseline (Annex VII and Current Annex III)	Option A (Annex VII+ and Current Annex III)	Option D (Annex VII+ and Annex III with ND)	Option B (Annex VII++ and Annex III with ND)	Option C (Annex VII+ and No Annex III)	Option E (Annex VII++ and No Annex III)
Increase in costs with information options (without CSA) relative to baseline (€ millions)	€ 0.0	€ 24.1	€ 114	€ 531	€ 494	€ 1,230
Increase in costs with information options (with CSA) relative to baseline (€ millions)	-€ 82.6	-€ 58.7	€ 36.6	€ 466	€ 434	€ 1,191
Total additional health and environmental benefits (€ million)	€ 0.0	€ 65,734	€ 125,120	€ 155,992	€ 219,031	€ 377,488
Percentage impact on total estimated damage costs (in the absence of REACH requirements)	16%	30%	42%	49%	62%	95%
Percentage impact on damage costs remaining after registration 2018	-	16%	31%	39%	55%	95%
Number of substances withdrawn under information options (No CSA)	-	0	187	956	1,132	2,525
Number of CMRs withdrawn (under CSA)	0	0	19	135	113	244
Number of substances withdrawn options plus CSA	0	0	206	1,091	1,245	2,769
Percentage of substances withdrawn (no CSA)	-	0.0%	1.0%	4.9%	5.8%	12.9%
Percentage of substances withdrawn options plus CSA	0.0%	0.0%	1.1%	5.6%	6.4%	14.1%
Number of MIs withdrawing one or more substances (no CSA)	-	0	187	898	1,062	2,160
Number of MIs withdrawing a CMR under CSA	0	0	19	138	113	259
Total MIs withdrawing one or more substances with CSA	-	0	206	1,036	1,175	2,419
Percentage of MIs withdrawing one or more substances (no CSA)	-	0.0%	2.2%	10.7%	12.7%	25.8%
Percentage of MIs withdrawing a CMR under CSA	-	0.0%	0.2%	1.6%	1.4%	3.1%
Percentage of MIs withdrawing one or more substances (with CSA)	-	0.0%	2.5%	12.4%	14.0%	28.9%
Total number of vertebrates used in testing	252,677	46,374	120,428	416,995	419,410	929,618

Study to gather further information to be used in support of an Impact Assessment of potential options, in particular possible Amendments of REACH Annexes, to modify requirements for registration of low tonnage substances (1-10t/year) and the CSA/CSR Requirement for CMR substances in the framework of REACH

Methodology Annex to the Main Report

Written by Anthony Footitt (Project Manager)

March – 2017

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1 Introduction

1.1 Background to the study

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

Registration under REACH is staged over three phases with the timescales for registration dependent upon the quantities of substances manufactured or imported. The final phase-in registration deadline will be 1 June 2018 for substances manufactured or imported in quantities starting at 1 tonne but less than 10 tonnes per year per manufacturer or importer (1 to 10 tonne substances) and also for substances manufactured or imported in quantities of 10-100 tonnes per year.

Article 138(1) and 138(3) of REACH requires the Commission to undertake reviews of the requirements for 1-10t substances in relation to:

- the information that must be submitted in registration dossiers; and/or
- the obligation to perform a chemical safety assessment (CSA) and to document it in a chemical safety report (CSR) for substances which meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction(CMR), category 1A or 1B.

On the basis of these reviews the Commission may present legislative proposals to modify the requirements.

Following on from an initial (2012) study it had completed for the Commission on these issues, RPA was commissioned (in December 2013) to provide technical assistance to both of the reviews described above and, in particular to:

- identify, refine and analyse options for an extension of the current information requirements and provide sufficient information on the costs, benefits and impact on innovation and competitiveness of each of the options;
- provide a clear description of the envisaged main benefits and drawbacks of the extension of CSA/CSR obligations to 1-10t CMR 1A/1B substances including estimation of costs for manufacturers, importers and downstream users and distribution of the costs along the supply chain; and
- therein, provide the Commission with a solid basis to report on the issues and to envisage any (legislative) proposals.

On the basis of the outputs from the Phase 2 study and internal discussions, the Commission has selected five information options for further evaluation. Of these five options:

- three were assessed in detail using the Monte Carlo simulation in the previous study (options B, C and D);
- one option was not part of the full assessment but the report provided interpolated estimates for benefits and costs which identified it as potentially promising (Option A) ; and
- one other option which was not assessed at any level (Option E).

The table below summarises the five options (A to E) identified in the specification as requiring full analysis as well as those options analysed in the previous study (the green highlighted boxes).

Table 1-1: Final Combinations of Options to Progress to Full Impact Assessment			
Annex III Options	**Information Options**		
	Current Annex VII	**Annex VII+**	**Annex VII++**
Do nothing	**Baseline**	**Option A**	
Remove diffuse/dispersive use criterion		**Option D**	**Option B**
Remove all criteria		**Option C**	**Option E**

In addition to the information options, the Commission has selected the option to extend REACH CSA/CSR obligations (Article 14(1)) to all 1-10t substances known or expected to meet criteria for CMR 1A or 1B criteria for further evaluation alongside the information options.

RPA has been commissioned to generate further information on the selected policy options using the methods developed in Phase 2 suitably adjusted to take into consideration the new options for consideration and changes in context and timing of any changes since Phase 2 was undertaken.

Ultimately the information from this Phase 3 study may be used as part of the preparation of an Impact Assessment (IA) and Public Consultation. As such it has been important that the assessment is carried out in accordance with the Commission *Impact Assessment Guidelines* and related operational guidance.

1.2 Scoping of impacts

1.2.1 Overview

The core elements of the Commission *Impact Assessment Guidelines* and related operational guidance are that assessments should:

- ***Identify all potential impacts of the options –*** specifying how the options would address the issues that need to be addressed and mapping out impacts (positive and negative) and the parties that would be affected;

- ***Select the significant impacts for deeper assessment*** – justifying selection taking account of expected magnitude, relevance and Commission objectives such as human health, environmental protection, competitiveness and innovation; and

- ***Assess the most significant impacts*** – where this should be quantitative and monetised wherever possible as well as qualitatively.

The assessments completed for the 2012 study, the 2014 study and adjusted/carried through to this (current) study were all developed with the eventual need to undertake an impact assessment in mind. As such, considering the changes brought about under the options, the following overall sets of impacts were considered as being significant and worthy of deeper assessment owing to their expected magnitude, relevance for different stakeholders, and importance for the Commission's objectives and policies (particularly in relation to health and environmental protection but also competitiveness, innovation and employment):

- ***Increases in compliance costs under REACH –*** for manufacturers and importers registering 1-10t substances (including 1-10t CMRs 1A/1B needing to produce a CSA/CSR) as well as downstream users of those substances;

- ***Human health and environmental impacts –*** owing to the identification of a greater number of substances with hazardous properties for classification under the information options, more complete information on those substances (permitting more effective/consistent risk management) and enhanced communication of risks and risk management measures in respect of CMRs 1A/1B by the production of CSAs/CSRs; and

- ***Reduced costs of compliance with legislation on worker's health and safety in respect of CMRs 1A/1B*** – where information provided in extended Safety Data Sheets (eSDS) communicated to downstream users satisfies or makes easier the production of risk assessments required under the regulatory instruments that are triggered by classification in accordance with Regulation (EC) No 1272/2008.

The specific impacts considered under each are summarised briefly in the following sub-sections.

1.2.2 Compliance costs

The information options and the extension of the CSA/CSR obligation to 1-10t CMRs 1A/1B have various effects on different elements of REACH compliance and also parallel legislation. The information policy options are expected to impact on the following compliance costs under REACH (and so are being assessed in detail):

- ***Information Costs -*** cost of generating (and purchasing Letters of Access to) toxicological and ecotoxicological information including QSARs/Read Across (increase relative to the baseline);

- ***Registration Dossier costs*** - the costs of drafting and finalising a REACH registration dossier for submission (increase relative to the baseline) ;

- ***Cost of producing study summaries*** –which increases and varies from information option to information option because of differences in the information generated by different options and outcome in terms of any further mutagenicity testing and/or PBT/vPvB assessment that is required (increase relative to the baseline);

- ***Joint registration and SIEF administrative costs*** - where there is more than one registrant of the substance, the costs of liaising with the other registrants as part of sharing information

on the substance increases with the options depending on the information generated by different options and the outcome (increase relative to the baseline);

- ***Costs of revising Substance Safety Data Sheets (SDSs)*** – where there is a change in classification for a substance in the light of any new information generated there is a need to update the SDS (increase relative to the baseline);

- ***Costs of proposals for additional animal or alternative tests*** – where there is a need to undertake animal testing by virtue of following the Integrated Testing Strategy (ITS) for mutagenicity or for PBT/vPvB assessment there is a need to submit proposals for animal tests before testing can take place (increase relative to the baseline); and

- ***Registration fees*** – which vary by size of enterprise (micro, small, medium and large) but under the fees Regulation are zero for substances submitting all of the information in Annex VII (decrease relative to the baseline for substances submitting full Annex VII information [which increases under the options]).

The direct impact of the options on compliance costs (identified above) also have the potential to increase the number of substances withdrawn from the market. Withdrawal may occur under the baseline and the options when the increase in the cost of registering certain substances is unsupportable on the grounds of financial cost and/or because the newly identified substance's properties render it unsuitable for continued use.

Costs of compliance and withdrawal are considered for MIs as a direct cost and also as indirect costs for Downstream Users (DUs) [where the latter is associated with the passing of registration costs downstream and/or the costs to DUs of withdrawal of a substance and the need to reformulate or otherwise adjust their business to cope with the withdrawal].

In relation to the CSA/CSR option, the following REACH compliance costs have been identified as relevant and potentially significant for MIs (and so will be assessed in detail):

- ***Production of Robust Study Summaries –*** these would have to be produced as part of the CSR for 1-10t CMRs 1A/1B (increase relative to the baseline);

- ***Undertaking PBT/vPvB Assessment –*** where screening for PBT/vPvB properties required for substances undertaking a CSA/CSR suggests that the substance meets the criteria in Annex XIII additional information would be required to complete the assessment (increase relative to the baseline);

- ***Cost of Human Health Exposure Assessment and Risk Characterisation –*** MIs undertaking a CSA/CSR would have to consider downstream uses of the substance in the CSA and exposure assessment and recommend risk management measures and the technical means to achieve them (increase relative to the baseline);

- ***Cost of Environmental Exposure Assessment and Risk Characterisation -*** MIs undertaking a CSA/CSR would have to consider environmental exposures for identified uses (increase relative to the baseline); and

- ***Cost of increased Communication in the Supply Chain -*** MIs undertaking a CSA/CSR would have to provide an extended SDS to downstream users (increase relative to the baseline).

The extension of the CSA/CSR obligation to 1-10t CMRs 1A/1B is also expected to impact on the downstream users' compliance costs in the following ways:

- ***Costs associated with the duty to pass information sufficient for an exposure assessment up the supply chain*** **-** for all of the 1-10t substances with known or unknown 'CMR' properties, documentation that is useful for the exposure assessment must be passed up the supply chain by the DUs (increase relative to the baseline);

- ***Costs associated with the duty to prepare a CSR in accordance with Annex XII (under Article 37(4))*** **-** downstream users are required to prepare a CSR in accordance with Annex XII for any use outside either the conditions described in an exposure scenario or a use and exposure category in a SDS or for any use his supplier advises against. This situation is thought likely to be a rare event but in principle there may be additional costs for a limited number of DUs (increase relative to the baseline); and

- ***Costs of Compliance with Parallel Regulation*** **–** for substances known or identified as CMR 1A/1B and requiring a CSA/CSR under the relevant option, the resulting exposure scenarios would facilitate compliance with the many regulatory instruments that are triggered by classification in accordance with Regulation (EC) No 1272/2008, producing a cost saving (decrease relative to the baseline).

1.2.3 Human health and environmental impacts

REACH aims to provide a high level of protection of human health and the environment while at the same time enhancing the competitiveness and innovative capability of the EU industry. The main objectives of the possible changes to the requirements for 1-10t are expected to be:

- to improve the detection of substances with hazardous properties;
- provide more useful information on the properties of those hazardous substances and;
- through a combination of the above (and also CSA/CSR for CMRs 1A/1B), improve risk management and communication in a way that would increase the level of protection afforded to human health and environment through REACH (and parallel legislation).

The impacts on human health and environment are considered to stem from the identification of more substances with hazardous properties and better information on those substances in particular regarding the following properties:

- Mutagenicity (and via this route genotoxic carcinogens[1]) (increase relative to the baseline);
- Dermal, inhalation and/or oral toxicity (increase relative to the baseline);
- Aquatic toxicity (increase relative to the baseline); and
- Persistence, bioaccumulation and toxicity (increase relative to the baseline).

[1] Note that no testing for carcinogenicity or reproductive toxicity is required in Annex VII of REACH or under any of the options. Thus non-genotoxic carcinogens/reproductive toxins will not be identified for any 1-10t substances.

In addition, the higher information options are expected to also provide for:

- better information on dermal/inhalation exposure limits for the substances with the relevant classifications (increase relative to the baseline);
- identification of substances with properties meeting classification for Single Target Organ Toxicity – repeated exposure (STOT RE 1 or 2) (increase relative to the baseline); and
- sufficient information to derive a Predicted No Effect Concentration (PNEC) for substances meeting classification for aquatic toxicity (increase relative to the baseline) and so provide a more robust basis for pollution prevention.

The CSA/CSR option is expected to have an impact on:

- Implementation of consistent and adequate risk management measures in relation to worker exposure (increase relative to the baseline);
- Adequate risk management measures in relation to articles (increase relative to the baseline);
- Identification and control of CMRs 1A/1B that are also PBT/vPvB substances (increase relative to the baseline); and
- Control of environmental risks (increase relative to the baseline).

When combined, all of these changes are expected to produce impacts on:

- the incidence of diseases, disorders and impacts (occupational and wider public) associated with each of the classifications for hazardous properties (reduction relative to baseline); and
- environmental pollution and impacts on the ecological status of the environment (reduction relative to baseline).

1.3 Methods applied to quantify significant impacts

1.3.1 Overview

The *Better Regulation Guidelines* identify that an assessment should be made of the significant impacts and that this should be quantitative where possible and also monetised where possible. As such, the objective for the assessment in Phase 3 has been to quantify all of the costs and benefits described above and, by consideration of the results, draw conclusions on the scale and significance of impacts on micro, small, medium and large enterprises, competitiveness, innovation and employment.

1.3.2 Quantification of compliance costs

In terms of the methods used to quantify and attribute costs, the assessments completed for the 2012 study, the 2014 study and adjusted/carried through to this Phase 3 study have all sought to improve upon past assessments of REACH such as the original (2003) and revised (2006) Business Impact Assessments (BIAs) (undertaken by RPA) and the Commission's 2006 Extended Impact Assessment (ExIA) (which was informed by and based on the BIAs).

A shortcoming of these past studies was the (low) resolution of costs. Here, because the focus was initially on producing estimates of the total (overall) cost of the proposals to industry as a whole[2] to inform negotiations on REACH, when it came to (later) assessment of likely effects on sub-groups such as small to medium sized enterprises (SMEs), it was difficult to break down the estimates of total costs into representative estimates of the costs to individual enterprises or groups of enterprises. The highest resolution that could be obtained by breaking down the total costs was by expressing costs as averages per substance or per tonne of substance. Whilst this enabled some consideration of likely impacts on individual and groups of enterprises, assessments had no means of identifying the impacts of costs that were higher and lower than the average.

In the light of these issues, in 2006 RPA was engaged by DG ENT to provide Technical Assistance for REACH Impact Assessment Updates (ENTR/05/100) to inform the Commission's assessments of the impact of the final proposals for the detailed text of REACH. One of the issues of concern for DG ENT was the impact of final proposals (and options) for low tonnage (1-10t) substances and the impact of the proposals on company level costs (owing to the fact that it was considered that a higher proportion of the low tonnage substances would be manufactured by SMEs).

The solution that RPA (and DG ENT) developed to address this question was one of calculating costs at an individual substance level first and aggregating to a total cost later; so reversing the order used in the preceding BIAs and the ExIA. When considering how this could be achieved it was clear that the costs of registration would be different under different circumstances. For example, costs would be different for substances requiring:

- a full information dossier but no additional testing;
- a full information dossier using non testing information (such as QSARs) to fulfil (all or some of) the missing test endpoints;
- a full information dossier requiring additional tests to be undertaken; or
- a physico-chemical only dossier.

To be able to capture these differences it was necessary to have an analysis capable of distinguishing between (and accounting for) substances with different cost outcomes.

To achieve this, the 2006 analysis for DG ENT began by considering the factors that would dictate each outcome. Continuing the above (simplified) example, owing to requirements under Article 12 and Annex III, the following factors logically dictate the eventual outcome:

- whether a substance is likely to be identified as potential CMR/PBT/vPvB;
- whether a substance has a diffuse/dispersive use;
- whether a substance is likely to be identified with any other HH or ENV classification;
- whether there is toxicological and ecotoxicological information already available for the substance; and
- whether non-testing methods (such as QSARs) could be used instead of full testing for the substance.

By describing each of these factors statistically (using real data or, where not available, informed assumptions) it becomes possible to calculate the percentage of substances that would be exposed

[2] i.e. chemical manufacturers/importers (MIs) and downstream users (DUs) as a single block.

to each of the different circumstances or, put another way, the statistical probability that a given substance would be exposed to costs of each type (and magnitude).

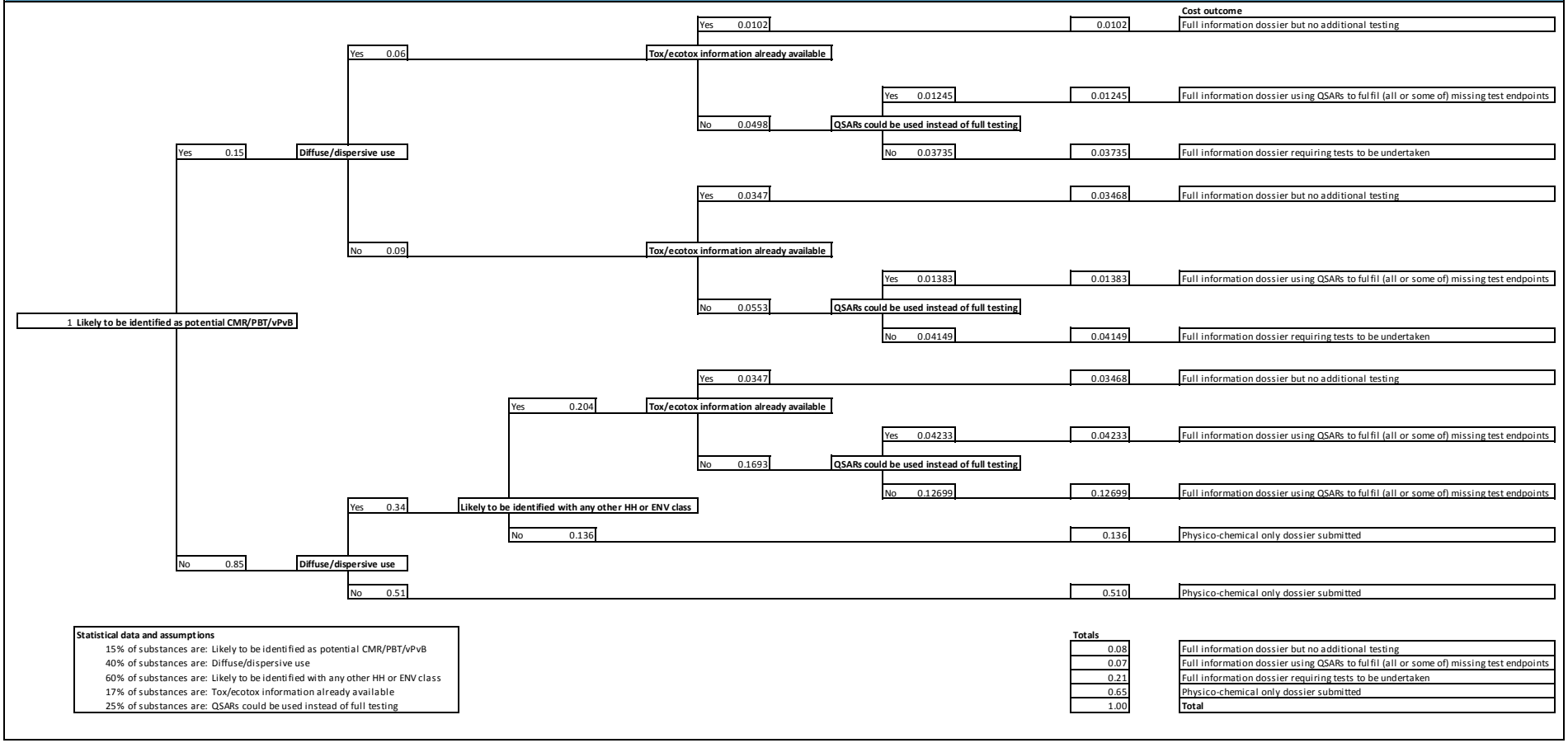
Using a simple example based on illustrative data, if the following is the case (please note that these are not real statistical values):

- 15% of substances are likely to be identified as potential CMR/PBT/vPvB by the application of QSARs or existing information;
- 40% of substances have a diffuse/dispersive use;
- 60% of substances are likely to be identified with any other human health (HH) or environmental (ENV) classification;
- 17% of substances already have toxicity/ecotoxicity information;
- 25% of substances could use non-testing information (such as QSARs) instead of full testing to complete information requirements;

one can begin to construct a simple probability tree such as that in the figure overleaf. In the figure, each branch of the tree represents a divide passing down the above list. So, at the first branch 15% of substances are likely to be identified as potential CMR/PBT/vPvBs (i.e. there is a probability of 0.15) and 85% will not. Of the 85% that are not, 40% may have a dispersive/diffuse use – so, overall 35% would not be identified as CMR/PBT/vPvBs but would have a dispersive/diffuse use (i.e. a probability of 0.35). As can be seen from the figure, continuing this to the end of the tree and grouping by outcome would suggest that, using these 'dummy' assumptions, overall:

- 8% of substances would require a full information dossier but no additional testing (i.e. the probability of this outcome is 0.08);
- 7% of substances would require a full information dossier using QSARs to fulfil (all or some of) missing test endpoints (i.e. the probability of this outcome is 0.07);
- 21% of substances would require a full information dossier requiring tests to be undertaken (i.e. the probability of this outcome is 0.21); and
- 65% of substances would require a physico-chemical only dossier to be submitted (i.e. the probability of this outcome is 0.65).

Figure 1-1: Probability tree example



Building on these principles the analysis undertaken in 2006 sought to build cost estimates that were sensitive to multiple factors. Unlike the example in the figure, however, the analysis needed to consider many more factors than the six used in the tree diagram. Around 80 individual factors were applied to estimate costs with additional factors including descriptors of:

- physicochemical factors – which dictated waiving of tests;
- level of existing data available – which dictated for which endpoints there was already information available;
- availability/applicability of QSARs – which dictated, for each endpoint, the likelihood that a reliable QSAR would/would not be available; and
- classification – which, for each endpoint, dictated whether or not a classification would be made or could be predicted (depending on the availability of information and QSARs for the endpoint).

Considering all of the factors necessary required an alternative methodological approach to that of a probability tree (which would have been difficult/impossible to develop for this number of factors).

As with similar problems in risk analysis and other applications, a Monte Carlo simulation approach was applied to generate 'draws' from the long sequence of probabilities and probability distributions associated with all of the factors combined. Applied to this particular problem, the Monte Carlo approach generates a 'draw' for a substance based on the string of probabilities and their magnitude, attributing a cost to the outcome of that 'draw'. Repeating this 20,000 times provides 20,000 draws, describing 20,000 1-10t substances.

This process can be likened to that of dropping marbles one by one into a marble run such as that pictured in Figure 1-2 below. Unlike marble run in the picture, however, the probabilities are not equal (50:50 left:right) at each set of gates but vary from one set of gates to another (c.f. the tree diagram).

Figure 1-2: Marble run

The Monte Carlo simulation model that was developed in 2006 was provided to DG ENT and used by the Commission to assess the options and final REACH proposals for the 1-10t substances. The same model was applied by RPA in 2012 in a thematic study (the Phase 1 study) for DG ENV to contribute to the first general report[3] on the functioning of REACH which was published on 5 February 2013.

The conclusion of the General Report on the 1-10t requirements, however, was that "*The Commission has […] insufficient information on the impact on innovation and competitiveness to propose changes to the information requirements for substances produced in low tonnages*" but that "*given the potential benefits whilst also considering the costs, the Commission will continue to work in these areas in co-operation with Member States and other stakeholders..*"

As such, in 2014 DG ENV commissioned RPA to re-examine the issue and provide a more detailed analysis of the impacts on innovation and competitiveness (the Phase 2 study). This work required modelling of costs to provide even greater resolution than that already achieved for DG ENT in 2006 (and subsequently DG ENV in 2012) where, as described above, the range of costs at the level of a substance had been calculated.

In order to provide the necessary information it was necessary to calculate costs down to the level of each of the MIs registering each of the substances (rather than across all MIs of each substance) and then calculate the likely cost burden of REACH registration for all substances registered by each MI. To enable assessment of impacts on SMEs, this also had to distinguish between micro, small, medium and large MIs.

As with the other factors dictating costs, all of these factors could be incorporated using statistics describing the:

- The number of companies of different sizes; and
- The number of 1-10t substances likely to be in the portfolios of companies of different sizes.

Adding these factors into the string of probabilities used by the Monte Carlo model and combining these with cost assumptions specific to size of enterprise, allowed the Monte Carlo model to be used to predict costs for every MI of every substance. This allowed the outputs of the model to be grouped and examined by size of MIs, allowing estimation and comparison of the costs to companies of different sizes as well as the overall burden. This, in turn, permitted a more detailed appreciation of the likely business impacts and, therein, information to inform consideration of the impacts on innovation and competitiveness as well as equity and fairness.

As well as addressing such issues, the Phase 2 (2014) model included cost elements that had not previously been accounted for in previous studies (such as the cost of letters of access). The Phase 2 model was subsequently employed in the 2015 DG GROW study Monitoring Impacts of REACH on Innovation, Competitiveness and SMEs where further refinements were made to the costs and costing approach and updated estimates of numbers of MIs. These refinements have been carried through to the model in this Phase 3 study.

[3] COM/2013/049 final

1.3.3 Calculation of Benefits

As well as providing information for the calculation of costs, the string of probabilities used in the Monte Carlo simulation also provides matching information on the numbers of different types of hazardous substance detected under each option. This, in turn, provides a basis for estimating the benefits of each option in terms of the human health and environmental damages avoided.

1.4 Structure of the remainder of the report

A suitably adjusted and updated version of the Monte Carlo model has been applied to examine the likely costs and benefits of the new suite of options. For the benefit of transparency and future reference, this technical methodology report provides a highly detailed description of the numbers and probabilities applied within the model, the data sources, assumptions applied and their reasoning. The aim is to provide a definitive reference document to accompany the estimates produced by the model.

The discussion is loosely divided into estimation of:

- ***the number and nature of substances:*** estimation of the number and nature of hazardous properties within the population of 1-10t substances;
- ***number of substances requiring toxicological and ecotoxicological information:*** estimation of the number of substances that will be identified by QSARs and other evidence as priority substances and will be required to generate toxicological and ecotoxicological information;
- ***substance costs of testing and information:*** estimation of the cost of generating the necessary toxicological and ecotoxicological information for substances;
- ***substance registration costs:*** estimation of the costs of registration including dossier preparation, sharing of information, administration costs of joint registrations, fees, etc.
- ***aggregated costs:*** calculation of costs by substance and by manufacturer/importer.
- ***human health and environmental benefits:*** methods used to calculate the benefits under the baseline and each of the options.

2 1-10t Phase-in Substances: Expected Numbers, Nature and Hazardous Properties

2.1 Total number of 1-10t substances

2.1.1 Substances to be registered only in the 1-10t band

It is estimated by ECHA that full registration for 20,000 unique phase-in substances will be submitted in the 1-10t band alone in/by the 2018 deadline. These are substances yet to be registered that will not also be registered in higher tonnage bands. In addition, as of June 2016, 56 unique substances have already been fully registered in the 1-10t band by virtue of their known C, M or R 1A/1B properties and requirements for earlier registration under Article 23(1)(a) of REACH.

2.1.2 Substances also registered in higher tonnage bands

Substances also registered in higher tonnage bands are less significant for the analysis as information equivalent to Annex VIII and above is already required for ALL of these substances. For these substances information leading to classifications including and going beyond those achieved under any of the information options being analysed will already be available and communicated to downstream users via Safety Data Sheets – (SDS and extended Safety Date Sheets – eSDS). As such, there is no effect or benefit from applying the options to these substances (as information in excess of that required under the options is already required and classifications communicated to downstream users and distributors).

2.2 Estimating the Properties of the 1-10t Phase-in Substances

2.2.1 Numbers of Phase-in 1-10t substances likely to have properties meeting classification for at least one endpoint

Until test and other information is gathered for the 20,000 1-10t substances there will be no information that describes exactly what number of substances possess hazardous properties and what these hazardous properties are. As such, one must predict what the properties of these substances are expected to be. This, in turn, provides the basis for identifying which of these substances and properties are already known (by existing test information, QSARs or other information) and the extent to which each option (and the baseline) is likely to detect further (and as yet unknown) hazardous substances and properties.

This is achieved in the model by dividing the 20,000 1-10t substances into those which, if subjected to toxicological and ecotoxicological testing (including *in vivo* mutagenicity testing), are expected to be identified with properties that would meet:

- At least one human health and at least one environmental classification (hereafter referred to as HH and ENV);
- At least one human health classification but no environmental classifications (HH not ENV);
- At least one environmental classification but no human health classifications (ENV not HH);
- No human health or environmental classifications.

Determining the percentage of substances fitting each of these categories has been informed by an analysis of the substances already registered under REACH and the classifications of these substances on the CLI (that would be identified by testing equivalent to Annex VII and the options and *in vivo* mutagenicity testing). An analysis by ECHA of REACH (fully) registered substances suggests in June 2016 that:

- 4,951 substances of 7,174 with full registration (69%) have one or more HH or ENV classification;
- 2223 have no properties meeting classification for HH or ENV; and
- 2,847 substances have an ENV classification.

Analysis of the CLI suggests that 72% of substances with a classification for ENV also have a classification for HH. Applying this provides the following:

- the number of substances with a classification for HH and ENV is equal to 2,050 (0.72 x 2,847)
- subtracting this from the total with an ENV classification (2,847) suggests that 797 substances have an ENV classification but no HH classification;
- Subtracting both of the above (2,050 and 797) from the total number of substances with an HH or ENV classification (4,951) provides the estimated number with an HH classification but no ENV classification as 2,104.

These numbers (and the percentages derived from them) can be applied to the number of 1-10t substances for registration to provide the expected number of 1-10t substances with hazardous properties. The table below provides the outcomes.

Table 2-1: Predicted numbers of 1-10t substances with hazardous/non-hazardous properties

Properties	Number of registered substances	Percentage of Total	Predicted numbers of 1-10t substances
Total	**7,174**	**-**	**20,000**
No HH or ENV properties for classification	2,223	31%	6,200
Total with ENV or HH properties	4,951	69%	13,800
Substances with HH and ENV properties	2,050	29%	5,720
Substances with HH not ENV properties	2,104	29%	5,860
Substances with ENV not HH properties	797	11%	2,220

2.2.2 Hazardous 1-10t substances and their classifications

The next step in the modelling is to statistically describe the classifications associated with the estimated 13,800 substances with properties that would meet HH or ENV classifications. This has been based on a statistical analysis of substances which are both already registered under REACH and having one or more HH or ENV classifications on the CLI. This provides data on the percentage of classified and REACH registered substances meeting each endpoint for classification (e.g. corrosive, acute oral, hazardous to the aquatic environment, etc.) and, therein, the percentage of substances with ENV/HH classifications that meet the classifications that are possible according to the tests and test endpoints that are currently in Annex and also the options for extended information (Options A to E). These percentages are then applied to the numbers calculated above in Section 2.2.1.

The table below provides the classifications, the percentage of REACH fully registered substances with those classifications and the number of 1-10t substances predicted to have properties that would meet each of the classifications (if they were subjected to testing) (obtained by multiplying the percentages by the numbers of substances with HH/ENV properties derived in Section 2.2.1).

Table 2-2: Numbers of 1-10t substances with properties that would meet certain classifications		
Classification	**As a Percentage of substances with ENV and/or HH classification**	**Implied numbers of 1-10t Substances with properties that would meet classification if subjected to testing**
Human Health Classifications		
Skin corrosive (1A, 1B & 1C)	20%	2,779
Skin irritation (2)	46%	6,415
Serious eye damage/irritation (1 &2)	66%	9,134
Skin sensitisation (1)	33%	4,553
Acute oral toxicity (1-4 - Hazard classes H300 to H302)	39%	5,356
Single target organ toxicity - repeated exposure (STOT RE 1 and 2)	11%	1,493
Environmental Classifications		
Hazardous to the aquatic environment acute (1)	50% (of substances with ENV)	4,005
Totals		
Total with ENV (from Table 2-1)		7,940
Total with HH and/or ENV (from Table 2-1)		13,800

In addition to the classifications set out in the table above, CMR 1A/1B and PBT/vPvB properties are of importance in the analysis.

CMRs

In relation to CMRs 1A/1B, ECHA has provided an analysis of the percentage of substances registered under REACH with these properties (June 2016). This suggests that around 3.7% of the 1-10t substances for full registration in 2018 (740 substances) are expected to meet classification for Mut. 1A/1B (carcinogenicity and reproductive toxicity are not endpoints that are tested for at 1-10t).

PBTs

In relation to PBTs, the work of Strempel *et al* (2012)[4] and others suggests that around 2% of substances with hazardous properties would be identified as potential PBTs by screening and this was applied in the Phase 2 analysis. Following its Annex III screening exercise in 2016, ECHA have suggested that Phase 3 should assume that 2.7% of substances would be identified as potential PBT/vPvB by screening. Of these substances only a proportion would be confirmed as PBTs by

[4] Strempel et al (2012): *Screening for PBT Chemicals among the "Existing" and "New" Chemicals of the EU*, Environ. Sci. Technol. 2012, 46, 5680−5687.

further assessment. ECB (2002)[5] suggests that around 20% of the substances identified as potential PBTs by screening would be identified as PBT substances after full PBT assessment.

Based on this it can be predicted that 2.7% of the 1-10t substances predicted to have a HH and/or ENV classification (373) would be identified by screening as potential PBTs if screening were carried out on all substances. Of these, 20% (75) would be identified as actual PBTs by further assessment and the remainder (298) would not be regarded as PBT/vPvB.

Resulting numbers of substances with different classifications

Having calculated the total expected numbers of substances that have properties that would meet each of the different classifications using the percentages described above, these have been divided into:

- Substances with HH and ENV properties;
- Substances with HH not ENV properties; and
- Substances with ENV not HH properties.

This provides the values in the table below describing the expected number of substances that would be identified with properties meeting each of the classifications **if all substances were subjected to full testing (including *in vivo* mutagenicity testing)**. In the table, for example, the data suggest that 13,800 1-10t substances have properties that would meet one or more HH or ENV classifications. Of these, 2,779 are expected to be skin corrosive (1A, 1B & 1C), 740 are expected to be 'CMR 1A/1B', etc.

Table 2-3: Hazardous Properties of 1-10t Substances				
	Numbers with HH and ENV properties	Numbers with HH NOT ENV properties	Numbers with ENV not HH properties	Total
All substances with any HH or ENV	5,720	5,860	2,220	**13,800**
Human Health Classifications				
Skin corrosive (1A, 1B & 1C)	1,373	1,406	0	**2,779**
Skin irritation (2)	3,169	3,246	0	**6,415**
Serious eye damage/irritation (1 &2)	4,512	4,622	0	**9,134**
Skin sensitisation (1)	2,249	2,304	0	**4,553**
CMR 1A/1B (Mut. 1A/1B)	366	374	0	**740**
Acute oral toxicity (1-4)	2,646	2,710	0	**5,356**
Single target organ toxicity - repeated exposure (STOT RE 1 and 2)	737	756	0	**1,493**
Environmental Classifications				
Hazardous to the aquatic environment acute (1)	2,885	0	1,120	**4,005**
PBT/vPvB Properties				
Would screen as PBT/vPvB	155	158	60	**373**
Actual PBT/vPvB (after assessment)	31	32	12	**75**

[5] ECB (2002): Identification of Potential PBTs or vPvBs Among the IUCLID High Production Volume Chemicals (ECB 4/14/02 (PBT strategy – report).

3 Number of Substances undergoing Testing

3.1 Number of Substances Requiring Toxicological and Ecotoxicological Information

3.1.1 Introduction

The estimates provided in Table 2-3 describe the number of 1-10t substances that would be identified with different hazardous properties if all substances were subjected to full testing (including *in vivo* mutagenicity testing).

Neither the baseline nor the options require *in* vivo mutagenicity testing on all substances and only Options C and E require *in vitro* testing on all 1-10t substances. Options (including retaining the baseline) differ in terms of:

- The number of substances required to undertake testing (by virtue of their being required to submit full Annex VII information); and
- The number of tests required.

Thus, options (including retaining the baseline) will differ in terms of:

- ***Costs*** – the more substances providing full test information, the higher the total cost; and
- ***Benefits*** – the more substances providing full test information, the higher the number of hazardous substances and classifications identified.

Under the baseline (current requirements) and Option A, only "*priority substances between 1 and 10 tonnes*" require generation of toxicological and ecotoxicological information. These substances are defined by a combination of Article 12 and Annex III and are "*substances for which it is **predicted** (i.e. by the application of (Q)SARs or other evidence) that they are likely to meet the criteria for":*

- classification as C, M or R 1A/1B or PBT/vPvB; or
- any health or environmental hazard classes or differentiations under CLP **and** have a dispersive or diffuse use.

Under Options B and D, reference to dispersive or diffuse use would be removed from Annex III such that, in effect, *all substances for which it is predicted (i.e. by the application of (Q)SARs or other evidence) that they are likely to meet the criteria for any health or environmental hazard classes or differentiations under CLP* would be required to submit toxicological and ecotoxicological information.

Under Options C and E, all substances would be required to submit toxicological and ecotoxicological information.

Having derived the expected number of 1-10t substances with hazardous properties (in Table 2-3), the first step in the modelling is to estimate how many of these would be "***predicted** by the application of (Q)SARs or other evidence*" as *"likely to meet the criteria for classification".* To do this, the **current** model considers 'evidence' in the following order:

- ***Step 1: Existing test information –*** some substances will already have some test results on some endpoints. The model estimates this number and therein the numbers of substances likely to be identified as being likely to meet criteria for CMR 1A/1B and PBT/vPvB based on this existing information. **The numbers that are <u>not</u> identified as such are then considered in Steps 2 and 3**;

- ***Step 2: Application of Read Across (RA)* -** RA is a technique used to predict endpoint information for one substance by using data for the same endpoint from another substance which is considered to be similar in some way (on the basis of structural similarity and similar properties and/or activities). As described in Section 3.1.3 below, the model estimates the number of substances for which information from RA might be applied. It then estimates the number of substances likely to be identified as likely CMRs 1A/1B, PBTs/vPvBs or other HH or ENV classifications; and

- ***Step 3: Application of (Quantitative) Structure Activity Relationships ((Q)SARs)* -** A SAR is a qualitative relationship that relates a (sub)structure to the presence or absence of a property or activity of interest. A QSAR is a mathematical model (often a statistical correlation) relating one or more quantitative parameters derived from a chemical structure to a quantitative measure of a property or activity. The model estimates the number of substances for which information may be derived from (Q)SARs and, therein, the number of substances likely to be identified as likely CMRs 1A/1B, PBTs/vPvBs or other HH or ENV classifications.

The outcome of applying these steps is predictions of:

- The number of substances for which hazardous properties are already known from test information;
- The number of substances for which hazardous properties would be suspected from the application of QSARs or other information; and, therefore
- The number of substances required to generate toxicological and ecotoxicological information under the options.

When the model was first developed the assumption was that MIs would undertake the work to review the likely status of substances, submitting the type of dossier appropriate to that outcome. However, since the model was first developed, there has been a change in strategy and ECHA has carried out a screening of pre-registered substances not yet registered to develop a list of substances known or suspected of meeting either or both of the Annex III criteria relating to CMRs 1A/1B/PBT/vPvB and or/any other HH or ENV classification.

The resulting list has been analysed to provide some insight into the outcome of ECHA's Annex III screening. From a starting pool of around 125,000 substances the Annex III list identifies 68,366 substances that meet a number of criteria of relevance to Annex III. 66,751 of these can be categorised as meeting the following criteria (placing them within the bounds of the Annex III criteria set out in the Regulation):

- CMR/PBT/PB;
- Not CMR/PBT but PB and other HH or ENV; and
- Not CMR/PBT/PB but other HH or ENV.

Further analysis of ECHA's list suggests the following:

- 53% of the substances screened are included in the Annex III inventory because they are known or suspected to meet at least one of the hazard criteria in Annex III (i.e. CMR or any other HH or ENV classification);
- 1.7% of the listed substances (0.9% of the total number of screened substances) are known to be CMR cat. 1 because of harmonised classification from Annex VI of CLP -> Annex III criterion a) will apply;
- For the remaining substances listed in the inventory, Annex III criteria a) or b) will apply depending on the case by case assessment. These substances are either:
    - suspected CMR (without possibility to differentiate between Cat. 1 and Cat. 2, the registrant would need to clarify in further investigation, ~37% of the total number of screened substances), and/or
    - suspected to meet any other HH or ENV classification, and/or
    - suspected to meet any of the P, B or T criteria (but PBT as such would occur only when P and B and T apply for the same substance).

The data and assumptions that were used in the Phase 2 analysis suggested a slightly different outcome. The table below provides a comparison of the predictions from the (previous) 2014 model compared with that found from the screening carried out by ECHA.

Table 3-1: Comparison of percentages meeting each criteria from the ECHA Annex III list versus the Phase 2 model assumptions

	Predictions from Phase 2 model	Suggested by ECHA analysis
Suspected CMRs/PBTs/vPvBs	25%	37%
Not CMR/PBT etc. but any other HH or ENV	33%	16%
Total known or suspected to meet key Annex III criteria (i.e. excluding diffuse/dispersive use)	58%	53%
Not suspected	42%	47%

As can be seen from the table, compared with the analysis of the ECHA list the Phase 2 model predicted a lower percentage of suspected CMRs/PBTs/vPvBs and a higher percentage of non CMRs/PBTs/vPvBs suspected of having properties likely to meet any other HH or ENV classification. The modelled estimate of the total known or suspected to meet the key Annex III criteria (i.e. excluding diffuse/dispersive use) is closer to that obtained from analysis of the ECHA list (but still larger).

In light of these findings the inputs and assumptions used in the Phase 2 model have been adjusted so that its predictions more closely match those of the ECHA screening that has been carried out - in effect the ECHA screening has permitted calibration of the model developed in Phase 2. Following the order of steps in the modelling, the subsections below describe the Phase 2 model inputs and assumptions the changes made to deliver the outcome suggested by the ECHA screening for Annex III.

3.1.2 Step 1: Existing Testing Information

For some 1-10t phase-in substances there will already be some data available on some endpoints.

The model differentiates between substances with:

- Test information on all current Annex VII endpoints;
- Test information on some (simple) toxicological endpoints in Annex VII[6]; and
- No test information.

Drawing on estimates first made in 2006, the model that was employed in the 2014 Phase 2 study (the Phase 2 model) assumed the values in the table below. These values have been revised downwards to deliver a final outcome calibrated to be comparable to that predicted using the ECHA Annex III analysis. The new values are also provided in the table.

Table 3-2: Testing information already available		
	Percentage of 1-10t substances	
	Phase 2 inputs	New (revised) values
Substances with test information on all current Annex VII endpoints	17%	10%
Substances with test information on skin/eye corrosion and irritation and acute toxicity (oral)	13%	8%
Substances with no test information	70%	82%

Applying these new percentages to the estimates of the number of substances with different properties (HH and or ENV and none) provides the breakdown of the numbers of substances with different levels of existing test information by type of hazardous property in the table below.

The values highlighted in red are substances for which existing test information suggests they are likely to meet the criteria for classification for one or more human health or environmental endpoints. These substances are potentially captured by the Annex III criteria on the basis of existing test information alone. The other values relate to substances for which there is, at present, no test information but for which properties might be identifiable by the application of Read Across (RA) or QSARs. This is considered in the next section.

Table 3-3: Numbers of substances with different levels of information by type of hazardous property			
	With test information on all Annex VII endpoints	With test information on skin and eye corrosion irritation and acute oral toxicity only	Without test Information
Numbers with HH and ENV	**572**	**458**	4,690
Numbers with HH not ENV	**586**	**469**	4,805
Numbers with ENV not HH	**222**	178	1,820
Numbers with no properties matching any HH or ENV class	620	496	5,084
Total numbers of substances where existing test information suggests may meet a classification for HH	1,380	927	0

[6] The model assumes availability of information on skin/eye corrosion and irritation and acute toxicity (oral) on the basis that these are the most fundamental and relatively inexpensive tests to have performed

Substances with test information on all Annex VII Endpoints that are Prioritised as CMR 1A/1B or PBT/vPvB

The Annex III criteria prioritise CMRs 1A/1B and PBTs/vPvBs. For substances with test information on all Annex VII endpoints there will be test information from *in vitro* gene mutation studies (GM Bact) and also sufficient information to allow screening for PBT/vPvB. To determine the numbers likely to be identified as priority 1-10t substances based on existing test information, the model first considers substances that may be identified as CMR 1A/1B. It then considers the remaining substances and the number of these that may be identified as PBT/vPvB.

Regarding CMRs 1A/1B, *in vitro* studies are not perfect predictors of *in vivo* mutagenicity and may, on the one hand, fail to identify mutagenic properties of a substance that is actually mutagenic and, on the other, falsely predict that a substance is mutagenic when the subsequent *in vivo* testing triggered by such 'false positive' indication will identify that it is not. The extent to which *in vitro* tests are able to correctly identify *in vivo* mutagens versus *in vivo* non-mutagens is expressed in terms of the sensitivity and the specificity of the test where here:

- **sensitivity** expresses the extent to which a given *in vitro* test is able to correctly predict that a substance is mutagenic (expressed as the percentage of *in vivo* mutagens that would be correctly identified); and
- **specificity** expresses the extent to which a given test is able to correctly predict that a substance is not mutagenic (expressed as the percentage of *in vivo* **non**-mutagens that would be correctly identified).

For those substances identified as likely to meet CMR 1A/1B from the existing test information (GM Bact), then, there will be two types:

- True positives - actual CMRs 1A/1B that presented (true) positive in the GM Bact test already conducted; and
- False positives – non-CMRs 1A/1B that presented (false) positive in the GM Bact test already conducted.

The model applies a GMBact sensitivity value of 52% and a specificity value of 72%[7] to the predicted numbers of actual CMRs and non-CMRs to identify the numbers of substances that would be identified as likely CMRs 1A/1B (whether true positive or false positive) and those that would not (whether false negatives or true negatives).

Concerning the identification of PBTs/vPvB for the purposes of Annex III criteria, to eliminate double counting, the model considers substances not already prioritised on the basis of their being likely to meet classifications as CMR 1A/1B (as estimated above). The Monte Carlo model applies the estimated percentage of substances likely to be identified as potential PBT/vPvB by screening (2%).

For substances with existing test information on all current Annex VII endpoints, the table below summarises the outputs from the model (employing all of the inputs described in the sections above) concerning the numbers of substances prioritised as CMR, PBT/vPvB and also those substances expected to be identified with any other HH or ENV properties.

[7] Based on 3711 chemicals including tests with Salmonella and Escherichia – see Matthews et al., 2006.

Table 3-4: Numbers of substances prioritised on the basis of existing test information on all Annex VII endpoints						
	Total with test information on all Annex VII endpoints	Of which identified as likely CMRs (true and false positives)	Total not identified as likely CMRs	Of which No. screening positive for PBT	Total identified as likely to be CMR 1A/1B or PBT/vPvB	Total identified as likely to meet other HH or ENV Classification
Numbers with HH and ENV	572	173	399	11	184	388
Numbers with HH not ENV	586	178	409	11	189	397
Numbers with ENV not HH	222	60	162	4	64	158
Numbers with no properties matching any HH or ENV class	620	167	453	0	167	0

Substances with test information on some Annex VII Endpoints

As noted above, for those substances with some simple toxicological information (but not all of those in Annex VII) the model assumes that data are available on skin and eye corrosion/irritation and acute oral toxicity only. These data alone are insufficient to make conclusions regarding potential CMR 1A/1B and PBT/vPvB properties and so all of these substances are assumed to be subjected to Steps 2 and 3 (RA and QSARs) along with substances with no information.

3.1.3 Steps 2 and 3: Application of Read Across (RA) and QSARs

To the remaining substances (those with little or no information from testing[8] see Table 3-2) the outcome of applying QSARs and Read Across (RA) is predicted using two stages.

Step 2: Application of Read Across (RA)

RA is a technique used to predict endpoint information for one substance by using data from the same endpoint from another substance which is considered to be similar in some way (on the basis of structural similarity and similar properties and/or activities).

RA may be qualitative or quantitative. In qualitative read-across, the presence (or absence) of a property/activity for the target substance is inferred from the presence (or absence) of the same property/activity for one or more source substances. Qualitative read-across gives a 'yes/no' answer. Quantitative read-across is used to obtain a quantitative value for an endpoint, such as a dose-response relationship.

RA is based on (and dependent upon) the identification of similar substances and it can be performed to determine whether the target substance belongs to an existing category (chemical

[8] The 82% with no information from testing and those of the 8% where there is some testing information but none of that information suggests a classification.

category) or to identify a similar substance to the target substance (analogue search). Reviewing available information, the 2012 Phase 1 study on 1-10t substances made tentative conclusions on the ability of RA to provide information on a range of test endpoints. This review tentatively suggested that RA might be applied to around 11% of substances.

Accordingly, the Phase 2 Monte Carlo model assumed that RA can be successfully applied (and likely properties and HH and ENV classifications can be predicted) for 11% of substances which currently have little or no information. This value has been revised downwards to 4% to deliver a final outcome calibrated to be similar to that suggested by the ECHA Annex III screening. Whilst this might, at first, seem like a large reduction, in the model, any substances for which properties are not identified in the RA step are still subjected to the QSAR step. In this way both RA and QSAR inputs in the model work together with one another. Thus it is the combination of the RA and QSAR inputs that is of importance rather than the individual inputs for RA.

The resulting numbers of substances and hazardous properties identified in this step are summarised in the table below. In the table, the number of substances identified with 'other HH or ENV classifications' are derived by deducting the numbers of likely CMRs and PBTs/vPvBs identified. However, substances identified as potentially CMR 1A/1B and identified as potentially PBT/vPvB may be:

a. the same substances - in which case the number of substances identified would be equal to the maximum number identified across the two endpoints. For example, if 10 CMRs and 4 PBTs/vPvBs are predicted by RA then this would equate to 10 substances in total for prioritisation; or
b. the substances may all be different - in which case the number of substances identified would be equal to the total of the numbers identified across the two endpoints. So, 10 CMRs and 4 PBTs/vPvBs predicted by RA would equate to 14 substances in total for prioritisation; or
c. most likely, some are the same and some are different - in which case the number for prioritisation lies between the two cases above. A best estimate is that the number prioritised is equal to an average of the maximum value across the endpoints and the total across all endpoints. So, 10 CMRs and 4 PBTs/vPvBs predicted by RA would equate to 12 substances in total for prioritisation.

The latter has been assumed in the model to eliminate double counting to the extent possible.

Table 3-5: Priority 1-10t substances identified through Read Across (RA)				
Type of substance	**Numbers of substances for which RA can be successfully applied**	**Suspected CMRs identified for prioritisation**	**Suspected PBTs/vPvBs identified for prioritisation**	**Total identified as likely to meet other HH or ENV Classification**
Numbers with HH and ENV	206	13	5	191
Numbers with HH not ENV	211	13	6	196
Numbers with ENV not HH	80	0	2	78
Numbers with no properties matching any HH or ENV class	223	0	0	0

Step 3: Application of QSARs

QSARs are assumed to be applied to all substances with little or no information and for which RA cannot be successfully applied.

A detailed review of QSARs and their applicability to (and adequacy for) various information requirements under REACH was undertaken as part of the Phase 1 study. This concluded that QSARs for the following endpoints could be applied in relation to Annex III (and others were not applicable or were not oriented towards the specific classification-based approach that Annex III takes):

- Acute toxicity
- Skin irritation/corrosion
- Eye irritation
- Skin sensitisation
- Mutagenicity/ carcinogenicity
- Aquatic toxicity – short term
- PBT & vPvB

The Monte Carlo model considers the following factors in relation to the applicability and accuracy of QSAR predictions.

- **QSAR domain:** The domain of applicability specifies a group of molecular structures for which the model is applicable. For molecule structures outside of this domain the model is not applicable – this is expressed as the percentage of substances to which QSARs can be applied to develop meaningful results;
- **QSAR sensitivity:** the extent to which a given QSAR for an endpoint is able to correctly identify substances with hazardous properties (for that endpoint) - this is expressed as a percentage substances correctly identified; and
- **QSAR specificity:** the extent to which a given QSAR for an endpoint is able to correctly identify substances **without** hazardous properties (for that endpoint) - this is expressed as a percentage substances correctly identified as non-hazardous for that endpoint.

In Phase 2, estimates of the percentages applied to each were based as much as possible on (the few) studies available that have attempted to assess the results of QSARs applied to substances for which test data are already available (and so the properties are known and correctness of

predictions can be assessed). Where data for an endpoint were not available from such studies, assumed values were used.

The table below provides the values which, in combination with the inputs described above for RA, produce a final outcome calibrated to be comparable to that obtained from analysis of the ECHA Annex III list. Only slight revisions have been made to values originally sourced from the literature and more significant revisions have been made to QSAR endpoints which relied on assumed values in Phase 2.

Table 3-6: Values for QSAR Domain, Sensitivity and Specificity Applied in the Monte Carlo model – Revised inputs

	QSAR Domain	QSAR Sensitivity	QSAR Specificity	Notes
Acute toxicity	14%	35%	50%	Revised assumed
Skin irritation/corrosion	65%	45%	84%	Slightly altered from Liew, C. Y. and Yap, C. W. (2013)
Eye irritation	35%	40%	80%	
Skin sensitisation	30%	45%	50%	
Mutagenicity/ carcinogenicity	70%	70%	60%	Slightly altered From UK COM
Aquatic toxicity – short term	35%	35%	50%	Revised assumed
PBT and vPvB	40%	70%	50%	Revised assumed

Given that there is (and will remain for some time) uncertainty over the accuracy/correctness of predictions from QSARs[9] the revisions and alterations are likely to be well within the bounds of possibility. QSAR domains, however, are more easily established. ECHA has provided the study with data on the percentage of substances within the domains of the models used to compile the Annex III list (and also from another study). These are provided in the next table and suggest the following:

- PBT/vPvB domain may be about 40%
- Aquatic toxicity is about 35%
- Skin sensitisation is about 35%
- Acute toxicity is about 14%

Thus the revised values for domain in the model appear broadly consistent with those provided by ECHA.

[9] Because one needs testing results as well as QSAR results to establish correctness of predictions. The availability of the former is limited. Indeed, for this reason it was anticipated that REACH would help QSAR prediction.

Table 3-7: ECHA data on model domains					
Endpoint	**Model**	**Substances**	**Number within domain**	**Percentage within domain**	**Weighted average %**
Ready biodegradability	VEGA (IRFMN)	72,336	42,537	59%	**56%**
	CATALOGIC	10,761	3,800	35%	
Bioconcentration	VEGA (CAESAR)	72,336	19,953	28%	**27%**
	CATALOGIC	10,446	2,097	20%	
Acute toxicity to fish	VEGA (EPA model)	72,336	27,044	37%	**38%**
	TOPKAT	9,035	4,505	50%	
Skin sensitisation	VEGA	72,336	26,877	37%	**35%**
	TIMES	10,202	2,331	23%	
Acute oral toxicity to rat	ACDLabs	66,617	9,077	14%	**14%**

Applying all of the modelling steps and inputs described above provides a prediction of the number of substances likely to be identified as likely to meet the following key Annex III criteria:

- substances identified by the application of QSARs or other evidence as likely to meet classification as CMR1A/1B or PBT/vPvB; and
- substances identified by the application of QSARs or other evidence as likely to meet classification as for any other human health or environmental classification (but not CMR/PBT/vPvB).

The table below provides a summary of the numbers and percentages of substances predicted by the model. As can be seen from these, the model delivers estimates consistent with those implied by the ECHA Annex III screening exercise.

Table 3-8: Predicted number of substances identified as likely to meet the key Annex III criteria				
		Predicted by calibrated Phase 3 model		ECHA Annex III List
		Numbers of substances	Percentages of sub-total or total	Percentage of total
With full Information	Suspected CMRs/PBTs	604	30%	
	Any other HH or ENV known or suspected	943	47%	
	Not suspected	453	23%	
	Sub-total	2,000		
With Partial Info	Suspected CMRs/PBTs	462	29%	
	Any other HH or ENV known or suspected	654	41%	
	Not suspected	485	30%	
	Sub-total	1,601		
With no info (predictions based on QSAR and RA alone)	Suspected CMRs/PBTs	6,235	38%	
	Any other HH or ENV suspected	1,684	10%	
	Not suspected	8,480	52%	
	Sub-total	16,399		
Total	Suspected CMRs/PBTs	7,301	**37%**	**37%**
	Any other HH or ENV known or suspected	3,281	**16%**	**16%**
	Total known or suspected to meet all but the diffuse use criterion	10,582	**53%**	**53%**
	Not suspected	9,418	**47%**	**47%**
	Total	**20,000**		

3.1.4 Numbers of Substances Requiring Toxicological and Ecotoxicological Information

The number of substances requiring toxicological and ecotoxicological information varies between the options. Substances requiring this information under the options are as follows:

- **Current Annex III criteria (Baseline and option A)** – substances identified by the application of QSARs or other evidence as likely to meet classification as CMR1A/1B or PBT/vPvB and substances with diffuse/dispersive uses likely to meet any other human health or environmental classification;
- **Annex III no diffuse/dispersive criterion (options D and B)** - substances identified by the application of QSARs or other evidence as likely to meet classification as CMR1A/1B or PBT/vPvB or any other human health or environmental classification; and
- **no Annex III criteria (options C and E)** – all substances registering.

For the baseline and Option A, substances with a HH or ENV classification other than for CMR1A/1B do not have to submit full information if there is no dispersive/diffuse use. Previous studies have estimated that between 20% and 40% of substances are used in wide dispersive uses (20% based on the Danish and Nordic Product Registers and 40% based on the Commission's previous estimates).

ECHA has analysed the current registrations and estimates that 25% of the 1-10t substances will have one or more dispersive uses for the purpose of Annex III. Applying this provides the expected numbers of substances requiring toxicological and ecotoxicological information for different Annex III options in the table below.

Table 3-9: Numbers of substances requiring toxicological and ecotoxicological information by application of the Annex III options										
		No Annex III (Options C and E)			No diffuse/dispersive use criterion in Annex III (Options D and B)			Current Annex III Criteria (Baseline and Option A)		
Availability of existing test information	**Type of hazardous properties (HH – Human Health ENV – Environmental)**	**Number of Substances to Annex VII**	**CMRs**	**Potential PBTs/ vPvBs**	**Number of Substances to Annex VII**	**CMRs**	**Potential PBTs/ vPvBs**	**Number of Substances to Annex VII**	**CMRs**	**Potential PBTs/ vPvBs**
Test information available on all endpoints	With HH and ENV properties	572	37	16	572	37	16	281	24	12
	With HH (not ENV) properties	586	37	16	586	37	16	288	24	12
	With ENV (not HH) properties	222	0	6	222	0	6	104	0	5
	Substances with no properties matching any HH or ENV class	620	0	0	167	0	0	167	0	0
Test information available on some endpoints	With HH and ENV properties	458	29	12	458	29	12	217	19	12
	With HH (not ENV) properties	469	30	13	469	30	13	222	19	13
	With ENV (not HH) properties	178	0	5	70	0	5	70	0	5
	Substances with no properties matching any HH or ENV class	496	0	0	119	0	0	117	0	0
No information available	With HH and ENV properties	4,690	300	127	2,613	167	44	1,997	157	42
	With HH (not ENV) properties	4,805	307	129	2,533	168	44	2,009	160	42
	With ENV (not HH) properties	1,820	0	49	844	0	16	721	0	16
	Substances with no properties matching any HH or ENV class	5,084	0	0	1,929	0	0	1,929	0	0
Total submitting full toxi/ecotox information	With HH and ENV properties	**5,720**	**366**	**155**	**3,643**	**233**	**72**	**2,495**	**200**	**66**
	With HH (not ENV) properties	**5,860**	**374**	**158**	**3,588**	**235**	**73**	**2,519**	**203**	**67**
	With ENV (not HH) properties	**2,220**	**0**	**60**	**1,136**	**0**	**27**	**895**	**0**	**26**
	Substances with no properties matching any HH or ENV class	**6,200**	**0**	**0**	**2,215**	**0**	**0**	**2,213**	**0**	**0**
Total submitting physico chemical data only	With HH and ENV properties	**0**	**0**	**0**	**2,077**	**133**	**83**	**3,225**	**166**	**89**
	With HH (not ENV) properties	**0**	**0**	**0**	**2,272**	**139**	**85**	**3,341**	**171**	**91**
	With ENV (not HH) properties	**0**	**0**	**0**	**1,084**	**0**	**33**	**1,325**	**0**	**34**
	Substances with no properties matching any HH or ENV class	**0**	0	0	**3,985**	0	0	**3,987**	0	0

4 Cost of Generating Toxicological and Ecotoxicological Information

4.1 Toxicological and Ecotoxicological Information Required

4.1.1 Standard Information Required under the Options

All substances identified by the analysis as requiring toxicological and ecotoxicological information under the relevant Annex III scenario (described in Section 3.1.4) must gather the information appropriate to the Information Option (current Annex VII, Annex VII+ or Annex VII++). The table below provides an overview of options A to E and also their relationship to options for changing Annex III criteria.

Table 4-1: Final Combinations of Options to Progress to Full Impact Assessment			
Annex III Options	**Information Options**		
	Current Annex VII	**Annex VII+**	**Annex VII++**
Do nothing	**Baseline**	**Option A**	
Remove diffuse/dispersive use criterion		**Option D**	**Option B**
Remove all criteria		**Option C**	**Option E**

Standard information required in Annex VII

The standard information required in the current Annex VII is that which is common to all of the options and the baseline. This is summarised in Table 4-2. The adaptations and refinements identify that certain tests are not required in the following cases:

- For substances that are strong acids/bases - no test required on 8.1 Skin irritation/skin corrosion, 8.2 Eye irritation or 8.3 Skin sensitisation;
- For substances that are corrosive to skin - no test required on 8.2 Eye irritation or 8.3 Skin sensitisation; and
- For substances that are flammable at room temperature - no test required on 8.1 Skin irritation/skin corrosion, 8.2 Eye irritation, or 8.3 Skin sensitisation.

In the Monte Carlo model, estimates of the percentage of substances likely to have such properties are applied to determine which substances do not require test information for the relevant endpoints. For those substances with HH properties, analysis of CLI suggests that around 20% of substances that are skin corrosive are strong acids/bases. Expressed as a percentage of substances with any HH classification this suggests 2.5% of substances with HH properties would satisfy this criterion (i.e. for substances with HH properties there is a probability of 0.025 that they meet this criterion) and no tests would be required for 8.1 Skin irritation/skin corrosion, 8.2 Eye irritation or 8.3 Skin sensitisation for these substances.

The analysis of expected classifications suggests that 22.7% of substances with HH properties are corrosive to skin (i.e. for substances with HH properties there is a probability of 0.227 that they meet this criterion) and so would not require information on 8.2 Eye irritation or 8.3 Skin sensitisation. Analysis of CLI suggests that only around 0.2% of substances would meet the flammability criteria,

eliminating the need for testing on 8.1 Skin irritation/skin corrosion, 8.2 Eye irritation, or 8.3 Skin sensitisation.

Table 4-2: Toxicological and Ecotoxicological Information Requirements in Annex VII		
Endpoints	**Requirements**	**Adaptations to Requirements**
Human Health Endpoints (Mammalian Toxicology)		
8.1 Skin irritation /skin corrosion	Following consecutive steps: (1) an assessment of the available human and animal data; (2) an assessment of the acid or alkaline reserve; (3) *in vitro* study for skin corrosion; and (4) *in vitro* study for skin irritation	Steps 3 and 4 is not needed where: 1) and 2) indicates classification as corrosive to the skin or irritating to eyes; the substance is flammable in air at room temperature; the substance is classified as very toxic in contact with skin; or an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level
8.2 Eye irritation	Following consecutive steps: (1) an assessment of the available human and animal data; (2) an assessment of the acid or alkaline reserve; and (3) *in vitro* study for eye irritation	Step 3 is not needed where: 1) and 2) indicates classification as corrosive to the skin or irritating to eyes; or the substance is flammable in air at room temperature
8.3 Skin sensitisation*	8.3.1. Skin sensitisation, in *vitro/in chemico* Information from in vitro/in chemico test method(s) recognised according to Article 13(3), addressing each of the following key events of skin sensitisation: (a) molecular interaction with skin proteins; (b) inflammatory response in keratinocytes; (c) activation of dendritic cells.	The(se) test(s) do not need to be conducted if — an *in vivo* study according to point 8.3.2 is available, or — the available *in vitro/in chemico* test methods are not applicable for the substance or are not adequate for classification and risk assessment according to point 8.3. If information from test method(s) addressing one or two of the key events in column 1 already allows classification and risk assessment according to point 8.3, studies addressing the other key event(s) need not be conducted.
	8.3.2.Skin sensitisation, *in vivo*	An *in vivo* study shall be conducted only if *in vitro/in chemico* test methods described under point 8.3.1 are not applicable, or the results obtained from those studies are not adequate for classification and risk assessment according to point 8.3.
8.4 Mutagenicity	8.4.1. *In vitro* gene mutation study in bacteria	Further testing shall be considered in case of a positive result
8.5 Acute toxicity	8.5.1. By oral route	Not required where: the substance is classified as corrosive to the skin; or a study on acute toxicity by the inhalation route (8.5.2) is available (requirement for 10 to 100 tonne substances)

Table 4-2: Toxicological and Ecotoxicological Information Requirements in Annex VII		
Endpoints	**Requirements**	**Adaptations to Requirements**
Environmental Endpoints (Ecotoxicology)		
9.1 Aquatic toxicity	9.1.1. Short-term toxicity testing on invertebrates (preferred species Daphnia)	9.1.1. Not required where: there are mitigating factors indicating that aquatic toxicity is unlikely to occur, e.g. substance is highly insoluble in water or the substance is unlikely to cross biological membranes; a long-term aquatic toxicity study on invertebrates is available; or adequate information for environmental classification and labelling is available. Long-term toxicity testing may be considered instead of 9.1.1. The long-term aquatic toxicity study on Daphnia (Annex IX, section 9.1.5) is considered if the substance is poorly water soluble
	9.1.2. Growth inhibition study aquatic plants (algae preferred)	9.1.2. Not required where there are mitigating factors indicating that aquatic toxicity is unlikely to occur e.g. substance is highly insoluble in water or the substance is unlikely to cross biological membranes
9.2 Degradation	9.2.1 Biotic/ 9.2.1.1. Ready biodegradability	Not required for inorganic substances
* Updated by Commission Regulation (EU) 2016/1688 of 20 September 2016 amending Annex VII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards skin sensitisation.		

Information on all endpoints is assumed to be required for all substances barring the exemptions identified above. It is assumed that this information is generated by carrying out the relevant *in vitro* tests (with the exception of strong acids/bases from which information on corrosivity etc. can be easily predicted). With the exception of the mutagenicity screening test (GM Bact – discussed in Section 4.2.2), the model assumes that each test undertaken positively identifies the corresponding properties and classification.

Additional standard information required under both Annex VII+ and VII++ Options (Applies to all Options A to E)

Additional information and requirements common to both Annex VII+ and VII++ options comprise:

- Screening and assessment for PBT/vPvB properties; and
- Section 9.1 Aquatic Toxicity – a third test is required (on fish).

The additional requirements and the variables applied in Monte Carlo modelling are summarised in the table below.

Table 4-3: Additional requirements common to the Annex VII+ and VII++ information options		
Additional Requirement	**Description**	**Modelling**
Screening and assessment for PBT/vPvB properties	Screening for PBT/vPvB properties in accordance with the criteria in Annex XIII is carried out for all substances. If the screening indicates that a substance may meet PBT/vPvB criteria, PBT/vPvB assessment is required. This requires the collection of additional information on the substance, its properties, fate and behaviour in accordance with Annex XIII.	Screening is carried out for all substances requiring toxicological and ecotoxicological information. Note that where existing test information is already available for substances, the screening is carried out as part of the assessment of whether the substance is likely to be a PBT/vPvB for the purposes of Annex III (where it applies under the option combination). As noted in Section 2.2.2, around 2.7% of substances subjected to screening are expected to be identified as potential PBT/vPvBs (i.e. there is a probability of 0.027). These substances are assumed to gather the additional information for assessment. The assessment based on the additional information will identify those that are actual PBTs/vPvBs. As noted in Section 2.2.2, around 20% of substances identified by screening as potential PBT/vPvB are actual PBT/vPvB (i.e. the combined probability is 0.027 x 0.2 = 0.0054). This percentage is applied in the Monte Carlo model to provide the number of PBT/vPvBs identified under each option.
Section 9.1 Aquatic Toxicity	Testing in accordance with Section 9.1.3 - short-term toxicity testing on fish would be undertaken: • for any substances identified with a classification as hazardous to the aquatic environment by testing in accordance with Section 9.1 of Annex VII; and	Based on predicted properties of substances in Table 2-2 50% of substances with ENV properties (that undergo testing) will be identified as hazardous to the aquatic environment (acute) by testing in accordance with Section 9.1 of Annex VII. Under the Annex VII+ and VII++ information options, these substances undertake a further aquatic toxicity study in fish
	• for any substances where screening for P and B in PBT/vPvB identifies that criteria for both P and B (or vP and vB) are met.	On the basis of work Strempel *et al* (2012)[10] the Monte Carlo model assumes that 5% of substances would be identified as meeting the criteria for both P and B (or vP and vB) and potentially T. Under the Annex VII+ and VII++ options, these substances undertake a further aquatic toxicity study in fish (if one is not already required in the light of the results of aquatic toxicity testing in accordance with Section 9.1 of Annex VII).

[10] Calculated from Strempel et al (2012): *Screening for PBT Chemicals among the "Existing" and "New" Chemicals of the EU*, Environ. Sci. Technol. 2012, 46, 5680−5687 and described in Section A1.6 of the Phase 2 Report on the extension of CSA/CSR requirements available at http://ec.europa.eu/environment/chemicals/reach/pdf/1-10t%20P2%201-10t.pdf

Additional standard information required under the Annex VII++ Option alone

The additional information and requirements unique to the Annex VII++ option comprise: Section 8.4 Mutagenicity – additional screening test for cytogenicity; Section 8.5 Acute Toxicity – dermal or inhalation toxicity studies; and Section 8.6 Repeated Dose Toxicity – for lower toxicity substances.

The additional requirements and the variables applied in Monte Carlo modelling are summarised in the table below.

Table 4-4: Additional requirements under VII++ information options		
Additional Requirement under VII++ options	**Description**	**Monte Carlo modelling**
Section 8.4 Mutagenicity	In addition to the standard testing in Annex VII (GM Bact) a further screening test is required in the form of the current Annex VIII Section 8.4.2 in vitro cytogenicity study in mammalian cells (CAbvitro) or in vitro micronucleus study (MNTvitro)	All substances undergo the additional test. It is assumed that 80% undertake the MNTvitro and 20% the CABvitro. A positive result in any of the two tests triggers further studies on mutagenicity.
Section 8.5 Acute Toxicity	Classification for acute oral toxicity in accordance with Section 8.5.1 of Annex VII triggers consideration of dermal or inhalation toxicity in accordance with Sections 8.5.2 and 8.5.3 of Annex VIII.	The data in Table 2-2 suggest that around 39% of substances with HH and/or ENV properties are expected to have properties meeting classification as acute toxic (oral). Under the Annex VII++ option, these substances are required to undertake either a dermal or an inhalation study depending on the most likely route of exposure. The Monte Carlo model assumes that 80% of the required testing is on dermal toxicity and 20% on inhalation. Analysis of toxicity classifications on CLI suggests that 91-96% of substances that are classified as acute toxic oral also have a classification for toxicity by inhalation or dermal routes. As such, the model assumes that 93.5% of the substances subjected to dermal/inhalation tests (i.e. those identified with a classification for oral toxicity in accordance with Section 8.5.1 of Annex VII) will be classified accordingly.
Section 8.6 Repeated Dose Toxicity	Short term repeated dose toxicity in accordance with Section 8.6.1 of Annex VIII for substances identified by testing under 8.5.1 as Acute Tox 4.	37% of substances with harmonised classifications for oral toxicity on the CLI are Acute Tox 4. The Monte Carlo model applies a probability of 0.37 to the substances for which a classification for oral toxicity to provide the numbers undertaking repeated dose toxicity studies. For all of these substances, improved toxicological information will be available for management of risks. The Monte Carlo model also assumes that the information will lead to classification as STOT RE 1 or 2 for 14% of the substances tested. This on the basis of the implied number of harmonised substances with classification as Acute tox 4 and STOT RE 1 and 2.

4.2 Estimating the Costs of Generating the Toxicological and Ecotoxicological Information

4.2.1 Cost of undertaking individual tests

The costs applied to the standard information requirements (and further information as required) within the model are provided in Table 4-5. With the exception of the following, all costs have been drawn from the 2012 CEFIC testing catalogue which lists the average cost of testing for each endpoint and costs have been updated to reflect 2016 prices:

- Cost of Screening for PBT/vPvB Properties – PBT/vPvB screening requires cross checking the results of tests with the screening criteria in Annex XIII. The Monte Carlo model assumes that this would cost around €500 (i.e. a half person day). This applies to Options VII+ and VII++ (because there is no requirement to screen in Annex VII) and also for all substances which already have information available or predicted through QSARs and this information is used as part of the identification of likely PBT/vPvB properties for the purpose of prioritisation and Annex III (which applies to Annex VII as well as the higher information options);
- In vitro skin irritation – around €1,000 per substance based on information from Cosmetics Europe;
- In vitro eye irritation - around €2,000 per substance based information from Cosmetics Europe CRO;
- Skin sensitisation –around €1,000 per substance based on information from Cosmetics Europe;
- Further testing for PBT/vPvB Assessment – further testing and assessment applies to those substances identified as potential PBT/vPvB by screening. For such substances additional information comprising simulation testing on degradation in surface water/soil/sediment, assessment of the toxicokinetic behaviour of the substance or results from a bioconcentration or bioaccumulation study in aquatic species. The costs of testing and information may vary considerably. The Monte Carlo model assumes that the cost of further information is €20,500.

In the case of substances where information on some or all endpoints in Annex VII is available, the model assumes that other registrants of the substance (where there are other registrants) must buy access to that information from the owner of that information. The Monte Carlo model assumes that the owner of any existing information is one of the registrants and that the value of that information is equivalent to the sum of the costs of the relevant tests set out in Table 4-5 below.

Table 4-5: Costs of Testing and Information	
Cost component	**Cost (€)**
Annex VII 8.1. Skin irritation/ corrosion - In vitro skin corrosion/irritation*	€ 1,000
Annex VII 8.2. Eye irritation - In vitro eye irritation*	€ 2,000
Annex VII 8.3. Skin sensitisation*	€ 1,000
Annex VII 8.4.1 GMbact: gene mutation test in bacteria (Ames test)	€ 3,534
Annex VIII 8.4.2 CAbvitro, in vitro chromosome aberration test	€ 20,482
Annex VIII 8.4.2 MNTvitro, in vitro micronucleus test	€ 16,848
Annex VIII 8.4.2 MNTvitro/CAbvitro (weighted average based on % conducting MNTvitro)	€ 17,576
Annex VIII 8.4.3 GMvitro:gene mutation assay in mammalian cells	€ 17,967
Annex IX 8.4.4 Cytvivo:cytogenetic assay in experimental animals	€ 28,285
Annex VIII 8.4.3 GMvivo:gene mutation assay in experimental animals - Mouse micronucleus assay	€ 12,872
Annex VII 8.5. Acute toxicity - Oral toxicity	€ 1,516
Annex VIII 8.5.2. Acute toxicity - Toxicity via Inhalation	€ 12,512
Annex VIII 8.5.3. Acute toxicity - Toxicity via Dermal routes	€ 2,536
Annex VIII 8.6.1. Repeat dose toxicity - Short term (Oral)	€ 53,984
Annex VII 9.1.1. Aquatic Toxicity - Invertebrate - short-term	€ 5,337
Annex VII 9.1.2. Aquatic Toxicity - Algal - short-term	€ 5,922
Annex VIII 9.1.3. Aquatic Toxicity - Fish – short-term	€ 4,942
Annex VII 9.2.1.1. Degradation - Biotic - Ready biodeg	€ 3,779
Cost of Screening for PBT/vPvB Properties	€ 500
Further testing for PBT/vPvB Assessment (once identified by screening)	€ 20,500
* based on information provided to the study in 2016 by Cosmetics Europe in relation to new *in vitro/in chemico* tests for sensitisation.	

4.2.2 Further Mutagenicity Testing under the Options

Mutagenicity Testing for Annex VII and VII+ Information Options (Baseline and Options A, C and D)

As noted in Section 4.1.1, all substances completing the full Annex VII requirements are required to gather data in relation to the Annex VII gene mutation test (GMBact). In the event of a negative result, it is concluded that the substance is non-genotoxic and no further testing is required. In the event of a positive result, substances are required to gather additional data from Annex VIII and above.

For the Phase 2 study the Monte Carlo model drew on ECHA *Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.7a: Endpoint Specific Guidance* which set out specific guidance on meeting the information requirements set out in Annexes VI to XI to the REACH Regulation. The guidance includes, for each endpoint, an Integrated Testing Strategy (ITS) "*providing guidance on how to define and generate relevant information on substances in order to meet the requirements of REACH*[11]".

In relation to further studies on mutagenicity, the general route followed by the ECHA guidance is one of undertaking relevant mutagenicity testing progressing up through Annex VIII and above to

[11] Structure of Chapter R.7a – page 15

establish genotoxicity[12]. The guidance indicates that the following would be required in the event of a positive result for GMBact:

- either or both of CAbvitro/MNT Vitro or GMvitro tests in Annex VIII as appropriate to the ITS;
- Cytvivo or GMvivo[13] *in vivo* tests in Annex IX as appropriate to the ITS.

For a substance presenting negative in the *in vivo* tests the guidance identified that it would be concluded that the substance is not genotoxic and no further testing is required and, for a substance presenting positive in either of the *in vivo* tests it would be concluded that the substance was genotoxic.

Based on the ECHA guidance, the Monte Carlo model separately considers substances predicted in the model to have CMR 1A/1B properties and those that are not (non-CMRs). Sensitivity data for the different tests are applied to the numbers of CMRs to identify the outcome of each test in terms of the number of true positives (TPs) and false negatives (FNs) identified. Specificity data are applied to the numbers of non-CMRs to identify the number of false positives (FPs) and true negatives (TNs). All of the resulting positives (whether TPs or FPs) from the battery of tests are then required to generate *in vivo* test data.

The sensitivity and specificity data used in the Monte Carlo model are drawn from the UK Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) *Guidance on a Strategy for Genotoxicity Testing of Chemical Substances*[14]. This guidance reviewed the effectiveness of testing strategies using adjusted data based on the Kirkland et al (2005)[15] study. The values applied in the Monte Carlo model are provided in Table 4-6.

Table 4-6: Sensitivity and specificity of different *in vitro* mutagenicity tests

	Sensitivity	Specificity
GMBact	52%	72%
GMvitro	71%	44%
MNTvitro	88%	23%
Cabvitro	55%	63%
MNTvitro/CAbvitro (80% conducting MNTvitro)	81%	31%

[12] Note that no testing for carcinogenicity or reproductive toxicity is required in Annex VII of REACH or under any of the options. Thus non-genotoxic carcinogens/reproductive toxins will not be identified for any 1-10t substances.

[13] GMbact: gene mutation test in bacteria (Ames test); CAbvitro, in vitro chromosome aberration test; MNTvitro, in vitro micronucleus test; GMvitro:gene mutation assay in mammalian cells; Cytvivo:cytogenetic assay in experimental animals; GMvivo:gene mutation assay in experimental animals

[14] the UK Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) (2011) Guidance on a Strategy for Genotoxicity Testing Of Chemical Substances. http://www.iacom.org.uk/guidstate/documents/COMGuidanceFINAL.pdf

[15] Kirkland, D., Aardema, M., Henderson, L., Müller, L. (2005): Evaluation of the ability of a battery of three in vitro genotoxicity tests to discriminate rodent carcinogens and non-carcinogens: I. Sensitivity, specificity and relative predictivity, Mutation Research - Genetic Toxicology and Environmental Mutagenesis, 584 (1-2), pp. 1-256.

Considering the standard GMBact test in Annex VII (and VII+), the data suggest that:

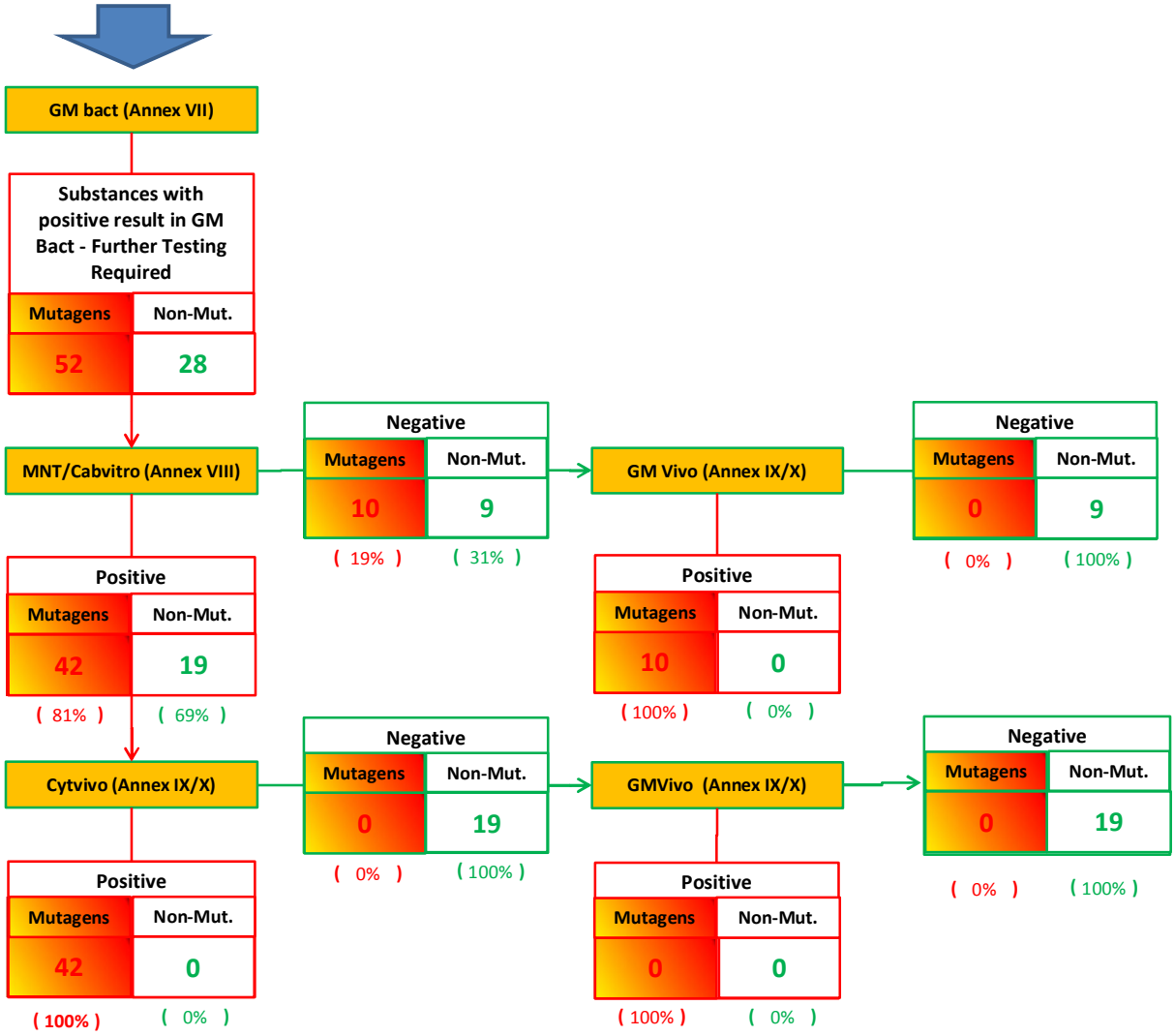
- 52% of CMRs for which toxicological and ecotoxicological information is required will show a true positive result (TP) triggering the requirement to undertake further studies; and

- 28% of non-CMRs for which toxicological and ecotoxicological information is required will show a false positive result (FP) triggering the requirement to undertake further studies.

In terms of the further studies that are required for substances, there are a number of combinations depending on the results obtained from each successive test suggested by the ITS. The results can be predicted statistically by applying the relevant sensitivity/specificity value to the outcome of the previous test. In this way the Monte Carlo model uses a cascade approach to predict how many substances are likely to carry out which combination of tests (and at what cost).

The approach is illustrated in the figure below which shows the outcome of applying the ITS to the 52% of mutagens and 28% of non-mutagens that would be identified as requiring further studies (because they show a positive result in GMBact). In the figure, the numbers in brackets are the relevant sensitivity and specificity values assumed for the associated tests (as given in Table 4-6).

Figure 4-1: Illustration of cascade modelling of the outcome of further mutagenicity following a positive result for GM Bact in Option VII and VII+



Mutagenicity Testing for Annex VII++ Information Options (Options B and E)

As noted in Section 4.1.1, for the Annex VII++ Information Options (Options B and E) all substances completing the full Annex VII requirements are required to gather data in relation to both the Annex VII gene mutation test (GMBact) and the Annex VIII CAbvitro/MNTvitro studies.

Considering these standard tests application of the sensitivity/specificity data suggest that:

- **For CMRs -** 52% of CMRs for which toxicological and ecotoxicological information is required will show a true positive result (TP) to the GM Bact and 48% a false negative (FN) result. Of the 48% showing a false negative, 81% will show a true positive (TP) result in the CAbvitro/MNTvitro – i.e. 39% overall (81% times 48%). Overall, then, 91% (52% plus 39%) of CMRs will be identified as requiring further studies by the combination of the two tests;

- **For non-CMRs -**28% of non-CMRs for which toxicological and ecotoxicological information is required will show a false positive result (FP) and 72% a true negative (TN) result. Of the

72% showing a true negative result, 69% will show a false positive (FP) result in the CAbvitro/MNTvitro – i.e. 49% overall (69% times 78%). As such, 77% of non-CMRs will be identified as requiring further studies by the combination of the two tests.

As with the further studies required under Annex VII and VII+ options, the Monte Carlo model uses a cascade approach to predict the test combination that will apply for further studies and the associated costs under the Annex VII++ options.

4.2.3 Number of vertebrates used in tests

In addition to the costs of testing for each substance undergoing individual tests, the Monte Carlo model also calculates the number of vertebrates used in the associated tests. These numbers are provided in Table 4-7.

Table 4-7: Number of vertebrate animals used in tests

Test	Number vertebrates used
Annex VII 8.1. (3) Skin irritation/ corrosion - In vitro skin corrosion - Classification (if any): Skin corrosive (1A, 1B & 1C)	2
Annex VII 8.2. Eye irritation - In vitro eye irritation - Classification (if any): Serious eye damage/irritation (1 &2)	2
Annex VII 8.3. Skin sensitisation - In vivo LLNA - Classification (if any): Skin sensitiser (1). In the analysis it has been assumed that the new *in vitro* test is only applicable to 50% of substances so 50% would undertake *in vitro* (no vertebrates) and 50% *in vivo* (23 vertebrates)	23
Mutagenicity – In vivo mammalian chromosome aberration test	50
Mutagenicity – In vivo mammalian micronucleus test	30
Annex VII 8.5. Acute toxicity - Oral toxicity - Classification (if any): Acute oral toxicity (1-4)	8
Annex VIII 8.5.2. Acute toxicity - Toxicity via Inhalation or Dermal Classification (if any): Acute inhalation toxicity (1-4)	15
Annex VIII 8.6.1. Repeat dose toxicity - Short term (1 route only) - Classification (if any): Single target organ toxicity - repeated exposure (STOT RE 1 and 2)	50
Annex VIII 9.1.3. Aquatic Toxicity - Fish – short-term - Classification (if any): Hazardous to the aquatic environment acute (1)	14
Longer-term aquatic study	400
Identified as potential PBT - Need to Undertake Further testing for Assessment inc. Annex VIII 8.8.1. Toxicokinetics	108
Source: Katinka van der Jagt , Sharon Munn, Jens Tørsløv & Jack de Bruijn (2004) Addendum to the report: Assessment of additional testing needs under REACH Effects of (Q)SARS, risk based testing and voluntary industry initiatives, ECB, November 2004.	

5 Costs of Substance Registration

5.1 Cost of different registration requirements

5.1.1 Overview

The cost of generating toxicological and ecotoxicological information represents only one element of the costs of registration. To these must be added:

- ***Registration Dossier costs*** - the costs of drafting and finalising a registration dossier for submission;
- ***Cost of producing study summaries*** – which varies from information option to information option (because of differences in the information generated by different options) and outcome in terms of any further mutagenicity testing and/or PBT/vPvB assessment;
- ***Joint registration and SIEF administrative costs*** - where there is more than one registrant of the substance, the costs of liaising with the other registrants as part of sharing information on the substance (Substance Information Exchange Fora – SIEFs), sharing the costs of that information, preparing the registration dossier and other technical and administrative liaison costs;
- ***Costs of revising Substance Safety Data Sheets (SDSs)*** – where there is a change in classification for a substance in the light of any new information generated;
- ***Costs of proposals for animal tests*** – where there is a need to undertake animal testing by virtue of following the ITS for mutagenicity or for PBT/vPvB assessment; and
- ***Registration fees*** – which vary by size of enterprise (micro, small, medium and large).

In addition to these cost elements, the assessment is also considering the option of extending REACH CSA/CSR obligations (Article 14(1)) to all 1-10t substances known or expected to meet criteria for CMR 1A/1B. For these substances, in addition to the above, the following costs will also apply:

- ***Human Health and Environmental Hazard Assessment*** – including production of robust study summaries in relation to the human health and environmental hazard assessments (upgraded from study summaries required in the absence of CSA/CSR);
- ***Human health and Environmental Exposure Assessment and Risk Characterisation***;
- ***Communication in the Supply Chain*** - adding results of the PBT/vPvB assessment to an extended Safety Data Sheet (eSDS), expanding sections of the SDS in relation to, in particular, Sections 7 and 8 (Handling and storage; Exposure controls/personal protection) to reflect the relevant risk management measures and the technical means to achieve them; and including the relevant exposure scenario(s) in an annex to the eSDS.

The following sub-sections provide a description of the cost estimation and application of costs in the Monte Carlo model. With the exception of fees (which are fixed by Regulation), the cost of each component is estimated by consideration of likely time and effort for each element. Some of the cost elements described above will be similar from one substance to another but many will vary depending on a range of factors including the extent to which further testing has been undertaken, the number of other manufacturers and importers (MIs) and the size of the MI enterprise (which influences the technical capacity and experience of the registrants completing the relevant tasks and, hence, the time required and associated costs).

Owing to the fact that registrations for 1-10t substances are substantially different from the much larger dossiers that must be produced for higher tonnage substances (which, include, for example, CSA) there is little that can be drawn from the experience of registrations submitted for the higher tonnage substances (>100t per year). That said, since the previous study the model has been used to model the costs of the Registration 2018 exercise for DG GROW[16]. In the same study, the costs of Registration 2013 were assessed and the need for changes to cost and cost assumptions in the Monte Carlo model was assessed and a few alterations were made to the estimates of the administrative and legal costs of consortium/joint registration and SIEF formation as well as the numbers of substances expected to be registered by more than one MI.

5.1.2 Registration dossier costs

Registration dossier costs relate to the general compilation of material for the dossier including physico-chemical information, general administration of the submission and liaison with ECHA. The costs of providing study summaries in the dossier are considered separately as these vary depending on the information gathered for a substance.

Two levels of information are relevant for the registrations of 1-10t substances; registrations for substances needing only to provide physicochemical information and registrations for substances providing the full toxicological and ecotoxicological information appropriate to the information option.

For both levels, in the Phase 2 study the Monte Carlo model distinguished between joint registrations (by a consortium of manufacturers and or importers - MIs) and individual registrations (by single MIs). The latter was considered possible either where there is only one MI of a substance or in situations where one or more members of a consortium decide to make a separate (individual) submission of their own. Since the time of that study an Implementing Act on Data Sharing has been adopted which allows ECHA to start blocking individual registrations in REACH-IT. Accordingly, the latter situation (where one or more members decide to register separately) can no longer occur and this is reflected in the Phase 3 model. So, in the Phase 3 model, joint registrations are made by a consortium of all MIs in cases where there is more than one MI and individual registrations are only made in circumstances where this is only a single MI of the substance.

In terms of unit costs, the Monte Carlo model distinguishes between dossiers compiled and submitted by MIs of different sizes, with separate costs applied for micro, small, medium and large enterprises on the broad assumption that in-house expertise and experience is less developed in smaller companies and this affects the time taken to compile and submit a dossier (and increases the costs).

The per substance costs of compiling full registration dossiers used in the Monte Carlo model are provided in Table 5-1 for joint and individual full registrations. Costs are estimated as a range and reflect person day costs of €1,000 per day. Registrations containing physico-chemical information only are assumed to be 90-95% of the full registration costs in Table 5-1 (as study summaries of toxicological and ecotoxicological testing information are considered separately) because costs are unlikely to differ significantly between full and physico-chemical only registrations for this category

[16] RPA & CSES (2015): Monitoring Impacts of REACH on Innovation, Competitiveness and SMEs (http://ec.europa.eu/growth/sectors/chemicals/reach/studies_en)

of cost. For joint registrations, the Monte Carlo model applies the cost for the largest size of MI registering a substance (as it is assumed in the model that the largest MI will be the lead registrant).

Table 5-1: Registration Dossier submission costs (€ per substance)		
	Lower bound	Upper Bound
Cost of Individual Registration dossier for:		
Micro enterprises	€ 2,200	€ 3,200
Small enterprises	€ 2,000	€ 3,000
Medium enterprises	€ 2,000	€ 2,800
Large enterprises	€ 1,500	€ 2,000
Cost of Joint Registration dossier if:		
All members are micro enterprises	€ 2,800	€ 3,800
Small is the largest member (no medium or large MIs)	€ 2,500	€ 3,500
Medium is the largest member (no large MIs)	€ 2,500	€ 3,300
Large	€ 2,000	€ 2,500

Cost of updating and/or upgrading dossiers

When Phase 2 of the study was being undertaken it was envisaged that the options would be implemented in time for the 2018 REACH registration deadline. As this time is now relatively close, the Commission has decided that changes in requirements under the options would only apply after the 2018 registration deadline and not before.

In practical terms the changes in costs for a substance depend on:

- Whether a substance would have been required to submit physico-chemical information or full information under the baseline (current requirements); and
- Whether a substance would have to submit physico-chemical information or full information under an option.

These factors determine whether a dossier would need to be upgraded, updated or both under an option. Here the following can be observed:

- **For substances requiring only physico-chemical information under the baseline and under an option**: no upgrading or updating is required and there is no change in costs;
- **For substances requiring only physico-chemical information under the baseline (current requirements) but full information under the option:** costs are associated with the additional (full) information and for updating and upgrading the dossier to one containing the toxicological and ecotoxicological information required;
- **For substances required to submit full information under the baseline:** costs are associated the additional (full) information and for updating the dossier to reflect new information.

The costs applied to each situation in the Monte Carlo model are detailed in Table 5-2. As can be seen from the table, the core assumptions for updating dossiers (note not the additional information contained in those dossiers as that is calculated separately) after 2018 are as follows:

- The additional cost of updating a full Annex VII dossier to a new specification is estimated as being equal to 20-30% of the costs of the full dossier already produced for 2018 for

substances without a change in classification and 30-40% for substances with a change in classification; and

- The additional cost of updating a physico-chemical registration dossier and upgrading it to a full dossier is estimated as being equal to 70-80% of the costs of producing a full dossier before 2018 (as the administrative, use and physico-chemical information will remain the same as the original 2018 dossier).

As will be seen in the following sections, these percentages are also applied to joint registration and SIEF administrative costs for these types of substances.

Table 5-2: Costs for updating and upgrading dossiers

		Substances requiring only physico-chemical information under the baseline (current requirements) but full information under the option	Substances required to submit full information under the baseline
Dossier produced to new specification after 2018	**Information costs**	Cost of producing the information required under the Option (baseline information costs are zero for physico-chemical information)	Cost of information additional to that required under the baseline – Annex VII (i.e. Option information cost minus Annex VII information cost)
	Registration dossier costs	Cost of updating and upgrading the dossier to one containing full toxicological and ecotoxicological information – this is taken as 70-80% of the costs of submitting a full dossier set out in Section 5.1.2. Refunding of fees: crediting fees charged under the baseline.	Cost of updating the dossier – this is taken as: • 20-30% of the costs of submitting a full dossier set out in Section 5.1.2 for substances where new information does not lead to a change in classification; or • 30-40% of the costs of submitting a full dossier set out in Section 5.1.2 for substances where new information leads to a change in classification

5.1.3 Cost of producing study summaries

The total cost of producing study summaries for presentation in the dossier depends on the number and nature of the testing studies undertaken. The table below provides estimated costs of providing study summaries for each of the tests included in each of the information options. Costs are based on estimated time for a toxicologist (whether in-house or consultant) at €1,000 per day.

Table 5-3: Cost of summarising information (€ per substance)		
Cost of summarising QSARs and other information for Annex III		€ 500
Annex VII 8.1. Skin irritation/ corrosion - In vitro skin corrosion/irritation		€ 100
Annex VII 8.2. Eye irritation - In vitro eye irritation		€ 100
Annex VII 8.3. Skin sensitisation - In vivo LLNA		€ 100
Annex VII 8.4.1 GMbact: gene mutation test in bacteria (Ames test)		€ 250
Annex VIII 8.4.2	CAbvitro, in vitro chromosome aberration test	€ 250
	MNTvitro, in vitro micronucleus test	€ 250
Annex VIII 8.4.3 GMvitro:gene mutation assay in mammalian cells		€ 250
Annex IX 8.4.4 Cytvivo:cytogenetic assay in experimental animals		€ 500
Annex VIII 8.4.3 GMvivo:gene mutation assay in experimental animals - Mouse micronucleus assay		€ 500
Annex VII 8.5. Acute toxicity - Oral toxicity		€ 100
Annex VIII 8.5.2. Acute toxicity - Toxicity via Inhalation		€ 100
Annex VIII 8.5.3. Acute toxicity - Toxicity via Dermal routes		€ 100
Annex VIII 8.6.1. Repeat dose toxicity - Short term (1 route only)		€ 250
Annex VII 9.1.1. Aquatic Toxicity - Invertebrate - short-term		€ 100
Annex VII 9.1.2. Aquatic Toxicity - Algal - short-term		€ 100
Annex VIII 9.1.3. Aquatic Toxicity - Fish – short-term		€ 100
Annex VII 9.2.1.1. Degradation - Biotic - Ready biodeg		€ 100
Screening for PBT/vPvB Properties		€ 250
Further tests for PBT/vPvB Assessment		€ 1,000

5.1.4 Joint registration and SIEF administrative costs

Joint registration and SIEF administrative costs are associated with time spent by each MI when engaging with other registrants on shared information (as part of SIEFs) and also on the preparation of the dossier. Costs applied are as follows:

- Cost of engaging on information (applies to each registrant) = € 1,000 per MI registering; and
- Cost of engaging on dossier preparation (applies to each registrant in a consortium) = € 750 per MI jointly registering.

For registrations that only include only physico-chemical information, costs are 80-90% of the above.

For dossiers that are required to be updated or upgraded after 2018 the following percentages of these costs are applied in addition to the above:

- Where a full Annex VII dossier needs updating to a new specification, 20-30% of the above costs for substances without a change in classification and 30-40% for substances with a change in classification; and
- Where a physico-chemical registration dossier needs upgrading it to a full dossier 70-80% of the above costs.

5.1.5 Cost of revising Substance Safety Data Sheets (SDSs)

In the event that additional information under REACH results in a change in classification for a substance, there is a need to update the SDS for the substance. The Monte Carlo model applies a cost of €500 per substance for updating the SDS.

5.1.6 Cost of proposals for animal tests

Before animal tests are carried out a proposal for animal testing must be submitted to ECHA. The Monte Carlo model applies a cost of €500 per test proposal per substance.

5.1.7 Registration fees

Registration fees and charges that apply to different sizes of enterprise are established under Commission Regulation[17]. The fees relevant to registration of 1-10t substances are provided as Table 5-4. Under Article 74(2) of REACH these fees do not apply when full toxicological and ecotoxicological data are provided. Under the options, fees paid in 2018 are to be refunded if a physico-chemical only dossier is upgraded to a full dossier after 2018.

Table 5-4: Registration fees for 1-10t substances (€ per MI per substance)

	Individual	Joint
Micro enterprises	€ 86	€ 64
Small enterprises	€ 600	€ 450
Medium enterprises	€ 1,114	€ 835
Large enterprises	€ 1,714	€ 1,285

[17] Regulation No 340/2008 of 16 April 2008, as amended by the Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013.

6 Calculation and Aggregation of Costs

6.1 Calculation of Costs for Each Registrant

6.1.1 Numbers of MIs registering 1-10t substances by size of enterprise

When applying and aggregating costs to provide an assessment of costs and cost impact, the Monte Carlo model accounts for variations in costs between, for example, micro, small, medium and large enterprises. To achieve this, the model applies information describing the registrants of the 1-10t substances and their size.

Regarding the numbers of MIs of different sizes expected to register 1-10t substances, ECHA estimate that 60% of registrants will be large enterprises and 40% SMEs. Since the Phase 2 study, a version of the model has also been applied in the DG GROW study on the impact of REACH on innovation and competitiveness[16]. As part of that DG GROW study, ECHA had supplied RPA with an anonymised database of registrations by all registrants and for all substances registered in all tonnage bands to date by companies of differing size. We were able to analyse that data and obtain information describing the distribution of M/Is and substances in the terms used in the model (i.e. Only one M/I, 2-3 M/Is, 4-6 M/Is, 6-10 M/Is, and >10 M/Is) for each of the four tonnage bands and also the overall average number of MIs registering per substance which was estimated at 2.3.

Accordingly, 2.3 MIs per substance implies that there are 8,696 MIs expected to register (20,000 ÷ 2.3), 5,218 of which will be large enterprises and 3,478 will be SMEs. Assuming that 40% of SMEs will be medium, 35% small and 25% micro this provides the following numbers of MIs:

- 870 Micro enterprises;
- 1,217 Small enterprises;
- 1,391 Medium enterprises; and
- 5,218 Large enterprises.

6.1.2 Numbers of substances in MI portfolios

As noted above, it has been estimated that there will be an average of 2.3 registrants per substance. Combining this with the numbers of registrants of different sizes allows the derivation of the average number of 1-10t substances in the portfolios of SMEs and Large enterprises. The derived values in Table 6-1 below are consistent with an average of 2.3 MIs per substance.

Table 6-1: 1-10t registrations by size of company				
Size of enterprise	**Micro**	**Small**	**Medium**	**Large**
Number of companies registering 1-10t substances	870	1,217	1,391	5,218
Average number of 1-10t substances in MI portfolio	1.9	2.4	2.9	7

6.1.3 Numbers of substances with one and more than one MI

Based on new information provided to the DG GROW study on Innovation and Competitiveness[16] by ECHA it has been estimated that 60% of substances (12,000) will be fully registered by only one MI.

By implication, 8,000 will therefore be registered by more than one MI. In combination with the average of 2.3 MI's per substance it is possible to mathematically derive estimates of the average number of substances to be registered by 2-3, 4-6, 6-10 and 10-15 MIs. The estimates provided in the table below are consistent with an overall average of 2.3 MIs per substance overall.

Table 6-2: Number of registrants for different 1-10t substances		
	Expected percentage of substance registrations	Expected Number of substance registrations
Only one MI	60%	12,000
2-3 MIs	25%	5,000
4-6 MIs	8%	1,600
6-10 MIs	5%	1,000
10-15 MIs	2%	400

6.1.4 Allocation and aggregation of costs

The estimated cost of registration for a substance produced by the Monte Carlo simulation is a function of many factors where these include (but are not limited to):

- whether (and how much) toxicological and ecotoxicological information is required (or not);
- the number of manufacturers and importers (MIs) submitting a registration for the substance;
- the number of these MIs that will be part of a joint submission and the number that will submit an individual submission; and
- the size(s) of the MI enterprise(s) registering a substance.

Different combinations of factors produce different outcomes. For this reason a Monte Carlo approach is needed to capture the range and distribution of costs accounting for the likelihood of each combination. Taking one substance at a time, the Monte Carlo simulation carries out the following steps in order in order to calculate and attribute costs:

- ***Generate property profile and pathway*** - the Monte Carlo model generates a profile and pathway through registration and information according to the option. This profile is developed probabilistically using the information already provided in Section 2.2 which governs:
  - whether a substance must generate toxicolocial and ecotoxicological information under each of the options;
  - the cost of generating standard the information for an option for that substance considering the available information and the need to purchase any existing test information from the owner versus generate new information;
  - whether a substance meets any of the criteria requiring further studies for mutagenicity and/or PBT/vPvB assessment and, therein, the costs of providing that information (and summarising it in a dossier).
- ***Generate number of MIs registering*** **-** the Monte Carlo model allocates a number of MIs registering the substance based on the percentages given in Table 6-2 (for example, there is a 60% chance that a substance may only have one MI, a 25% chance that it will have 2-3, etc.);

- ***Identify size of MIs registering*** **-** having assigned a number of MIs to the substance (above), the Monte Carlo model then assigns a code denoting the size of each of the MIs registering the substance (micro, small, medium or large) based on the values in Table 6-1 which, when expressed as a percentage gives the percentage probability of a MIs being micro versus small versus medium versus large; and
- ***Identify whether joint versus individual registration*** – where there is only one MI the registration for the substance is an individual registration. Where there is more than one MI all manufacturers will submit a joint registration.

Applying the above steps, the modelled simulation allocates the appropriate cost to the individual and/or joint registration of the substance accounting for the size of the M/Is (which affects the registration dossier costs), the number of M/Is (which affects the costs of SIEFs and administration of the joint registration) and the property profile and pathway of the substance (which affects costs of testing and information, updating the SDS, proposals for animal tests, study summaries).

Where there is more than one M/I registering a substance, costs are shared between all registrants. These costs comprise testing and information costs, participation in SIEFs, study summaries, SDS costs and registration dossier submission costs Where test information exists, the cost of access to this information is shared between all but the first registrant (who is assumed to own the information). All cost sharing between members of the consortium is allocated on the basis of the tonnes produced by each manufacturer. Finally, the appropriate fee is allocated to each manufacturer.

For each substance the modelled simulation produces the total cost of registration for each M/I registering that substance where each M/I is allocated a unique identity number. When run on 20,000 substances, then, this produces a results table of the estimated costs of registration under each of the options for each of the 12,600 M/Is of these 20,000 1-10t substances. Using a pivot table, these data can be re-ordered and summarised to produce data on the total costs of the each of the options to each M/I considering the number of 1-10t substances registered each M/I. In other words, for each M/I the modelled simulation produces estimates of the total costs across all of the 1-10t substances registered by that M/I. Grouped into M/Is of different sizes, this allows assessment of impacts on SMEs versus larger enterprises (amongst many other things).

Applying the above steps, the modelled simulation generates a profile of a substance and allocates the appropriate cost to the registration of it for each of the MIs. When run on 20,000 substances this produces a very large results table of the estimated costs of registration under each of the options for each of the MIs of these 20,000 1-10t substances. Using a pivot table, these data can be analysed to produce an assessment of costs, business impacts and benefits.

6.2 Cost of registration and of substance withdrawal

6.2.1 Identifying substances likely to be withdrawn (and not registered)

The first analytical task to be undertaken on the raw data from the model is to establish which substances would be registered and which would be withdrawn (not registered). The decision to withdraw a substance depends on a number of factors of which the most important are likely to be the cost of registration and the value of the product to each of the MIs. Whilst the relationship decision to withdraw the substance is not straightforward and may also depend on a number of other factors, in an analysis such as this, only the cost of registration can be estimated with some

degree of certainty. As such, in order to account for withdrawal at all within the analysis, one must apply a proxy to estimate the point at which registration cost is likely to become unsustainable for MIs. This can be derived from the raw data itself in combination with analysis undertaken by the Commission in its ExIA.

Using its microeconomic model, the Commission estimated in its ExIA that some 1-2% of substances across all tonnage bands were likely to be withdrawn owing to registration costs across all of the scenarios it examined. The ExIA also assumed higher levels of withdrawal for lower tonnage tonnage suggesting that the higher end of the range (i.e. 2%) of 1-10t substances might be expected to be withdrawn under the current registration requirements and 98% would be registered.

Applying this 'baseline 98 percentile rule' to the raw data allows the analysis to estimate which substances will be registered and which will be withdrawn under each of the options (and the baseline). The raw dataset can be divided into two separate datasets (substances registered and substances withdrawn) for analysis of the cost and impacts of withdrawal and also of registration.

6.2.2 Cost of registration

For those substances that are registered under the baseline and the options, the dataset produced by the Monte Carlo model provides the cost of registration under the baseline and the additional cost of revising/upgrading dossiers under each option (where the substance is not withdrawn under that option). As such, data can be analysed and organised in terms of:

- costs by substance across all MIs registering; and
- costs by MI across all substances registered.

The costs of revising/upgrading dossiers will be incurred initially by MIs registering those substances. A proportion of these costs will be absorbed by the MIs themselves (representing the MI costs of revising/upgrading) and a proportion will be passed down the supply chain (to downstream users) as, for example, an increase in product price over a period of time. In the absence of information (or information to the contrary), it is assumed that MIs are able to pass only half of the total costs of revising/upgrading dossiers for a substance on to Downstream Users (DUs) and must absorb the remainder.

6.2.3 Cost of withdrawing a substance from the market and reformulation

The cost of withdrawing a substance from the market is associated with both the income foregone from manufacture or import (for MIs[18]) and the need to reformulate products (incurred by DUs). In both cases, the scale of costs is related to the commercial value of the product being withdrawn. In the absence of any better indication of this value, raw data on what the cost of revising/updating dossiers for a substance would have been (if it were to be revised/upgraded instead of withdrawn) has been used. In the rest of the document this is referred to as the 'hypothetical cost of revising/upgrading' for a substance.

The underlying assumption is that, for all of the substances withdrawn from the market on the grounds of cost, the magnitude of the hypothetical cost of revising/upgrading that triggers the

[18] Although an importer may find a substitute with lower registration requirements, hence no income would be foregone.

decision to withdraw is at the 'break-even' point and so equals the maximum value of the substance. Owing to the fact that there are differences in the level of these costs between the options, for withdrawn substances the 'break even' point for a substance is taken as being the lowest of the hypothetical revision/upgrading costs triggering that withdrawal. So, for example, if a substance withdrawn under an option has a hypothetical cost of €n and €(3n) under another option, the break-even point or commercial value of the substance is €n across all options where that substance is withdrawn (because, clearly, the commercial value of the substance should not vary between options).

The annual income foregone by a MI is a function of the commercial value of the substance. As there is no data from which to extrapolate from one to the other, in the absence of any other information, as with the Phase 2 study, lost annual income has been taken as being equal to 10% of the indicative 'commercial value' for each substance per year and costs are incurred for five years. The resulting totals have been discounted at 4% to provide Present Value (PV) costs.

In addition to income foregone by MIs through withdrawal, there are costs to the downstream users (DUs) associated with, for example, reformulation. Regarding the level of these costs, logically, if reformulation costs were higher than the hypothetical costs of revising/upgrading then DUs would be keen to help sponsor the continued registration of the substance (and so the substance wouldn't be withdrawn). By extension, in the absence of any other information, the maximum costs of re-formulation for DUs are taken as being equal to the hypothetical costs of revising/upgrading. In practice, the value of some substances may be considerably less than this but, by the same token, some may be more. Applying this same value across all withdrawn substances provides a means to account for these costs and make fair comparisons between options (because the same assumption applies equally across all options and the baseline).

7 Quantification of Human Health and Environmental Benefits

7.1 Introduction and overview

Once a substance has been identified with one or more hazardous properties and is classified under CLP actions to reduce risks are triggered under various pieces of parallel legislation and, where applicable, under REACH. Accordingly, the human health and environmental benefits of the information options (and the baseline) are associated with:

- the identification of substances with previously unknown hazardous properties for classification;
- the control of the risks associated with those substances, where, in addition to permitting the identification of previously unknown hazardous substances/properties, information generated and submitted under the options facilitates effective risk control; and
- through risk management, avoidance of future cases of disease and environmental damage (which can be valued in monetary terms).

The baseline and the information options all aim to generate better information (and on more substances) than is available at present and in particular (depending on the option) regarding:

- Mutagenicity (and via this route genotoxic carcinogens) [19];
- Dermal, inhalation and/or oral toxicity;
- Aquatic toxicity; and
- Persistence, bioaccumulation and toxicity.

In addition, better information on short term toxicity, long term toxicity and aquatic toxicity under the information options (A to E) also leads to the identification of:

- Substances for which there is better information on dermal/inhalation exposure limits;
- Substances identified with classification from STOT RE 1 or 2; and
- PNECs for aquatic toxic substances.

The approach to estimating the benefits associated with each of the options (including the current requirements) involves:

- estimating how many substances are identified as having previously unknown hazardous properties for classification;

- identifying the disorders, diseases and impacts that are associated with each of those hazardous properties;

[19] Note that no testing for carcinogenicity or reproductive toxicity is required in Annex VII of REACH or under any of the options. Thus non-genotoxic carcinogens/reproductive toxins will not be identified for any 1-10t substances.

- applying appropriate economic metrics for the single cases avoided or units of environmental area improved for each type of hazardous properties (in €s);

- estimating the number of cases of these diseases, disorders and impacts that would be expected in the future if no action to control risks was taken (and so would be avoided by taking action); and

- combining the above, calculating total present value (PV) benefits (in €s) for each of the options and the baseline.

These steps are described in the sub-sections below.

7.2 Number of substances identified with previously unknown hazardous properties

Sections 3.1.1 to 3.1.4 have described estimation of the numbers of substances that would be identified with different types of classification under the different testing scenarios presented by the options and the baseline (current requirements).

Depending on the option, the following classifications are possible using the toxicological and ecotoxicological information generated:

- classification for skin/eye damage and irritation;
- classification for skin sensitisation;
- classification as CMR 1A/1B;
- availability of sufficient information to establish dermal/inhalation exposure limits;
- classification for long term toxicity;
- classification for STOT RE 1 or 2;
- classification for acute aquatic toxicity;
- availability of sufficient information to establish a PNEC for aquatic toxicity; and
- identification of PBT properties.

Table 7-1 overleaf provides the number of substances identified with each of the above hazardous properties/additional information under the baseline and the **additional numbers** of substances that would be identified under each of the information options.

Table 7-1: Number of substances with identified with previously unknown hazardous properties							
	Substances identified under the Baseline	Additional substances identified under the options					
		Option A	Option D	Option B	Option C	Option E	Maximum substances with hazardous properties not identified under the baseline
Annex III option	Current Annex III	Current Annex III	No diffuse/ dispersive use criterion in Annex III	No diffuse/ dispersive use criterion in Annex III	No Annex III	No Annex III	
Information Option	Current Annex VII	Annex VII+	Annex VII+	Annex VII++	Annex VII+	Annex VII++	
Substances classified for skin/eye damage and irritation	2,757	0	899	899	4,330	4,330	4,330
Substances classified for skin sensitisation	1,534	0	640	640	2,351	2,351	2,351
CM(R) 1A/1B	209	0	34	217	176	465	531*
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	0	0	0	3,344	0	5,356	5,356
Substances with long-term toxicity information	0	0	0	903	0	1,446	1,446
Substances that would have classification for STOT RE 1 or 2	0	0	0	131	0	210	210
Substances classified for acute aquatic toxicity	1,515	0	495	495	2,089	2,089	2,089
Substances classified for acute aquatic toxicity with enough information for PNECs	0	1,709	2,411	2,411	4,005	4,005	4,005
PBTs/vPvB substances non diffuse use	0	22	25	25	55	55	55
PBTs/vPvB substances diffuse use	0	8	9	9	19	19	19
* 740 mutagens would be identified if in vivo testing were carried out on all 1-10t substances. Of these 209 would be identified under the baseline leaving 531 (740-209) mutagenic substances unidentified and unclassified under the current requirements for 1-10t substances. Not all of these are detected under the options because all options employ in vitro screening tests to trigger any in vivo testing and this is not 100% successful at identifying all mutagenic substances.							

7.3 Outcomes and damage costs associated with different classifications

7.3.1 Overview

A range of disorders, diseases and impacts can be associated with each of the hazardous properties to which can be applied appropriate economic metrics to provide a monetary value for the associated damages. Valuing damages in this way provides a means of estimating the benefits of each option in terms of the damage costs avoided through identification of hazardous properties and appropriate risk control. At the same time, the range of possible outcomes from exposure and environmental releases is much larger than the range of available metrics. As such, valuation must rely on selected 'representative' outcomes. These are summarised in the table below.

Table 7-2: Classifications and 'representative' outcomes

Groups of substances	Classification/identification under Options	Representative outcomes for valuation
Skin Sensitizers and irritants	Skin/eye damage and irritation	Cases of skin damage and disorders of varying severity
	Skin Sensitisation	
Substances classified as Toxic	Substances identified with a classification for dermal or inhalation toxicity as well as oral	Cases of poisoning
	Substances for which there is better information on dermal/inhalation exposure limits	
	Substances for which there is better long term toxicity information	Cases of kidney disease of varying severity
	Substances identified with classification for STOT RE 1/2	
Carcinogens and mutagens	Mutagenicity 1A/1B	Fatal and non-fatal cancers
Environmental hazards	Number of substances identified with acute aquatic toxicity classification	Levels of improvement to chemical status of waterbodies. Implied willingness to pay to eliminate PBT substances.
	Number of substances identified as toxic to the aquatic environment with enough information for PNEC where applicable	
	number of PBTs/vPvBs identified	

As will be seen in later sections, for health outcomes the analysis is limited to the consideration of occupational (worker) exposure because this group is the only group for which expected levels of exposure can be estimated. For the environmental component very few metrics are available and this limits the ability of the analysis to assess the full breadth and depth of possible impacts.

In order to estimate the economic value of the associated human health benefits, a cost-of-illness approach has been adopted. This considers medical treatment costs, productivity losses and, where available, individual's willingness to pay (WTP) to avoid the disease/discomfort in question. derivation of metrics and values is described in the subsections below.

7.3.2 Skin Sensitizers and irritants

Skin sensitizers and irritants are present in a wide range of products and can cause skin disorders. According to EU-OSHA "*occupational skin diseases are estimated to cost the EU €600 million each year, resulting in around 3 million lost working days. They affect virtually all industry and business sectors and force many workers to change jobs*"[20].

Valuation using treatment cost and willingness to pay

In valuing the impacts, a cost-of-illness approach has been adopted. This considers medical treatment costs, productivity losses and individual's willingness to pay (WTP) to avoid the occupational disease in question.

In relation to medical treatment costs, the UK National Health System (NHS) reference costs[21] provide a robust source to calculate the unit costs for the treatment of skin disorders. These reference costs are the average unit cost to the NHS of providing secondary healthcare to NHS patients. The unit costs and the number of treatments for skin disorders in 2014 and 2015 are presented in Table 7-3 below.

The weighted average treatment unit cost for skin disorders has been calculated by multiplying the average unit cost by the number of treatments across the different types of interventions. The weighted average treatment cost is equal to £1,620[22] or €2,100[23].

Table 7-3: Unit costs and number of treatments for skin disorders in the UK in 2014 and 2015

Currency*	Currency description	Activity	Unit cost in GBP
JD07A	Skin Disorders with Interventions, with CC**Score 12+	2,432	£ 8,458.44
JD07B	Skin Disorders with Interventions, with CC Score 8-11	2,689	£ 6,293.22
JD07C	Skin Disorders with Interventions, with CC Score 4-7	5,627	£ 4,014.34
JD07D	Skin Disorders with Interventions, with CC Score 0-3	18,218	£ 2,192.92
JD07E	Skin Disorders without Interventions, with CC Score 19+	845	£ 4,979.63
JD07F	Skin Disorders without Interventions, with CC Score 14-18	6,918	£ 3,377.74
JD07G	Skin Disorders without Interventions, with CC Score 10-13	16,865	£ 2,450.22
JD07H	Skin Disorders without Interventions, with CC Score 6-9	34,998	£ 1,759.22
JD07J	Skin Disorders without Interventions, with CC Score 2-5	60,824	£ 1,137.32
JD07K	Skin Disorders without Interventions, with CC Score 0-1	60,390	£ 667.87

*Notes: *Currencies are defined as the units of healthcare for which a payment is to be made. **CC stands for "complications or comorbidities" and each CC recorded is assigned a score in order to reflect the increment in complexity and treatment costs.*
Source: https://www.gov.uk/government/collections/nhs-reference-costs

In terms of productivity losses for less serious cases, UK data on the average days lost for all injuries and illnesses has been used[24] to which we applied the one percent value estimated by HSE for skin

[20] EU-OSHA Factsheet 40. Available at: https://osha.europa.eu/en/tools-and-publications/publications/factsheets/40
[21] Available at: https://www.gov.uk/government/collections/nhs-reference-costs
[22] This is the cost in the UK. It is assumed the cost in the EU28 is equivalent.
[23] Rounded to the nearest 100. Average exchange rate GBP/EUR 2014/2015: 1.31. Source: http://www.ukforex.co.uk/forex-tools/historical-rate-tools/yearly-average-rates
[24] Table SWIT1 available at: http://www.hse.gov.uk/statistics/lfs/index.htm

conditions. This suggests an average of around 1.3 days per case at an assumed €300 per day. For more serious cases of occupational skin disease it has been 7 days of lost productivity have been assumed.

Regarding WTP, a recent ECHA report[25] reviewing estimates of willingness to pay to avoid certain health impacts provides a range of WTP values to avoid dermatitis, depending on its nature (acute or chronic), intensity (mild or severe), occurrence frequency in one year and over two, five and ten years. Values range from €227 for a single episode of mild acute dermatitis to €1,055 for a case of severe chronic dermatitis.

Whilst the review identifies that the €227 value for one acute episode of mild dermatitis matches previous WTP and also monetised disability weights quite well, it identifies that the value of preventing a case of severe, chronic dermatitis (€1,055) appears too low considering the duration and potential severity of the symptoms. Using valuations in Hauber *et al* (2011)[26], the review study calculates an implied value of around €1,800 per year (as opposed to €1,055 *per case*) that can be converted into a cost per case by applying estimates of average age at onset and life expectancy for those affected. Assuming an average of 30 years between onset and end of life, the value for one case of severe, chronic dermatitis would be around €54,000.

Whilst this is much higher than the €1,055 per case quoted by the ECHA study, the review of that study also identifies that values based on the weights for controlled and uncontrolled psoriasis (in Schmitt *et al*, 2008[27]) and the median value for a VOLY of €64,000 from NewExt (2003)[28] would approach €12,000 per year, i.e. €360,000 (undiscounted) per case assuming the same 30 year period.

In spite of the apparent inconsistencies identified in the abovementioned reports, for the purpose of estimation in this study we have taken the more conservative value of €1,055 per case as the estimates of incidence are based on single episodes and the other values would seem too high for application to this.

For the less serious cases we have applied the lower (€227) WTP value and no treatment cost.

For fatal cases of occupational skin diseases, the highest treatment cost in the above table has been used (£8,458 or €11,000 rounded to the nearest 100) and a value of a statistical life (VSL) of €4 million has been applied to be consistent with advice from DG Employment (pers. comm.) and based on the figure set out in the Better Regulation Guidelines. The total values are summarised in Table 7-4 below.

[25] ECHA (2015): Valuing selected health impacts of chemicals: Summary of the results and a critical review of the ECHA study. Available at: http://echa.europa.eu/documents/10162/13630/echa_review_wtp_en.pdf

[26] Hauber, A. B., Gonzalez, J. M., Schenkel, B., et al. (2011): *The value to patients of reducing lesion severity in plaque psoriasis.* Journal of Dermatological Treatment, 22(5): 266-275.

[27] Schmitt, J., Meurer, M., Klon, M., et al. (2008). *Assessment of health state utilities of controlled and uncontrolled psoriasis and atopic eczema: a population-based study*. British Journal of Dermatology, 158(2): 351-359.

[28] NewExt (2003). New Elements for the Assessment of External Costs from Energy Technologies. Final report. http://www.ier.uni-stuttgart.de/forschung/projektwebsites/newext/newext_final.pdf.

Table 7-4: Metrics applied to hazardous property endpoints and associated monetary value of avoiding a single occurrence of each		
Substance properties	**Valuation metric used**	**Monetary Value applied to metric**
Substances classified for skin/eye damage and irritation	Medical treatment cost + Productivity loss + WTP to avoid a single episode of mild acute dermatitis = **Cost of a case of mild acute dermatitis**	€ 0 + € 390 + € 277 **€ 667**
Substances classified for skin sensitisation	Medical treatment cost + Productivity loss + WTP to avoid a single episode of case of chronic dermatitis = **Cost of a case of severe chronic dermatitis**	€ 2,100 + € 2,100 + € 1,055 **€ 5,255**

7.3.3 Substances classified as Toxic

As with skin diseases, the cost of poisoning can be estimated with reference to medical treatment costs and lost productivity as follows:

- With regard to substances identified with dermal, inhalation and/or oral toxicity classifications, the medical treatment cost of €1,370[29] has been assumed to be the average cost in the EU for a 'non-fatal poisoning incident'; the value has been added to €1,500 of lost productivity (assuming that a poisoning event results in 5 days' sick leave@ €300 per day) to give a total cost of €2,870 for a 'non-fatal poisoning incident';

- With regard to substances identified with long term toxicity classifications, kidney disease 'kidney disease of short-term duration' has been considered as an end-point; the medical treatment of €4,500[30] has been assumed to be the average cost in the EU; the value has been added to €6,000 of lost productivity (assuming that a chronic kidney disease results in 20 days' sick leave at €300 per day) to give a total cost of €10,500 for a case of 'kidney disease of short-term duration';

- For substances with long term toxicity classifications and substances with classification for STOT RE 1 or 2, non-fatal chronic kidney disease has been considered as an outcome. Regarding treatment costs, the average cost of dialysis in the UK is £30,800 per patient per year[31] (equal to around €40,300[32] per patient per year) and this has been assumed to be the average cost in the EU. Assuming that a chronic kidney disease results in 20 days' sick leave, the productivity loss is around €6,000 per year making a total cost of €46,300 per year. Assuming 10 years of treatment this equates to €390,500 per case (expressed as in PV discounted at 4%).

[29] Unit cost referring to "Poisoning, Toxic, Environmental and Unspecified Effects" (UK National Schedule of Reference Costs for the year 2012-13).

[30] Average unit cost referring to "Chronic Kidney Disease with and without Interventions" plus the average cost of haemodialysis, filtration or peritoneal dialysis (UK National Schedule of Reference Costs for the year 2012-13).

[31] http://www.kidney.org.uk/archives/news-archive-2/campaigns-transplantation-trans-cost-effect/

[32] Rounded to the nearest 100.

The resulting total costs for each occupational disease outcome are summarised in Table 7-5 below.

Table 7-5: Metrics applied to hazardous property endpoints and associated monetary value of avoiding a single occurrence of each

Substance properties	Valuation metric used	Monetary Value applied to metric
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	Medical treatment cost + Productivity loss **Cost of a 'poisoning event'**	€ 1,370 + € 1,500 + = **€ 2,870**
Substances with long-term toxicity information	Medical treatment cost + Productivity loss **Kidney disease of short-term duration**	**€ 4,500+** **€ 6,000** **=** **€ 10,500**
Substances with a classification for STOT RE 1 or 2	Medical treatment cost per year+ Productivity loss per year Annual cost of a case of chronic kidney disease **Total cost of a case of chronic kidney disease assuming 10 years of treatment**	€ 40,300+ €6,000 = € 46,300 per year **€ 380,400**

7.3.4 Carcinogens and mutagens

Owing to the fact that testing for carcinogenicity and reproductive toxicity is not required for the 1-10t substances (under any of the options), only mutagenic substances will be identified for classification[33] and, thus, only the 'M' component of CMRs will be identified for classification under the options (and the baseline).

This, however, does not mean that the baseline and the options have no benefits in terms of reduced exposure to carcinogenic substances. Mutagens may also be carcinogens (even if they are not classified as such) and the risk management measures that would be required to reduce/eliminate exposure to mutagenic substances will also reduce/eliminate exposure to any carcinogenic effects that these same substances may have. Analysis of the harmonised classification in the Classification and Labelling Inventory suggests that all substances classified as mutagenic 1A/1B are also classified as carcinogenic 1A/1B.

On the basis of this, the analysis assumes that all of the mutagens identified are also carcinogens and that their identification reduces the number of cases of cancer.

Valuation using treatment cost and willingness to pay

In terms of the valuation of cancer cases, a number of different potential economic impacts can be identified from the health economics literature, and these can be categorised in terms of those who may bear the impacts:

[33] Because under the Integrated Testing Strategy (ITS) limits consideration to mutagenicity testing (i.e. it does not extend to carcinogenic/reproductive effects). As such classifications can only be made for mutagenicity.

- **individuals/workers and their families**: financial costs, which consist of loss of earnings as a result of absence from work or the loss of a job and any extra expenditure required, for example on drugs or the need to attend hospitals; 'human costs' which relate to the loss of quality of life or of general welfare, and may include pain and suffering to the affected individual, and worry and grief caused to family and friends;

- **employers**: loss of output; payments related to sick leave; administrative costs related to a worker's absence[34] including additional recruitment costs; loss of experience/expertise; overtime working; compensation payments (although this is usually covered by some form of employer's liability insurance); and insurance premiums; and

- **taxpayers**: costs borne by taxpayers for national health care provision, disability and other social security benefits.

The total social costs of occupational cancers are measured by the costs born for health care provision, together with lost output (including productivity losses), the non-wage labour costs of absent workers (such as loss of experience), administrative costs and human costs. These represent the direct and indirect resource costs and the non-market 'external' costs of illness. The other costs listed above (e.g. insurance premiums) relate to what are commonly referred to as 'transfer payments', which do not give rise to net welfare effects. As a result, they are not considered in economic analyses, even though they may be important in financial terms to an individual worker or an employer.

When deriving a single value for a cancer case several factors need to be considered within the same expression. These are as follows:

- fatality rate – not all cases of cancer result in a fatality. For fatal cancers the value of a statistical life (VSL) applies and for non-fatal cases the value of cancer morbidity (VCM) applies. Survival rates for cancer vary from one type of cancer to another and are conventionally expressed as a percentage surviving after five years of treatment thus:

    - for a fatal case of cancer the value can be taken as equal to 5 treatment years + (VSL x the fatality rate[35]);

    - for a non-fatal case of cancer the value can be taken as being equal to 5 treatment years + (VCM x the survival rate);

    - which, when combined gives the statistical value of a case of cancer being equal to 5 treatment years + (survival rate x VCM) + (1-survival rate x VSL);

- latency period – every case of cancer (fatal or non-fatal) is preceded by a period of latency before diagnosis and treatment. As such, the benefit of any action taken to reduce exposure to a carcinogen in the present day will not manifest itself until a time in the future that is equal to the latency period of the cancer. This means that costs for each of the five years of

[34] Clerical and management related costs. Legal costs may also be relevant where compensation payments are required in the case of disablement, for example.

[35] i.e. one minus the survival rate.

treatment and the appropriate VCM and VSL values need to be discounted to reflect the current value of a future case of cancer;

- costs of healthcare, productivity and lost working days vary from one cancer to another.

Costs of health care, productivity losses and lost working days

For the costs of each treatment year, data from Luengo-Fernandez, et al (2013[36]) have been applied. These are provided in Table 7-6 below and provide estimates for the following categories of cost for different cancers:

- health care;
- productivity losses;
- lost working days; and
- informal care.

For the purposes of calculating the costs of illness, we use the "all cancers" figure of €14,966 per case of cancer per year of treatment.

Table 7-6: Estimates of the annual cost per patient of cancer

Mortality rate after 5 years	Cancer	Health care	Productivity losses	Lost working days	Informal care	Total cost per case (€)
22%	Prostate	€ 4,027	€ 543	€ 290	€ 1,390	€ 6,250
80%	Lung	€ 6,952	€ 16,319	€ 1,337	€ 6,278	€ 30,887
24%	Breast	€ 4,378	€ 2,118	€ 1,164	€ 2,086	€ 9,747
44%	Colorectal	€ 5,037	€ 3,411	€ 833	€ 2,567	€ 11,849
47%	All cancers	€ 6,047	€ 5,047	€ 1,118	€ 2,753	€ 14,966

Source: Luengo-Fernandez, R. et al (2013): Economic burden of cancer across the European Union: a population-based cost analysis; Lancet Oncology; 14: 1165–74, published online October 14: http://dx.doi.org/10.1016/S1470-2045(13)70442-X

Fatal cancers and the value of a statistical life (VSL)

The European Chemicals Agency (ECHA) guidance on preparing SEAs in the context of REACH authorisations and restrictions provides two figures for the value of a statistical life[37], a central value of €1,052,000 (2003 prices) and a sensitivity value of € 2,258,000 (2003 prices). These values do not include any adjustment for the fact that people may be willing to pay more to reduce their risk of dying from cancer than to reduce their risk of dying from other illnesses, due to the fact that death from cancer may be preceded by a long period of ill health. For this reason, previous guidance from DG Environment[38] recommended adding a "cancer premium"; the paper also recommended

[36] Luengo-Fernandez, R. et al (2013): Economic burden of cancer across the European Union: a population-based cost analysis; Lancet Oncology; 14: 1165–74, published online October 14: http://dx.doi.org/10.1016/S1470-2045(13)70442-X

[37] Based on environmental pollution willing-to-pay values.

[38] DG Environment (2000): Recommended Interim Values for the Value of Preventing a Fatality in DG Environment Cost-Benefit Analysis, available at: http://ec.europa.eu/environment/enveco/others/pdf/recommended_interim_values.pdf

adjusting for age, where a cancer may affect populations of an average age. If these adjustments are made, the above values are increased to around €2.8 million for the central value and €6.0 million for the sensitivity value (2015 prices).

The recent study led by the Charles University in Prague (Alberini and Scasny, 2014[39]) and undertaken for ECHA (but which is yet to be formally adopted in SEA guidance) found a value of a statistical life for the avoidance of a death by cancer to be €5 million (2014 prices). This is also consistent with figures given by the OECD[40] for the EU 28 (around €3.38 million in 2011 prices). In this assessment a VSL of €4 million has been applied to be consistent with advice from DG Employment (pers. comm.) and based on the figure set out in the Better Regulation Guidelines.

Non-fatal cancers and the value of a cancer morbidity (VCM)

The available literature offers a broad range of estimates for willingness to pay to avoid a non-fatal cancer. Estimates range from a low of €16,000 (1999 prices) to a high of €1,950,000 (1999 prices) depending on the type of cancer (Pearce, 2000); the average across the range of endpoints is a figure of around €550,000 (2014 prices). The ECHA SEA guidance reports of a value of €400,000 (2003 prices) for calculating the costs associated with morbidity for non-fatal cancers, but the origin of this estimate is not referenced and no details on how the figure was derived or what type of cancer it relates to are provided. More recent WTP studies undertaken for ECHA found a figure of €410,000 and this value has been applied in this study as the WTP value for a non-fatal cancer.

Accounting for latency, extrapolation over time and discounting

The latency period between exposure and development of cancer means that any action taken to reduce exposure to a carcinogen in the present day will not manifest itself until a time in the future that is equal to the latency period of the cancer. For example, for a cancer with a latency of 15 years, a cancer exposure that would otherwise have occurred tomorrow would not develop into cancer until 15 years hence. Thus, when calculating the benefits of taking action in the present one must consider the benefits in the future and discount them as appropriate to arrive at Present value (PV) benefits.

To accomplish this, the value of cancer prevention has been calculated on the basis of the aggregated cost of one cancer exposure a year over a period of 40 years of exposures. Total costs in each year are calculated and to these has been applied the 4% standard discounting rate applied in EC impact assessments to give costs as NPV. The sum of these NPV costs provides the cost of one cancer exposure per year for 40 years (and thus the benefits associated with prevention of one exposure per year).

When calculating this, average 'all cancer' values have been applied as follows:

- Latency = 15 years
- Survival/treatment period (years) = 5 years
- Fatality rate at end of period = 47%[41]

[39] Alberini and Scasny (2014): Stated-preference study to examine the economic value of benefits of selected adverse human health due to exposure to chemicals in the European Union, Part III: Carcinogens, FD7. Final report, Service contract No. ECHA/2011/123.

[40] http://www.heatwalkingcycling.org/index.php?pg=requirements&act=vsl&PHPSESSID=q3jkco40bnm8aj7poon2v765o5

[41] Based on data for the EU from International Association of Cancer Registries http://www.iacr.com.fr/

- Annual cost per patient (€) = € 14,966
- VSL (€) = € 4,000,000
- VCM (€) = € 410,000

This provides an aggregated NPV of €22,673,090 for the prevention of one cancer exposure per year over a period of 40 years.

7.3.5 Environmental hazards

For environmental damages the willingness to pay of UK households for improving the quality of water bodies to different Water Framework Directive Status levels is used to provide indicative values[42]. The so called NWEBS (National Water Environment Benefit Survey values) are used in the UK as part of the assessment of the costs and benefits of catchment level projects to increase the status of water bodies. Total NWEB values reflect improvement in six components of waterbody status. These are: fish; other animals such as invertebrates; plant communities; the clarity of the water; condition of the river channel/flow of water; and the safety of the water for recreational contact. Where projects/actions only target some of these components the approach used in the UK is to divide the overall NWEB values equally between the six components and then multiply by the number of components that are affected by the action/project. The annual average per component NWEB values applied in England and Wales are as follows for the following levels of improvement:

(1) from “bad” to “poor”: €4,083 per km river per year per component;
(2) from “poor” to “moderate”: €8,793 per km river per year per component;
(3) from “moderate” to “good”: €14,243 per km river per year per component.

To estimate the benefits of identifying substances which are toxic to aquatic life, it has been assumed that three components will be affected (fish; other animals such as invertebrates; plant communities) and that:

- The identification of acute aquatic toxic substances but without an associated PNEC would result in the quality of water bodies improving from “bad” to “poor” at a value of €12,250 per km river per year;

- The definition of PNECs would result in the setting of more stringent environmental risk management measures, with the effect of improving the quality of water bodies from "bad" to "moderate" at a value of €26,380 per km river per year.

These values have been applied to a range of assumed areas of waterbody improved to provide low, medium and high scenario estimates of the benefits of identifying and controlling substances with acute aquatic toxicity. The calculated values for each scenario are summarised in Table 7-7 below.

[42] Environment Agency (2013): Updating the National Water Environment Benefit Survey values: summary of the peer review. All benefit values are in 2012 prices. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/291464/LIT_8348_42b259.pdf

Table 7-7: Metrics applied to hazardous property endpoints and associated monetary value of avoiding a single occurrence of each					
Substance properties	Valuation metric used	Monetary Value applied to metric (€ per km^2 improved per year)	Calculated benefits for each type of substance under scenarios		
			Low	Medium	High
			2 km^2 'improved' per substance	5 km^2 'improved' per substance	10 km^2 'improved' per substance
Substances classified for acute aquatic toxicity	Improvement of WFD water body status from 'bad' to 'poor' per km^2 per year	**€ 12,250**	€ 24,500	€ 61,250	€ 122,500
Substances classified for acute aquatic toxicity with enough information for PNECs	Improvement of WFD water body status from 'bad' to 'moderate' per km^2 per year	**€ 26,380**	€ 52,760	€ 131,900	€ 263,800

PBTs and vPvBs

Estimation of the benefits of preventing emissions and losses of PBTs and vPvBs is a difficult, topical and ongoing issue. In its document *Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances*[43], ECHA's Committee for Socio-Economic Analysis (SEAC) identifies that "*data on P, B and T properties does not often allow for quantitative assessment of the human health or environmental impacts. The valuation of benefits via the assessment of the impacts on the environment and human health – the standard 'impact pathways' approach to benefits assessment for chemicals – is therefore not possible, and other options for benefits assessment need to be considered*". Accordingly, SEAC has pursued the approach of establishing a benchmark for the proportionality/disproportionality of action to reduce emissions of PBTs considering the cost of past action.

Benchmarking approach

In 2015, IVM conducted a study (IVM, 2015[44]) to provide SEAC with information that could be used in the development of such a benchmark. The study gathered information on the past (and current) cost of PBT emission reduction or on reductions in the use of, or exposure to PBTs/vPvBs. In turn, the study identifies that this information provides an indication of "public willingness to pay" for such reductions through a revealed preferences. Examples of the values calculated in the case studies are provided in Table 7-8 below in relation to PFOS.

[43] See Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC - SEAC/24/2014/04 https://echa.europa.eu/documents/10162/13580/approach_for_evaluation_pbt_vpvb_substances_seac_en.pdf

[44] IVM Institute for Environmental Studies (2015): Benchmark development for the proportionality assessment of PBT and vPvB substances - a report for the Dutch Ministry of Infrastructure and the Environment; by Oosterhuis, F & Brouwer, R - Report R-15/11, 21 September 2015. http://echa.europa.eu/documents/10162/13647/R15_11_pbt_benchmark_report_en.pdf

Table 7-8: Examples of implied minimum willingness to pay to reduce/eliminate contamination from the PBT PFOS	
Barendrecht railway tunnel (Netherlands):	The cost of flushing out and removing PFOS in the firefighting system in the Barendrecht railway tunnel provides a minimum implicit social willingness to pay of €3,500 per kg. No maximum can be determined from the values.
Schiphol airport (Netherlands)	More than EUR 5 million spent or budgeted to immobilize and remove (less than) 143 kg of PFOS. This implies a social willingness to pay of at least €35,000 per kg PFOS. If full sanitation is to be completed this could increase to between €200,000 and €300,000 per kg.
Public water supply in Arnsberg (Germany)	Treatment plant to remove PFOS and PFOA from surface water suggests implicit social willingness to pay of at least €10,000 per kg. Estimated costs for remediation of agricultural land polluted by some 400 kg PFOS and PFOA are €6,750 per kg.
Source: IVM, 2015[44]	

As can be seen from the PFOS case study in the table, whilst the maximum willingness to pay is often difficult to determine, the 'largest minimum' willingness to pay implied by spent or budgeted investment on PFOS is at least €35,000 per kg. Considering potential further investment, this minimum value might increase to between €200,000 and €300,000 per kg.

Taking all of the available evidence into account and also differences between PBTs/vPvBs and their effects, the study identifies a very wide 'grey zone' of somewhere between €1,000 and €50,000 per kg PBT substituted, remediated or emission reduced. Within this 'grey' zone, measures may be either proportionate or disproportionate from a cost-effectiveness perspective (depending on factors including the nature of the PBT/vPvB).

These lower and higher bound WTP estimates have been used to develop the following scenarios for this benefit assessment.

- Low WTP = €1,000 per kg PBT substituted, remediated or emission reduced;
- Medium WTP = €25,500 per kg PBT substituted, remediated or emission reduced; and
- High WTP = €50,000 per kg PBT substituted, remediated or emission reduced.

In terms of the quantity of PBT substituted, remediated or emission reduced, based on the cost assessment the total annual average production of an average 1-10t substance is 19,550 kg/year.[45] Only a percentage of that annual production may ultimately be released to the environment and this is likely to differ between substances with and without diffuse/dispersive uses.

It has been assumed later in the analysis (see Section 7.4.1) that, for substances with one or more diffuse/dispersive uses (25% of all 1-10t substances from Section 3.1.4), 40% of the uses of that substance will be diffuse/dispersive and the remainder (60%) will be non-diffuse/dispersive. Dividing the total quantity manufactured equally between these uses suggests the following:

[45] Average of 2.3 MIs each manufacturing/importing 8,500kg/year = 19,550 kg/year total production and use on average.

- **For substances with no diffuse/dispersive use:**
  - average annual production and use is 15,300 kg/year;

- **For substances with one or more diffuse/dispersive uses**:
  - 7,820 kg/year (40%) is used in diffuse/dispersive use applications; and
  - 11,730 kg/year is used in non-diffuse/dispersive use applications.

In terms of releases to the environment that would be eliminated by identification of the PBT status, Table R.16-7: Default parameters to derive the environmental release rate in ECHA's Guidance on information requirements and Chemical Safety Assessment[46] would suggest that:

- **For non-diffuse/dispersive uses:** around 10% by weight of the substance may ultimately be released to air, water and soil considering manufacture and all non-dispersive/diffuse downstream uses; and
- **For diffuse/dispersive uses (perhaps conservatively):** around 50% by weight of the substance may ultimately be released to air, water and soil considering manufacture and all diffuse/dispersive downstream uses.

Combining these together provides low, medium and high benefit estimates for the identification of 1-10t PBT substances set out in the table below. From the table, applying the three WTP scenarios, the benefits from identifying 1-10t PBT/vPvB substances are:

- **For substances with no diffuse/dispersive use:** €2.0 million, €49.9 million and €97.8 million per year on average for the low, medium and high scenarios respectively; and

- **For substances with one or more diffuse/dispersive uses**: €5.1 million, €129.6 million and €254.2 million per year on average for the low, medium and high scenarios respectively.

Table 7-9: Benefits of identifying and controlling 1-10t PBT/vPvB substances

		Quantity used (kg/year)	Percent released to the environ-ment	Environ-mental release eliminated (kg/year)	Benefit per 1-10t PBT substance identified (€million per year)		
					Low WTP@ €1,000 per kg	Medium WTP@ €25,500 per kg	High WTP@ €50,000 per kg
Substance with no diffuse use		19,550	10%	1,955	**€ 2.0**	**€ 49.9**	**€ 97.8**
Substance with one or more diffuse uses	**Non-diffuse use**	11,730	10%	1,173	€ 1.2	€ 29.9	€ 58.7
	Diffuse use	7,820	50%	3,910	€ 3.9	€ 99.7	€ 195.5
	Total	-	-	-	**€ 5.1**	**€ 129.6**	**€ 254.2**

[46] ECHA (2016): Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment, Version 3.0, February 2016 - http://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf

7.3.6 Summary of values

Table 7-10 summarises the monetary values discussed above and applied within the assessment of benefits.

Table 7-10: Metrics applied to hazardous property endpoints and associated monetary value of avoiding a single occurrence of each		
Substance properties	**Valuation metric**	**Monetary value calculated using cost of illness**
Substances classified for skin/eye damage and irritation	Case of mild acute dermatitis	€667 per case
Substances classified for skin sensitisation	Case of severe chronic dermatitis	€5,255 per case
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	'Poisoning event'	€2,870 per case
Substances with long-term toxicity	Case of kidney disease of short-term duration	€10,500 per case
Substances that would have classification for STOT RE 1 or 2	Case of chronic kidney disease requiring 10 years of treatment	€380,400 per case
Number of CM(R) 1A/1B substances identified	NPV cost of one cancer exposure per year over 40 years	€22,673,090 (NPV over 40 years)
Substances classified for acute aquatic toxicity	Low -Improvement of 2km^2 WFD water body status from 'Bad' to 'poor'	€ 24,500 per year
	Medium - Improvement of 5km^2 WFD water body status from 'Bad' to 'poor'	€ 61,250 per year
	High - Improvement of 10km^2 WFD water body status from 'Bad' to 'poor'	€ 122,500 per year
Substances classified for acute aquatic toxicity with enough information for PNECs	Low - Improvement of 2km^2 WFD water body status from 'Bad' to 'moderate'	€ 52,760 per year
	Medium - Improvement of 5km^2 WFD water body status from 'Bad' to 'moderate'	€ 131,900 per year
	High - Improvement of 10km^2 WFD water body status from 'Bad' to 'moderate'	€ 263,800 per year
PBTs/vPvB substances with no diffuse uses	Low WTP to eliminate	€ 2.0 million per year
	Medium WTP to eliminate	€ 49.9 million per year
	High WTP to eliminate	€ 97.8 million per year
PBTs/vPvB substances with one or more diffuse uses	Low WTP to eliminate	€ 5.1 million per year
	Medium WTP to eliminate	€ 129.6 million per year
	High WTP to eliminate	€ 254.2 million per year

7.4 Number of health cases avoided per substance identified

The sub-sections above have described:

- the number of substances identified under the options with previously unknown hazardous properties; and
- the diseases, disorders and impacts associated with these hazardous properties and metrics for valuing the avoidance of one case of disease/disorder.

The final piece of information for a complete assessment of the benefits of the options is estimation of the number of cases avoided for every substance identified with a previously unknown hazardous property.

Taking a similar approach to that described thus far, the Phase 2 analysis simply assumed that, for every substance identified one case per year of the corresponding representative disease/disorder would be prevented. Although this was considered to be a very conservative estimate, as it applied equally across all options, it was sufficient for the purpose of comparing the options to see which was likely to provide the greatest benefit relative to the cost.

For this Phase 3 analysis, however, we have been requested to provide an analysis which describes the actual benefits of each option rather than one that simply provides the likely relative benefits of the options. The starting point for this has been ECHA guidance on socioeconomic analysis (SEA) for Authorisation[47].

In relation to quantitative analyses of health impacts from individual chemicals, ECHA's SEA guidance identifies that a number of types of data are likely to be needed:

- an estimate of the total population exposed (and if possible the distribution of exposure within that population);
- an assessment of exposure, including, for example, the frequency and duration of exposure, the rate of uptake of the substance by the relevant route (e.g. inhalation, oral, dermal) in order to be able to estimate and average dose or a range of doses;
- quantitative estimates of the relationship between individual exposure and the incidence of a defined health effect (for example skin irritation, respiratory illnesses, cancer) and derivation of a probability of that effect being manifested (such as a dose-response relationship); and
- A measure of actual impact of the health effect (such as numbers of life years lost due to contracting cancer).

Figure 7-1 on page 71 (taken from the SEA guidance) provides an illustration of how these types of data could be used to quantify the risks associated with cancer from the exposure to a non-threshold carcinogen released from a consumer (or other) product and to which a defined population is exposed[48].

[47] http://echa.europa.eu/support/socio-economic-analysis-in-reach

[48] Note that the figure is only intended to illustrate a possible process for quantifying impacts and uses only demonstration values.

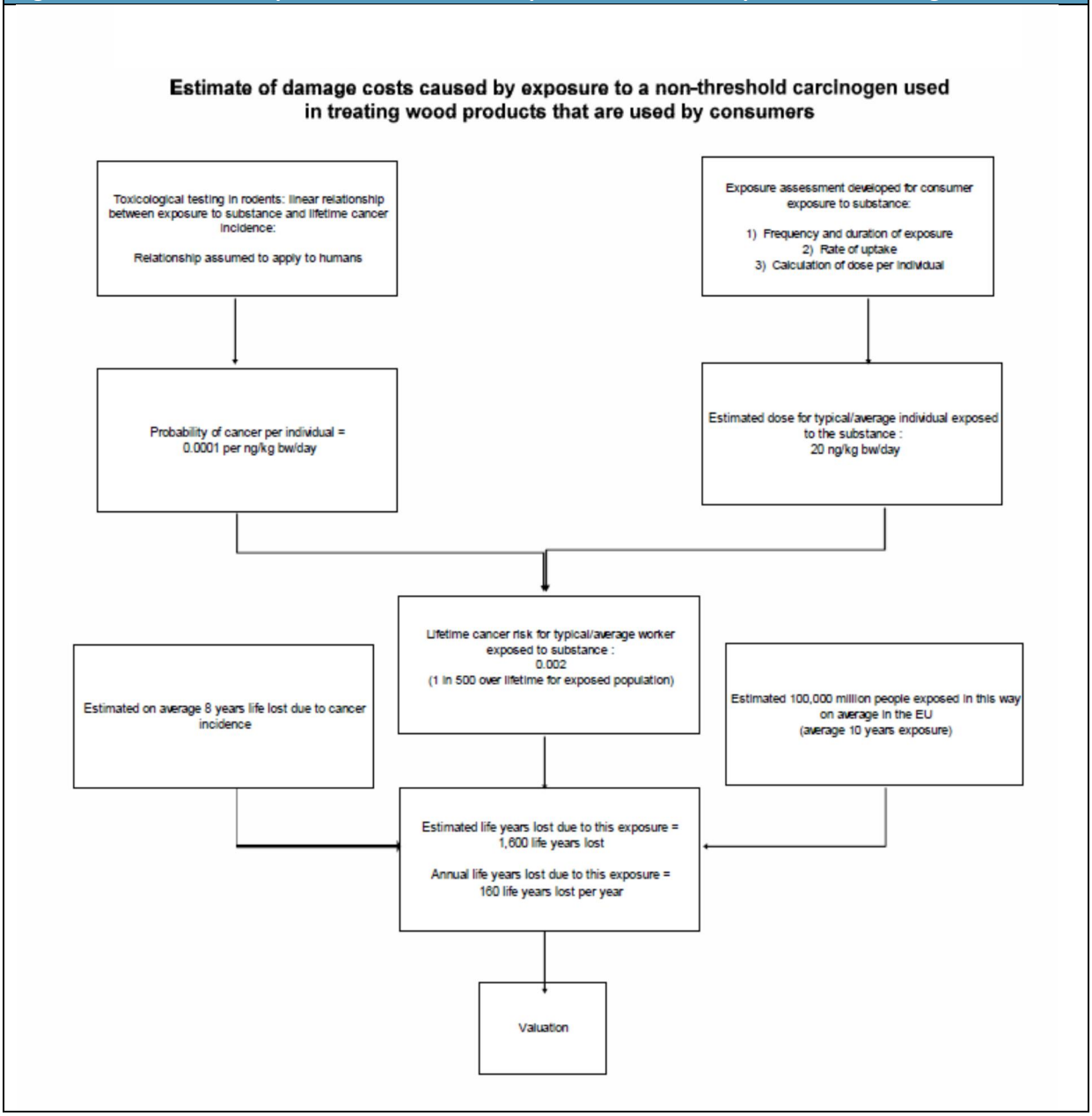
Regarding the application of such an approach to the options, analysis for SEA and Authorisation is carried out on individual, identified substances using real data on toxicity, doses and response as well as exposed populations. The analysis that is being attempted here, however, is on multiple substances for which no such substance specific data are available other than that predicted for:

- hazardous properties not previously known;
- average quantity likely to be manufactured;
- average number of downstream users; and
- number of substances with one or more dispersive/diffuse uses.

Whilst it is clearly not possible to apply the approach set out in ECHA's SEA guidance 'to the letter', it is possible to apply the stages and attempt estimation of the likely outcomes using conservative risk characterisations of an 'average substance'. When combined with the different scenarios and assumptions used in the assessment of costs, this adapted approach allows some assessment of:

- Exposed population;
- Frequency of exposure;
- Incidence of ill effects from acute and repeated exposure.

Figure 7-1: Illustration of quantification of health impacts for consumer exposure to a carcinogen



7.4.1 Exposed population

Manufacturers

As has been described in Section 6.1.1, data on the number of MIs of 1-10t substances have been used to allocate and distribute costs. Expressed as an average across all substances, there is an average of 2.3 MIs per 1-10t substance.

Following the low, medium and high scenarios used to model the costs of CSA/CSR described in Section 6 of the main report, three scenarios have been applied to exposure modelling to provide a

matching set of scenarios covering the range of uncertainties. Based on a range of possible scenarios these are as follows:

- **Low:** 5 potentially exposed individuals per MI on average;
- **Medium:** 10 potentially exposed individuals per MI on average; and
- **High:** 15 potentially exposed individuals per MI on average.

Combining these assumptions with the average number of MIs provides the average number of potentially exposed MI individuals per substance in the table below.

Table 7-11: Average number of potentially exposed MI individuals per substance			
Scenario	**Low**	**Medium**	**High**
Average number of MIs per substance	2.3		
Number of potentially exposed individuals per MI	5	10	20
Average number of potentially exposed individuals per substance (MIs)	11.5	23	46

Immediate (first level) Downstream Users

As with the number of MIs, estimates of the numbers of immediate downstream users (hereafter referred to as DU1s) have been used in the modelling of costs. The scenarios used for the modelling of CSA/CSR costs described in Section 6 of the main report were based on the following numbers of downstream users:

- **Low:** 20 DU1s per substance on average;
- **Medium:** 60 DU1s per substance on average; and
- **High:** 200 DU1s per substance on average.

Following the same scenario based approach, three scenarios have been applied to exposure modelling as follows:

- **Low:** 5 potentially exposed individuals per DU1 on average;
- **Medium:** 15 potentially exposed individuals per DU1 on average; and
- **High:** 30 potentially exposed individuals per DU1 on average.

Combining these together provides the average number of potentially exposed DU1 individuals per substance in the table below.

Table 7-12: Average number of potentially exposed DU1 individuals per substance			
Scenario	**Low**	**Medium**	**High**
Average number of DU1s per substance	20	60	200
Number of potentially exposed individuals per DU1	5	15	30
Number of potentially exposed individuals per substance (DU1s)	100	900	6,000

Second level Downstream Users

In addition to the immediate DUs (DU1s), individuals will be exposed further down the supply chain and, according to ECHA SEA guidance, additional levels of DUs should be considered (preferably

down to the level of the consumer). However, owing to the obvious uncertainties, this analysis has restricted itself to only one additional level where these are referred to as DU2s.

Following the same scenario based approach, three scenarios have been developed to estimate the number of DU2s:

- **Low:** 5 DU2s per DU1;
- **Medium:** 15 DU2s per DU1; and
- **High:** 30 DU2s per DU1.

In terms of the number of potentially exposed individuals at the level of DU2s, the following is assumed:

- **Low:** 5 potentially exposed individuals per DU2 on average;
- **Medium:** 15 potentially exposed individuals per DU2 on average; and
- **High:** 30 potentially exposed individuals per DU2 on average.

Combining these together provides the average number of potentially exposed DU2 individuals per substance in the table below.

Table 7-13: Average number of potentially exposed DU2 individuals per substance			
Scenario	**Low**	**Medium**	**High**
Average number of DU1s per substance	20	60	200
Number of DU2s per DU1	5	15	30
Number of potentially exposed individuals per DU2	5	15	30
Number of potentially exposed individuals per substance (DU2s)	500	13,500	180,000

Type of Use

As is noted in the ECHA guidance on SEA, if possible the analysis should reflect the distribution of exposure within that population, the type and nature of exposure. Considering this, other than the distribution of the exposed population between MIs, DU1s and DU2s, the only additional factor that can be considered is dispersive/diffuse versus non-dispersive/diffuse uses. Here the cost assessment estimates that 25% of substances have one or more diffuse uses (see Section 3.1.4).

Clearly, for those substances with one or more diffuse uses, not all of those uses will be dispersive/diffuse. As such, it has been assumed that for these substances 40% of the uses are dispersive/diffuse (and 60% non-dispersive/diffuse).

Applying this to the population of exposed individual at each level (MIs, DU1s and DU2s) gives the potentially exposed population for each use in the table below.

Table 7-14: Average number of potentially exposed individuals per substance (by use)						
Uses	**Scenario**	**Manufacture**	**DU1 use non-dispersive**	**DU2 use non dispersive**	**DU 1 use dispersive**	**DU2 use dispersive**
Substances with no dispersive uses	**Low**	12	100	500	0	0
	Medium	23	900	13,500	0	0
	High	46	6,000	180,000	0	0
Substances with 40% of uses being dispersive	**Low**	13	60	300	40	200
	Medium	23	540	8,100	360	5,400
	High	46	3,600	108,000	2,400	72,000

7.4.2 Frequency of exposure to a substance - at any concentration, for any duration

The frequency of exposure of each of the exposed populations is given by an individual probability of exposure to a substance per day. The values used in the model are provided in Table 7-15 below along with their equivalents in terms of an average frequency for a single exposure measured in days. In each case, the likelihood of a single exposure per day relates to any single event resulting in exposure to any concentration (however large or small) for any duration (long or short) whether or not that exposure is harmful. The probabilities for each use/exposed population have been estimated using the judgement of RPA in-house chemical risk experts who regularly consider such issues as part of work on authorisations. They have been made considering the following:

- That any hazardous properties of the substances are, as yet, unidentified and, hence, substances may not be handled as carefully (using appropriate risk control) as they otherwise might be;
- That, though the above may be the case, as the total volume of the substances produced annually by each manufacturer is small (1-10t), care is likely to be exercised to reduce emissions and losses during manufacture. So the likelihood of any exposure of an individual involved in manufacture is likely to be smaller compared with downstream uses;
- That the care exercised to reduce emissions and losses and associated risk control measures applied may be, on average, less for the second level of downstream uses (DU2s) than for the immediate downstream uses (DU1s) and so exposure of individuals is higher for DU2s than DU1s; and
- That individual exposure is more likely for dispersive/diffuse uses than non-dispersive/diffuse uses.

Table 7-15: Likelihood of a single exposure to a substance per day					
	Manufact-ure	**DU1 use non-dispersive**	**DU2 use non dispersive**	**DU 1 use dispersive**	**DU2 use dispersive**
Likelihood of a single exposure (per individual per day)	0.1	0.2	0.4	0.4	0.8
=1 chance in x days	10	5	2.5	2.5	1.25

7.4.3 Incidence of ill effects

As is noted above, the substance exposure probabilities in Table 7-15 above relate to the likelihood of any single event occurring that results in exposure to any concentration (however large or small) for any duration (long or short) whether or not that exposure is harmful. Some of the exposures will, however, be of sufficient dose/duration to result in ill effects (but most will not).

Estimating the incidence of ill effects must be divided into consideration of acute ill effects from individual (single) exposures and chronic ill effects (from repeated exposures). This requires two separate means of estimation and these are described in the following sub-sections.

Estimation of acute ill effects from individual exposures

As there is no dose-response function that one can apply to an average substance, one must estimate the likelihood that an individual exposure will be of sufficient dose/duration to have an acute ill effect on an exposed individual.

The starting point has been estimation of the likelihood of exposure to ill effects to individuals working in manufacture. Here the RPA in-house chemical risk experts have suggested that a reasonably conservative assumption that one in every 100 exposures is of a dose/duration sufficient to have an acute ill effect should be applied (i.e. a likelihood of 0.01).

Combined with the likelihood of a single exposure of 0.1 (per individual per day - described in Section 7.4.2 above) this gives:

- for manufacturers, the likelihood of an exposure event resulting in acute ill effects is 0.1x0.01 = 0.001 per day per individual or 0.24 per individual per year (i.e. one chance in 4 years) assuming 240 work days per year.

Given the expected dilution of a substance as it passes down the supply chain, the likelihood that an individual exposure will of sufficient dose/duration to have an ill effect can be expected to be smaller for a downstream user than for a manufacturer. To reflect this, the probabilities applied to downstream users have been estimated with reference to volumes passing down the supply chain (with these volumes being different for different scenarios).

Using a simple example, if a manufacturer is producing 10,000kg of a substance and has 10 immediate downstream users (DU1s) then on average each DU1 is handling 1,000kg - i.e. $1/10^{th}$ of the volume handled by the manufacturer. The analysis assumes that, whether by dilution or other effect, the risk is similarly reduced to the same extent. Thus, in this example, for DU1s the likelihood that an individual exposure will be of sufficient dose/duration to have an ill effect is $1/10^{th}$ of that for manufacturers (0.01), i.e. in this example 0.001.

As numbers of DUs vary between low, medium and high scenarios probabilities have been calculated for each scenario and downstream use, dividing the manufactured quantity equally between the downstream users. The average quantity of substances produced by individual manufacturers in the cost assessment is 8,500kg per year and so is applied across all scenarios. This is divided equally between the different DU entities according to the scenario to provide the quantities in Table 7-16 below.

Expressed relative to the starting quantity (8,500kg), these data provide the quantities used by DU entities relative to the manufacturer. These have then been applied to provide an equivalent adjustment in the likelihood estimated for manufacturers (0.01 per event) for application to DUs.

Table 7-16: Calculation of the likelihood of an exposure event resulting in acute ill effects				
		Manufacturer	DU1	DU2
Quantity handled by each entity (Kg)	Low numbers of DUs	8,500	425 kg	85 kg
	Medium Numbers of DUs		141.7 kg	9.4 kg
	High numbers of DUs		42.5 kg	1.4 kg
Relative quantity (~ relative risk/likelihood)	Low numbers of DUs	1	0.05	0.01
	Medium Numbers of DUs		0.017	0.0011
	High numbers of DUs		0.005	0.00017
Likelihood of an exposure event resulting in acute ill effects (per exposed individual per day)	Low numbers of DUs	0.01*	0.0005**	0.0001**
	Medium Numbers of DUs		1.7E-04**	1.1E-05**
	High numbers of DUs		0.5E-05**	1.7E-06**
* estimated likelihood of an exposure event leading to acute ill effects is 0.01 per event for manufacturers (given in text above) ** Likelihood derived from the manufacturer likelihood (0.01) times the appropriate relative quantity used by DUs – e.g. for low DUs and DU1, quantities used are 0.05 x those used by manufacturers. Therefore the likelihood of an exposure event leading to acute ill effects is equal to 0.01 x 0.05 = 0.0005 for low DU1.				

Combining the probability of any exposure event occurring (from Table 7-15) with the probability of an exposure event leading to acute ill effects (from Table 7-16) provides the overall probability of an exposure which leads to acute ill effects per individual per day. Assuming 240 days of work per year provides the resulting probabilities expressed per year are provided in Table 7-17 below.

Using the example of the low scenario DU1 non-dispersive use, values are calculated as follows:

- Likelihood of a single exposure (per individual per day) = 0.2 (Table 7-15)
- Likelihood of an exposure event resulting in acute ill effects (per exposed individual per day) = 0.0005 (Table 7-16)
- Likelihood of an exposure event resulting in acute ill effects per exposed individual per day = 0.2 x 0.0005 = 0.0001
- Likelihood of an exposure event resulting in acute ill effects per exposed individual per year (240 days) = 0.0001 x 240 = 0.024 (as in Table 7-17)

Table 7-17: Likelihood of an exposure to a substance leading to acute ill effects (per exposed individual per year)						
		Manufacture	DU1 use non-dispersive	DU2 use non dispersive	DU 1 use dispersive	DU2 use dispersive
Likelihood of an exposure event resulting in acute ill effects (per exposed individual per year)	Low numbers of DUs	0.24	0.024	0.0096	0.048	0.019
	Medium numbers of DUs	0.24	0.008	0.00107	0.016	0.002
	High numbers of DUs	0.24	0.0024	0.00016	0.0048	0.00032
Expressed as 1 chance in x years	Low numbers of DUs	4	42	104	21	52
	Medium numbers of DUs	4	125	938	63	469
	High numbers of DUs	4	417	6,250	208	3,125

As can be seen from the table, estimated likelihood of an exposure that causes acute ill effects varies widely between the scenarios and between uses. In virtually all cases the estimates suggest very low probabilities.

Application of these individual probabilities in Table 7-17 to the number of exposed individuals estimated in Table 7-14 provides the average expected number of acute cases of ill health per substance per year across the whole exposed population. The results are provided for each use in the table below.

Continuing the example above in relation to low scenario DU1 non-dispersive use:

- Likelihood of an exposure event resulting in acute ill effects per exposed individual per year (240 days) = 0.0001 x 240 = 0.024 (as in Table 7-17)
- Exposed individuals low scenario DU1 non-dispersive use = 160 (from Table 7-14)
- Average expected number of acute cases of ill health per substance per year = 0.024 x 160 = 4 (3.8).

Table 7-18: Average expected number of acute cases of ill health per substance per year						
	Manufacture	DU1 use non-dispersive	DU2 use non dispersive	DU 1 use dispersive	DU2 use dispersive	Total
Low numbers of DUs	6	4	8	2	4	**23**
Medium numbers of DUs	11	12	23	6	12	**63**
High numbers of DUs	22	23	46	12	23	**126**

From these data, the total number of cases of acute ill health associated with exposure to 1-10t substances with as yet unidentified acute hazardous properties is taken as 23, 63 and 126 cases per year per substance for the low, medium and high scenarios respectively.

Table 7-19: Total disease cases from acute exposure (all users per substance)		
	Number of cases per year	As a percentage of total exposed population (all uses/users)
Low	23	1.8%
Medium	63	0.2%
High	126	0.03%

Estimation of ill effects from repeated exposures

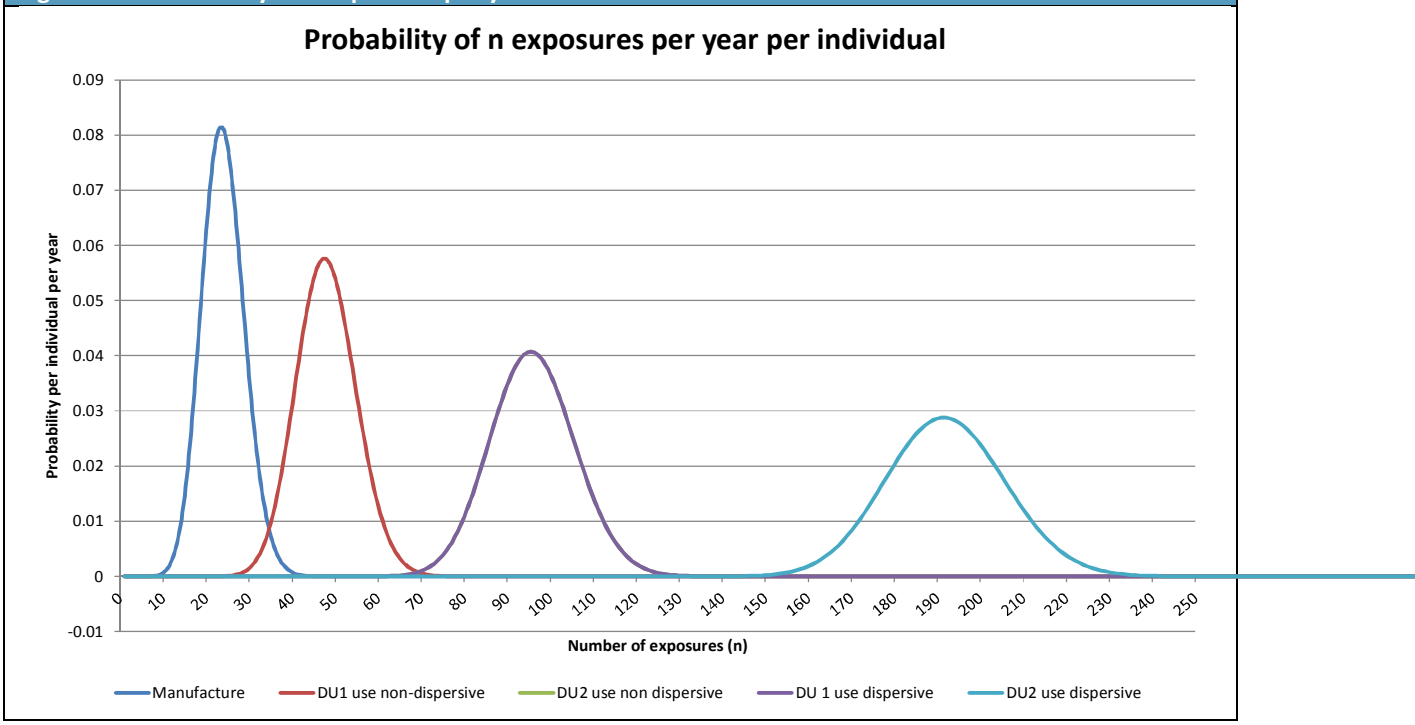
The estimation of incidence of ill effects from repeated exposures to substances involves:

- Calculating the likelihood of exposed individuals receiving n exposures per year (where n is between 1 and 1,000) for each use; and
- Estimating the probability that n repeat exposures will trigger an ill health outcome in an exposed individual.

The combination of these two sets of probabilities provides the cumulative probability that a disease outcome may be triggered per individual per year for application to the exposed population and, therein, the number of expected cases triggered per substance per year.

As is standard procedure in this type of probabilistic risk assessment, probability of n exposures per year is calculated using a probability distribution employing the estimates of the likelihood of individual exposure events described in Section 7.4.2. This provides the probability distributions in the figure below for each of the uses/users.

Figure 7-2: Probability of n exposures per year



The next step is to estimate the probability that n repeat exposures will trigger an ill health outcome. As with the analysis for acute (single) exposure the situation is first estimated for manufacturers and then adjustments are made to the estimates for users/uses further down the supply chain consistent with the lower volumes/concentrations used by DUs under the scenarios.

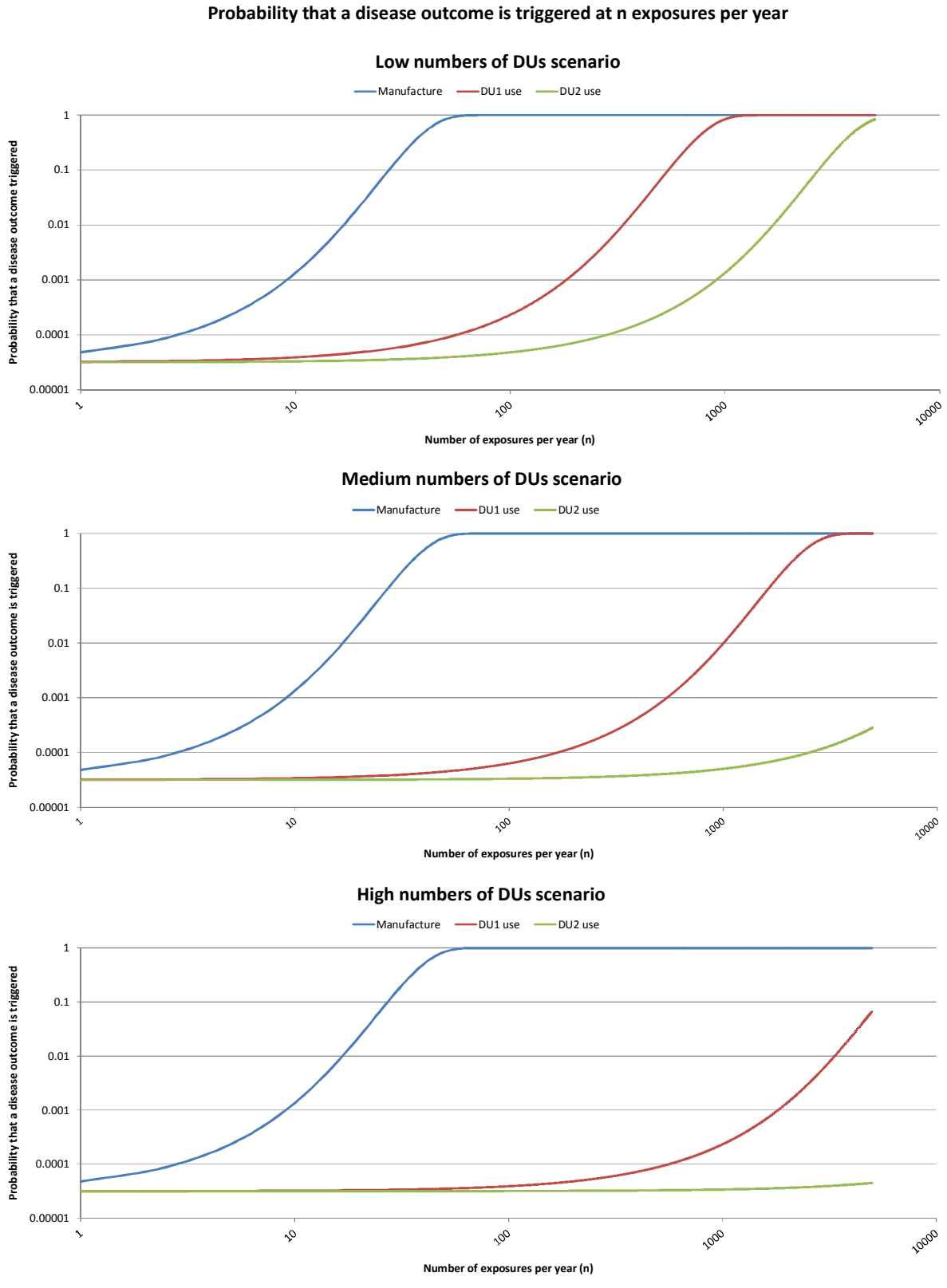
For manufacturers, estimation starts with the number of exposures expected to be required for there to be a 50% chance of triggering a chronic ill health outcome in an exposed individual. The RPA in-house chemical risk experts have suggested that a reasonably conservative assumption is that 40 exposures per year results in a 50% chance of a chronic health outcome for individuals exposed during manufacture. For the DUs, the number of exposures required to have a 50% chance of triggering a chronic ill health outcome has been changed in proportion to the relative volumes handled by DUs compared with manufacturers. Resulting values and relative volumes are provided in Table 7-20 below.

From the table, the number of exposures for a 50% chance of a disease outcome is 40 exposures for manufacturers (as described above). For each DU this value is adjusted in proportion to the quantities being used. So, for example, for DU1 use in the low scenario the quantities used are 0.05 times those used by the manufacturer and so the number of exposures required for a 50% chance might be expected to be 1/0.05 times larger, i.e. 800 exposures per year required for a 50% chance of a disease outcome. The resulting probabilities of diseases (P) at each interval (n – number of exposures) are plotted in the figures overleaf for each use/user and for each scenario.

Table 7-20: Derivation of number of exposures required for a 50% chance of triggering chronic ill health in DUs

		Manufacture	DU1 use non-dispersive	DU2 use non dispersive
Relative quantity used (~ relative risk/likelihood)	Low numbers of DUs	1	0.05	0.011
	Medium Numbers of DUs		0.017	0.001
	High numbers of DUs		0.005	0.00017
Number of exposures for a 50% chance of chronic ill health (per year)	Low numbers of DUs	40	800	4,000
	Medium Numbers of DUs		2,400	36,000
	High numbers of DUs		8,000	240,000

Figure 7-3: Probability of disease at intervals of n exposures per year



Combining the data for the probability of n exposures per year per individual and the probabilities that n exposures per year will lead to a disease outcome provides the overall probability that a disease outcome will be triggered by n repeated exposures received per individual per year. These probabilities have been calculated for n=1 [exposure] to n=1,000 [exposures]. The sum of the resulting 1,000 individual probabilities provides the cumulative probability for disease outcomes from repeated exposure for each of the uses/users and for each scenario per year of exposure. These are provided in Table 7-21 below.

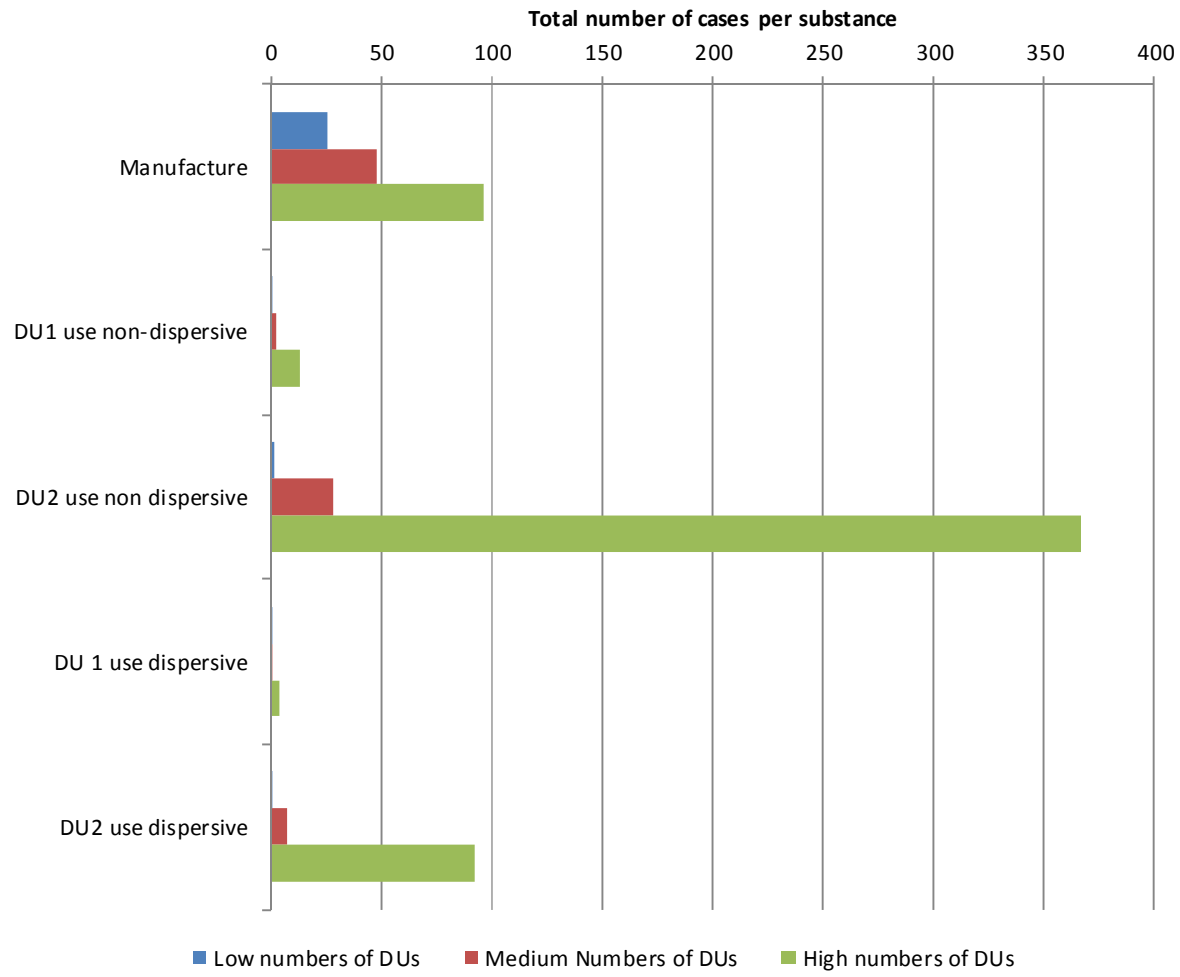
Table 7-21: Cumulative probability that disease outcome triggered (per individual per year)					
	Manufacture	DU1 use non-dispersive	DU2 use non dispersive	DU 1 use dispersive	DU2 use dispersive
Low numbers of DUs	0.076	8.6E-05	4.7E-05	2.2E-04	7.0E-05
Medium Numbers of DUs		4.4E-05	3.3E-05	6.2E-05	3.5E-05
High numbers of DUs		3.5E-05	3.2E-05	3.9E-05	3.2E-05

These annual probabilities have then been applied to the exposed population working in manufacture and the downstream uses over a 40 year period. Here, an average 10 year service life has been assumed (workers leave and are replaced after 10 years and so are only exposed to the risk for 10 years) and the disease outcomes are assumed to be serious long-term and slow onset diseases (such as cancer). As such, whilst the disease outcome (such as cancer) may have been triggered during service it may be after the end of service before the symptoms manifest themselves. As such, the probabilistic model accounts for the fact that that once a chronic disease outcome is triggered in an individual it cannot be triggered again in the same individual and so 'diseased individuals' are removed from the exposed working population progressively over the 40 year period.

The resulting total numbers of cases calculated for the 40 year period under the scenarios and for each of the uses are plotted graphically in Figure 7-4 below. The sum of cases for all uses and users provides the total number of cases of chronic disease over the 40 year period which can be converted into an average number of disease cases per year. These totals and annual averages are provided in Table 7-22 below as numbers of cases.

Table 7-22: Total number of disease cases (over a 40-year period) and average cases per year from chronic exposure - all uses and users		
Scenario	Total number of chronic cases over 40 years per substance	Number of cases per year per substance
Low	29	0.7
Medium	88	2.2
High	573	14.3

Figure 7-4: Total number of disease cases from repeated exposure (per substance)



Expected numbers of disease cases prevented by identification of substances with hazardous properties

The average number of disease cases avoided per year per substance are provided in the table below for both acute and repeated exposure effects. To provide some context, the table also provides these numbers expressed as a percentage of the exposed population. As can be seen from this, applying the assumptions and methods described in this sub-section, the resulting incidence rate for diseases from acute and repeated exposure is very low, suggesting perhaps that all scenarios may err towards underestimating the numbers of cases avoided rather than overestimating.

Table 7-23: Expected numbers of disease cases prevented by identification of substances with hazardous properties				
	Disease cases from acute exposure - all users		Disease cases from chronic exposure - all uses and users	
	Number of cases per year	As a percentage of total exposed population	Number of cases per year	As a percentage of total exposed population
Low	23	1.9%	0.7	0.06%
Medium	63	0.2%	2.2	0.008%
High	126	0.03%	14.3	0.004%

7.4.4 Final scenarios for human health and environmental impacts avoided

Finally, Table 7-24 below provides the resulting cases avoided per year per substance identified with the relevant classification/property (either acute or chronic) for the low, medium and high number of DU scenarios. For environmental impacts avoided, the scenarios have been completed using assumed areas of waterbody improved.

Table 7-24: Scenarios for human health and environmental impacts avoided				
Classification/identification under Options	Representative outcome	Cases avoided per year per substance identified with property		
		Low	Medium	High
Human health impacts avoided				
Substances classified for skin/eye damage and irritation	Cases of mild acute dermatitis	23	63	126
Substances classified for skin sensitisation	Cases of severe chronic dermatitis	0.7	2.2	14.3
CM(R) 1A/1B	Cancer exposures	0.7	2.2	14.3
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	'Poisoning events'	23	63	126
Substances with long-term toxicity information	Cases of kidney disease of short-term duration	0.7	2.2	14.3
Substances that would have classification for STOT RE 1 or 2	Cases of chronic kidney disease of longer-term duration	0.7	2.2	14.3
Environmental impacts avoided				
		Area of waterbody improved (km^2)		
		Low	Medium	High
Substances classified for acute aquatic toxicity	Improvement of WFD water body status from 'bad' to 'poor' per km^2	2	5	10
Substances classified for acute aquatic toxicity with enough information for PNECs	Improvement of WFD water body status from 'bad' to 'moderate' per km^2	2	5	10

7.5 Calculation of total damage costs avoided

The total annual damage costs avoided under each scenario (low, medium and high) for each representative outcome/metric is the product of:

- the monetary value applicable to the representative outcome (provided in Table 7-10); and
- the number of cases of the representative outcome that are avoided per substance newly identified with each type of classification/property (provided in Table 7-24).

The resulting values are provided in Table 7-25. This provides the estimated damage costs avoided per year from controlling a substance that is newly identified with the corresponding classification. Values for all three scenarios are provided.

With regard to the values for avoiding cancer triggering exposures, as discussed in Section 7.3.4, these are calculated on the basis of the aggregated cost of one cancer exposure a year over a period of 40 years of exposures. Total costs in each year are calculated and to these has been applied the 4% standard discounting rate applied in EC impact assessments to give costs as NPV. The sum of these NPV costs provides the cost of one cancer exposure per year for 40 years (and thus the benefits associated with prevention of one exposure per year).

When calculating this, average 'all cancer' values have been applied as follows:

- Latency = 15 years
- Survival/treatment period (years) = 5 years
- Fatality rate at end of period = 47%[49]
- Annual cost per patient (€) = € 14,966
- Value of a Statistical Life (VSL) (€) = € 4,000,000
- Value of a Cancer Morbidity (VCM) (€) = € 410,000

This provides an aggregated NPV of €22,673,090 for the prevention of one cancer exposure per year over a period of 40 years. Multiplied by the number of cancer exposures avoided per year, this provides the NPV of cases avoided over 40 years. This is presented in the table in spite of it not being an annual value. For comparison with the other damage costs avoided, the NPVs for each scenarios have been converted to Equivalent Annual Costs (EAC) using a discount rate of 4%.

Consistent with Commission guidance on Impact Assessment, the benefits under each of the information options (and in combination with the CSA/CSR option are provided as NPVs (over 40 years) in the main report. When aggregating damage costs avoided (i.e. benefits), present value human health benefits are assumed to begin in 2022 and are calculated over the remaining period (discounting at 4%). Environmental benefits are assumed to take longer to be established and are assumed to be accrued in the period after 2026 (and are also discounted at 4%).

[49] Based on data for the EU from International Association of Cancer Registries http://www.iacr.com.fr/

Table 7-25: Estimated annual damage cost avoided by the identification of a substance with the corresponding classification										
Damage Metrics/representative outcomes		Monetary value per unit incidence of representative outcome (from Table 7-10)			Cases/outcomes avoided per year (from Table 7-24)			Calculated annual damage cost avoided by the identification of one substance with corresponding classification		
		Low	Med	High	Low	Med	High	Low	Med	High
Substances classified for skin/eye damage and irritation	**Cases of mild acute dermatitis**	€ 667	€ 667	€ 667	23	63	126	€ 15,448	€ 41,941	€ 83,882
Substances classified for skin sensitisation	**Cases of severe chronic dermatitis**	€ 5,255	€ 5,255	€ 5,255	0.7	2.2	14.3	€ 3,755	€ 11,510	€ 75,260
CM(R)s 1A/1B	**NPV cancer over 40 years**	*€ 22,673,090**	*€ 22,673,090**	*€ 22,673,090**	*0.7*	*2.2*	*14.3*	*€ 16,200,952**	*€ 49,659,849**	*€ 324,713,183**
	Equivalent Annual Cost (EAC) cancer	Note that the EAC is calculated from the NPV over 40 years (in italics above)						€ 818,529	€ 2,508,989	€ 16,405,643
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	**'Poisoning events'**	€ 2,870	€ 2,870	€ 2,870	23	63	126	€ 66,469	€ 180,466	€ 360,931
Substances with long-term toxicity information	**Cases of kidney disease of short-term duration**	€ 10,500	€ 10,500	€ 10,500	0.7	2.2	14.3	€ 7,503	€ 22,998	€ 150,376
Substances that would have classification for STOT RE 1 or 2	**Cases of chronic kidney disease of longer-term duration**	€ 380,400	€ 380,400	€ 380,400	0.7	2.2	14.3	€ 271,813	€ 833,173	€ 5,447,907
Substances classified for acute aquatic toxicity	**Improvement of WFD water body status from 'Bad' to 'poor' per km2**	€ 12,250	€ 12,250	€ 12,250	2	5	10	€ 24,500	€ 61,250	€ 122,500
Substances classified for acute aquatic toxicity with enough information for PNECs	**Improvement of WFD water body status from 'Bad' to 'moderate' per km2**	€ 26,380	€ 26,380	€ 26,380	2	5	10	€ 52,760	€ 131,900	€ 263,800
PBTs/vPvBs non-diffuse	**WTP to eliminate emissions of 1-10t PBTs**	€ 1,955,000	€ 49,852,500	€ 97,750,000	1	1	1	€ 1,955,000	€ 49,852,500	€ 97,750,000
PBTs/vPvBs diffuse		€ 5,083,000	€ 129,616,500	€ 254,150,000	1	1	1	€ 5,083,000	€ 129,616,500	€ 254,150,000
* values reflect NPV damage costs avoided over a 40 year time period. These have been converted to an Equivalent Annual Cost using the standard approach and a discount rate of 4%.										

7.6 Benefits that have not been quantified

7.6.1 Overview

A number of benefits cannot be adequately/meaningfully assessed in monetary or other terms. These mainly relate to benefits of the CSA/CSR option (as opposed to the information options) and are described in the following subsections.

7.6.2 Implementation of Consistent and Adequate Risk Management Measures in Relation to Worker Exposure

The extension of the CSA/CSR obligation to 1-10t CMRs 1A/1B would for each substance, result in the identification of consistent and robust risk management measures for implementation by downstream users and manufacturers alike and communication of these, and other important information, to all downstream users of the substances.

Under the current regulatory regime that applies, each individual manufacturer and downstream user is required to assess their own situation individually with the aid of only the general information provided in the SDS (as opposed to that of an extended SDS including DNELs where they have been or can be established for the 23 substances (see table 7-24 and 7-25).where there may or may not be a threshold effect). In the course of duplicating effort in this way, and with the more limited information available to conduct assessments, the result may be the implementation of a range of different risk management measures by different manufacturers and different downstream users. Some of these may provide adequate control and some may not. The current regulatory regime does not provide a means of establishing this either way.

Substances also registered in higher tonnage bands would also be required to communicate information in the supply chain. At present, whilst it has been assumed in this analysis that uses of these substances would be covered in the CSAs required for the higher tonnage substances (and, as such, the costs of the obligation for these substances is zero), there is no requirement for manufacturers and importers to provide an eSDS to downstream users including the relevant exposure scenarios for those uses. Thus, at present, there is a risk that information supplied to downstream users may differ depending on whether the supplier manufacturers or imports the substance in quantities of 1-10t or >10t per year. **Extending the obligation would result in the communication of consistent and robust risk management information to all downstream users regardless of the volumes imported or produced by the registrants.**

7.6.3 Adequate Risk Management Measures in Relation to Articles

In relation to substances used in articles, where the substance is used in quantities of 1 tonne or more and the substance is intended to be released under normal or reasonably foreseeable conditions of use, that use must be registered as an identified use either in the registration for the substance or mixture or as a substance used in an article in its own right.

Here, under Article 7 of REACH, manufacturers and importers of such articles would have to complete a registration for the substance and its use if the use in the articles is not already registered.

In the case of 1-10t CMRs 1A/1B used in such articles there is no obligation to perform a CSA/CSR at present and the safety of the article is only a consideration under general product safety regulations (or specific product regulations where they are applicable to the article and its use).

If the CSA obligation were to be extended, the use of a substance in such an article would have to be included in the CSA/CSR (and an extended SDS provided to downstream users producing those articles). This would identify consistent and robust recommended risk management measures where these can be identified.

If risk management measures cannot be identified, under Article 37, '*where the manufacturer, importer or downstream user, having assessed the use in accordance with Article 14* [CSA/CSR], *is unable to include it as an identified use for reasons of protection of human health or the environment, he shall provide the Agency and the downstream user with the reason(s) for that decision in writing without delay and shall not supply downstream user(s) with the substance without including these reason(s) in the information referred to under Articles 31 or 32. The manufacturer or importer shall include this use in Section 3.7 of Annex VI in his update of the registration in accordance with Article 22(1)(d)*'.

As such, where a CSA identifies that use in the article cannot be supported '*for reasons of protection of human health or the environment*' ECHA is alerted of this fact and action concerning these articles on the market or to be put onto the market can be implemented. This is not possible under current regulation where the safety of the article is only a consideration under general product safety regulations (or specific product regulations where they are applicable to the article and its use).

7.6.4 Control of Environmental Risks

Extending the CSA obligation to 1-10t CMRs 1A/1B would require consideration of environmental exposure, its likely effects, and appropriate risk management for identified uses. Under the current requirements this would not otherwise be considered for these substances other than when action was identified as being required by Member States or the Commission under community regulation.

For PBT/vPvB substances it would have to be demonstrated through exposure assessment that there are no emissions or losses to environmental compartments. For non PBTs, under the current Annex VII information requirements quantitative comparison between environmental exposures and an established PNEC is unlikely to be possible because the two Annex VII tests are not sufficient to develop a PNEC and a third species would be needed to establish an acute PNEC for the aquatic compartment. There is no requirement to undertake a third test in the current Annex VII or Annex I and, as such, the environmental exposure assessment and risk characterisation in the CSAs of CMRs 1A/1B would remain incomplete.

This is a situation that is resolved when combining the CSA/CSR option with any of the Information Options A to E because all of these options include the third test necessary to establish a PNEC. However, it has not been possible to measure the benefits of this in a meaningful way.

7.6.5 Benefits for Member States and the Commission

Extending the CSA/CSR obligation to 1-10t CMRs 1A/1B and the subsequent consistent documentation of appropriate risk management measures for the concerned substances would simplify and improve the control on safe handling of substances in the workplace under all

applicable regulation enforced by all relevant authorities. It would also facilitate the identification of cases for which the Commission or Member States could consider that the manufacture, placing on the market or use of a substance, on its own, in a mixture or in an article poses a risk to human health and for which a restriction procedure could be initiated.

In addition, the extended CSA/CSR obligation would further ensure the generation of robust study summaries on selected human and environmental health endpoints. Currently these robust study summaries must be generated by Member States during the development of a harmonised classification and not by manufacturers and importers (as they would were the CSA obligation to be extended).

It has not been possible to measure these benefits in a meaningful way.

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