Technical assistance related to the review of REACH with regard to the extension of the obligation to perform a chemical safety assessment and to document a chemical safety report to substances manufactured or imported between 1 and 10 tonnes per year or not subject to registration, and the registration requirements for substances manufactured or imported between 1 and 10 tonnes per year (070307/2013/668917/SER/ENV.A.3)

Final Report on the extension of the obligation to perform a chemical safety assessment and to document a chemical safety report to CMR 1A and 1B substances manufactured or imported between 1 and 10 tonnes per year

prepared for

DG Environment

15 July 2014

RPA
Risk & Policy Analysts

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Author(s)	Anthony Footitt Marco Camboni
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Disclaimer

The views and propositions expressed herein are, unless otherwise stated, those of Risk & Policy Analysts and do not necessarily represent any official view of DG Environment or any other organisation mentioned in this report.

Executive Summary

1. Introduction

Article 138(1) of REACH places an obligation on the Commission to assess whether or not to extend the application of the obligation to perform a chemical safety assessment (CSA) and to document it in a chemical safety report (CSR) to substances manufactured or imported in quantities of less than 10 tonnes per year which meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1 or 2 (1A or 1B under CLP) and to substances not covered by this obligation because they are not subject to registration.

The Commission has contracted RPA and CSES to provide technical assistance in relation to the review described in Article 138(1). This Final Report provides an assessment of findings in relation to the key study objectives in respect of the review.

The report considers the current requirements in relation to 1-10t substances and provides an overview of requirements in relation to CSA and CSR. It considers the changes introduced by extending CSA/CSR requirements, the costs and benefits of these changes and, on the basis of this, conclusions.

2. 1-10t Substances to which the CSA Obligation would Apply

The analysis has considered the current requirements in relation to 1-10t substances[1] "meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, in accordance with Regulation (EC) No 1272/2008[2]" (to which an extended CSA obligation would apply). There are two distinct types of substances that need to be considered:

- ***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 records suggest that 46 unique substances were 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 but information that must be gathered as part of meeting registration requirements will identify properties that will lead to classification.*

In relation to substances with currently unknown 'CMR 1A/1B' properties, the analysis has identified that the application of Annexes VII to XI in conjunction with ECHA endpoint specific guidance will lead to the identification of 'CMRs' via the genotoxicity route alone. Two possible conclusions/outcomes are possible from the application of the Annexes:

[1] 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.

[2] Article 138(1) of REACH

- ***Conclusion 1 - the substance is genotoxic to germ cells and is classified as a category 1B mutagen and so would be subject to an extended CSA obligation:*** *according to the ECHA guidelines, the substance will not be classified as a carcinogen but any risk assessment should regard the substances as genotoxic carcinogens. The substance will not be classified for reproductive toxicity. However, because the CSA obligation does not currently apply to these substances under REACH, no assessment of the risk of exposure or recommended risk management measures would be provided in the dossier; or*

- ***Conclusion 2 - the substance is genotoxic to somatic cells only and is classified as a category 2 mutagen and so would <u>not</u> be subject to an extended CSA obligation:*** *as above, the substance will not be classified as a carcinogen but "unless there is clear evidence to indicate the contrary", any risk assessment should regard the substances as genotoxic carcinogens. The substance will not be classified for reproductive toxicity. However, because the CSA obligation does not currently apply to these substances under REACH, no assessment of the risk of exposure or recommended risk management measures would be provided in the dossier. As category 2 mutagens, these substances would <u>**not**</u> be identified as "meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, in accordance with Regulation (EC) No 1272/2008".*

In terms of the estimated numbers of these substances, the analysis suggests that:

- *106 substances are likely to be classified as Mut. 1B and, hence, would be required to undertake a CSA under any extended obligation;*
- *46 substances would be classified as Mut. 2. Assuming a small percentage (~5%) of those would also be classified as Carc 1A/1B (which is expected to be a rare/unlikely event) this suggests an additional 2 substances might be required to undertake a CSA under any extended obligation; and*
- *assuming that all of these substances proceed with registration (and do not withdraw from the market to avoid in vivo testing for mutagenicity and associated costs),* ***a total of around 108 previously unknown 1-10t substances would be required to undertake a CSA under any extended obligations****. These would all be mutagenic and, thus, non-threshold substances for the purposes of exposure assessment and risk characterisation (hence technical measures to implement closed systems are the starting point for risk management measures).*

3. REACH Requirements for Manufacturers and Importers of 1-10t 'CMR 1A/1B' Substances

3.1 Information Provided in the Registration Dossiers

In terms of the information supplied in the registration dossiers for 1-10t 'CMRs 1A/1B this information includes all of the following:

- ***The information stipulated in Article 10(a) and Annex VI on****: the identity of the manufacturer or importer and that of the substance; information on manufacture and uses; classification and labelling; guidance on safe use; exposure information concerning main use category, significant routes of human and environmental exposure and pattern of exposure; study summaries for information derived by the application of Annexes VII to XI;*

- ***Information in relation to tests and testing strategies applied following Annex VII:*** *information in respect of all of the physico-chemical, toxicological and eco-toxicological endpoints in Annex VII and associated study summaries; and*

- ***Information in relation to mutagenicity tests and testing strategies applied following Annexes VIII to XI:*** *owing to a positive result to the Annex VII test further mutagenicity further information in respect of the in vitro and in vivo tests from Annexes VIII to X applying both the general rules for adaptation set out in Annex XI and ECHA guidelines and the associated Integrated Testing Strategy (ITS).*

3.2 Information in the Supply Chain

Under REACH, all manufacturers and importers of substances with hazardous properties (including those produced in quantities of 1-10t per year) are required to provide a Safety Data Sheet (SDS). The aim of an SDS is to provide downstream users of a substance with information to enable them to implement controls to address the risks arising from use of a substance.

For the 1-10t substances no CSA is required and, as such, only general advice is required in the Safety Data Sheet (SDS) supplied to downstream users. The information in Sections 7 and 8 (Handling and storage; Exposure controls/personal protection) of the SDS, will draw from and build on the generic precautionary statements (P-statements) from CLP. Without an exposure assessment detailing risk management measures and the technical means to achieve them, manufacturers and importers of the 1-10t substances will have to expand on these based on experience and by applying a good measure of caution but will not have to quantitatively assess exposures and technical risk management measures. Thus, for example, they may identify in an SDS that a closed system is required but they will not detail technically how this should be achieved and place this as part of the exposure scenario in an Annex to the SDS (as would be the case with substances subject to CSA).

3.3 Evaluation, Authorisation and Restriction under REACH

In the event that a substance is classified as C, M or R 1A or 1B a substance could be subject to other provisions of REACH such as Evaluation, Authorisation and Restriction. These provisions are aimed at assuring that risks from substances with properties of very high concern are properly controlled. If a substance is prioritised under these provisions, assessment beyond that required for a CSA must be undertaken by manufacturers, importers and downstream users. In such cases, the costs of extending the CSA obligation would be zero. ***For the purposes of this analysis, it has been assumed that none of the 1-10t 'C, M, or R 1A/1B' substances would be prioritised for Evaluation, Authorisation and Restriction.***

4 Requirements under Parallel Regulation

4.1 Overview

In the event that a substance is identified as meeting the criteria for classification as C, M, or R 1A/1B in accordance with Regulation (EC) No 1272/2008, 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.

4.2 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, manufacturers and each 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.

4.3 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).

4.4 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).

5. Changes Introduced by Extending the CSA/CSR Obligation and Associated Costs and Benefits

5.1 Overview

The analysis has considered the changes that would be brought about by the extension of the CSA obligation considering the current requirements under both REACH and the parallel regulation described above. Thus, identification of additional requirements for manufacturers takes into account their existing obligations in relation to the assessment of exposure and risk under workplace and other regulation. Similarly, for downstream users, the identification of changes brought about takes into account their requirements under the same regulation and, therein, the extent to which information from CSAs and the associated eSDSs will confer or assist with compliance with parallel regulation.

The general conclusion of the analysis is that the extension of the CSA obligation would shift some of the work required to comply with existing parallel regulation from downstream users to manufacturers and importers. This places some additional burden on manufacturers and importers in relation to completing some the elements that are unique to CSA/CSR under REACH. Here, manufacturers and importers would have to consider the exposure, risk management measures and the technical means to achieve them on behalf of their downstream users for the identified uses. This results in an additional cost burden.

However, the study also finds that the shift of responsibilities from downstream user to manufacturer/importer is likely to benefit multiple downstream users of each substance because the CSA/CSR process and the exposure assessments provided in the resulting extended SDSs will enable downstream users to comply with their obligations under parallel regulation.

5.2 Costs to Manufacturers and Importers

The changes identified in respect of manufacturers and importers are summarised in Table 2.

Table 2: Costs to Manufacturers and Importers	
Change	***Description***
Human Health and Environmental Hazard Assessment	*Robust study summaries in relation to the human health and environmental hazard assessments would have to be produced as part of the CSR.*
PBT/vPvB Assessment	*Whilst no additional information is required to carry out a screening for PBT/vPvB properties, where the screening suggests that the substance meets the criteria in Annex XIII, the following additional information would be required to complete the assessment where this would represent an additional burden on manufacturers and importers:* • ***for assessment of P:*** *simulation testing on degradation in surface water/soil/sediment; and* • ***for assessment of B:*** *assessment of the toxicokinetic behaviour of the substance or results from a bioconcentration or bioaccumulation study in aquatic species.*
Human Health Exposure Assessment and Risk Characterisation	*Manufacturers and importers 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.* *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) may also be relevant and sufficient to cover downstream uses. Where the exposure and risk management measures for manufacturer's own use are sufficient to cover the downstream uses, there are no additional costs.* *Where the exposure scenario for a manufacturer's use may not cover the other uses (where this includes the assessment of consumer exposures for identified uses) the analysis assumes that an exposure scenario is required for each additional use (where this is perhaps an exaggeration of the numbers of individual exposure scenarios required).*
Environmental Exposure Assessment and Risk Characterisation	*Assessment of environmental exposures for identified uses (including the manufacturers own uses) is not currently required under parallel regulation. As such, this represents an additional cost to manufacturers and importers.* *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).*
Communication in the Supply Chain	*The addition of the following elements to provide an extended SDS would represent a small additional administrative burden on manufacturers and importers:* • *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.*

5.3 Costs and Benefits to Downstream Users

The changes identified in respect of downstream users are summarised in Table 3.

Table 3: Costs and Benefits to Downstream Users	
Change	***Description***
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.*
Article 37(4) - Duty to prepare a CSR in Accordance with Annex XII	*Article 37(4) requires a downstream user 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 assessments of their own uses under several pieces of parallel regulation including worker health and safety and product safety regulation.* *However, some additional work might 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.*
Reduced Costs of Compliance with Parallel Regulation	*An important change that would be brought about by the extension of CSA requirements to 1-10t substances classified as C, M or R 1A/1B is that the resulting exposure scenarios for the identified uses and other information in extended SDSs would facilitate compliance with the many regulatory instruments that are triggered by classification in accordance with Regulation (EC) No 1272/2008.* *For the (108) 1-10t substances for which mutagenic properties are, as yet, unidentified (and the substance is not yet registered), downstream users will not have complied the information necessary to comply with parallel regulation (because, currently, the substance is not classified for mutagenicity). For these substances, the outcome of the CSA/CSR that would be required by extending the obligation to 1-10t 'CMRs 1A/1B' is that this should provide compliance with other parallel regulation or, at the very least, greatly facilitate that compliance.* *Here, for example, the Commission has issued a guidance document for employers on controlling risks from chemicals concerning the interface between the Chemicals Agent Directive and REACH at the workplace[3]. 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.*

[3] Guidance for employers on controlling risks from chemicals, Interface between Chemicals Agents Directive and REACH at the workplace, European Commission, October 2010, link available at: http://ec.europa.eu/social/main.jsp?catId=716&langId=en&intPageId=223

5.4 Human Health, Environmental and Administrative Benefits

The benefits associated with an extension of the CSA obligation are summarised in Table 4.

Table 4: Benefits of Extending the CSA Obligation to 1-10t 'CMRs 1A/1B'	
Benefit	***Description***
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.*
Adequate Risk Management Measures in Relation to Articles	*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.*
Identification of PBT/vPvB Substances	*Extending the CSA/CSR obligation to 1-10t 'CMRs 1A/1B' is likely to permit the detection and control of around three PBT/vPvB substances that would not otherwise be identified.*
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.*
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.* *The extended 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. Analysis of Costs and Benefits

6.1 Approach to Cost Estimation

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 set out in Tables 2 and 3 as well as the numbers of uses of substances and the numbers of downstream users. Estimates for all three scenarios (low, medium and high) are provided in Annex II and the main text of this report provides results in relation to the medium scenario. Any differences

across scenarios are highlighted in the main report where these suggest a different outcome or conclusion in relation to the comparison of costs and benefits.

6.2 Conclusions on the Net Costs and Benefits of Extending the CSA Obligation

The net costs for manufacturers, importers and downstream users are summarised in Table 5. Costs are given for both currently unknown and known 1-10t 'CMRs 1A/1B' as well as the total across both.

For the 108 1-10t substances with, as yet, unknown 'CMR 1A/1B' properties the estimates suggest that:

- *there is a net benefit of around €19.4 million to downstream users in relation to compliance with parallel regulation on CMRs that is triggered by classification as C, M, or R 1A/1B in accordance with Regulation (EC) No 1272/2008;*
- *the CSA obligation would cost manufacturers and importers a total of around €3 million;*
- *as a result, across all actors and costs, there is a total net benefit of around €16.4 million; and*
- *on the basis of costs alone, extending the CSA obligation to CMRs 1A/1B that are, as yet, unknown and unregistered, the extension is likely to be justified.*

For the 46 1-10t substances with known 'CMR 1A/1B' properties, downstream users are likely to have already complied with the parallel regulation on CMRs that is triggered by classification as C, M, or R 1A/1B in accordance with Regulation (EC) No 1272/2008. As such, there are no/few benefits to downstream users of these substances in relation to compliance with parallel regulation and the estimated costs of extending the CSA obligation are around €1.3 million for manufacturers/importers and €3.2 million for downstream users.

Table 5: Net Costs of Extending the CSA Obligation to 1-10t 'CMRs 1A/1B'			
	Currently Unknown 'CMRs 1A/1B'	*Known 'CMRs 1A/1B'*	*All 'CMRs 1A/1B'*
Overall Costs to Manufacturers and Importers	*€ 2,976,480*	*€ 1,306,260*	***€ 4,282,740***
Overall Costs to Downstream Users	*€ 7,573,986*	*€ 3,225,957*	***€ 10,799,943***
Savings to Downstream Users (compliance costs avoided)	*€ 27,000,000*	*€ 0*	***€ 27,000,000***
Net costs to Downstream Users (a negative cost is a benefit)	*-€ 19,426,014*	*€ 3,225,957*	***-€ 16,200,057***
Net Costs of extending the CSA obligation to 1-10t 'CMRs 1A/1B' (a negative cost is a benefit)	***-€ 16,449,534***	***€ 4,532,217***	***-€ 11,917,317***

Viewed across all of the 154 1-10t substances known and yet to be identified with 'CMR 1A/1B' properties, there is a net benefit of around €11.9 million for the extension of the CSA obligation. This suggests that the extension of the CSA obligation to all 1-10t 'CMRs 1A/1B' is justified by the cost savings to downstream users alone[4]. In addition to the benefits to downstream users, extending the obligation will deliver a number of other benefits where these have been summarised in Table 4.

[4] It should be noted that all of the costing scenarios presented in Annex II suggest that extending the CSA obligation to all substances is likely to be justified on the basis of the cost savings to downstream users.

Estimation of the magnitude of each these benefits in economic terms is complicated by a number of confounding factors. However, ultimately one of the main objectives of extending the obligation would be the avoidance of cancer and cancer fatalities.

A cancer fatality is valued at €2 million per case, based on the value of a statistical life. The value of avoiding a non-fatal cancer is based on a willingness to pay estimate to avoid a non-fatal cancer case of €450,000[5]. For the purposes of example, a benefit of, say, €10 million would be achievable if extending the CSA obligation:

- *prevented five cancer fatalities; or*
- *prevented 22 non-fatal cancers.*

Concerning innovation and competitiveness, extending the CSA obligation to 1-10t 'CMRs 1A/1B' would promote the consistent application of recommended risk management measures across downstream users. Harmonising the regulatory framework in this way is likely to provide benefits in terms of consistency and competition. There are no significant impacts on innovation in the EU chemicals industry.

[5] See ECHA's Guidance on Socio-Economic Analysis under Restrictions, 2009

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1 Introduction

1.1 Study Objectives

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 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).

Article 138(1) of REACH places an obligation on the Commission to assess whether or not to extend the application of the obligation to perform a chemical safety assessment (CSA) and to document it in a chemical safety report (CSR) to substances manufactured or imported in quantities of less than 10 tonnes per year which meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1 or 2 (1A or 1B under CLP). The specific requirements of Article 138(1) are provided in Box 1.1.

Box 1.1: Review of Requirements for 1-10t substances set out in Article 138(1)

Article 138(1)

"By 1 June 2019, the Commission shall carry out a review to assess whether or not to extend the application of the obligation to perform a chemical safety assessment and to document it in a chemical safety report to substances not covered by this obligation because they are not subject to registration or subject to registration but manufactured or imported in quantities of less than 10 tonnes per year. However, for substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1 or 2, in accordance with Directive 67/548/EEC, the review shall be carried out by 1 June 2014. When carrying out the review the Commission shall take into account all relevant factors, including:

(a) the costs for manufacturers and importers of drawing up the chemical safety reports;

(b) the distribution of costs between actors in the supply chain and the downstream user;

(c) the benefits for human health and the environment.

On the basis of these reviews, the Commission may, if appropriate, present legislative proposals to extend this obligation."

The Commission has contracted RPA and CSES to provide technical assistance in relation to the review described in Article 138(1). This Draft Final Report provides an assessment of findings in relation to the key study objectives in respect of the review. The specific study objectives can be summarised as to:

- provide the Commission with a solid basis to report on the issue of extending CSA/CSR requirements and to envisage any (legislative) proposal;

- provide a clear description of the envisaged main benefits and drawbacks of the extension of CSA/CSR obligations to substances meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B;

- provide the Commission with a view on the possible causal link between the benefits which could be expected from extending the application of the CSA/CSR obligation to 1-10t substances and the information requirements for the Registration of those substances (in particular as regards the possibility of missing information in relation to hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B (CMR 1A/1B) and the added value of extending the CSA/CSR obligation to CMRs 1A/1B); and

- provide an estimation of the costs of extending the CSA/CSR obligation for manufacturers, importers and downstream users, including the distribution of the costs along the supply chain.

1.2 Structure of the Report

The remainder of this Interim Report is organised as follows:

- Section 2 considers the current information requirements in relation to 1-10t substances;
- Section 3 provides an overview of the current requirements in relation to parallel regulation on CMRs 1A/1B;
- Section 4 considers the changes introduced by extending CSA/CSR requirements;
- Section 5 provides an analysis of costs and benefits; and
- Section 6 provides conclusions.

2 Current Requirements under REACH for 1-10t Substances Meeting the Criteria for C, M, or R 1A/1B

2.1 Introduction

This section sets out the current requirements in relation to 1-10t substances in general and CMRs 1A/1B in particular (as it is these substances to which an extended obligation would apply).

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.

In relation to the latter (substances in articles >1t intended to be released), these uses can be considered alongside substances used on their own and in mixtures because, 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. Here, the registration and the information requirements in relation to quantities manufactured or imported per producer are identical to those for the equivalent substance (on its own or part of a mixture) because Article 12(3) identifies that the Article "shall apply to producers of articles adapted as necessary". As such, one way or the other, the use of substances 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 must be registered.

In relation to substances meeting classification as CMR 1A/1B (to which an extended CSA obligation would apply) there are two distinct types:

- ***those substances that are already known to be CMR 1A/1B:*** These are substances that, prior to REACH, were already known to have CMR 1A/1B properties. These substances have already been registered owing to the requirements of Article 23(1)(a) of REACH. ECHA's records suggest that 46 unique substances were fully registered with such properties in the 1-10t band[6]; and
- ***those substances with CMR 1A/1B properties that are, as yet, unidentified:*** these are substances for which there is little or no toxicological information at present but information that must be gathered as part of meeting registration requirements will identify such properties. The number of these substances is estimated in later sections of the report.

The following sub-sections consider the information required under REACH in respect of:

- registration dossier information requirements;
- downstream user obligation; and
- drawing from this, a summary of the information provided under REACH.

[6] The obligations would also apply, in principle, to substances also registered in higher tonnage bands. 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 are zero or near zero.

2.2 Registration Dossier Information Requirements for Registration of 1-10t CMRs 1A/1B

2.2.1 Article 10 - Information Submitted for General Registration Purposes

The general information required in technical registration dossiers of substances (on their own and, as mixtures or in articles) is set out in Article 10(a) of REACH. This identifies eleven information elements (i to xi) that all technical dossiers "*shall include*", where the exact requirements in relation to each are expanded upon in Annex VI.

Article 10(a) points (i) and (ii) simply set out information on the identity of the manufacturer or importer and that of the substance.

Article 10(a) points (iii), (iv), (v) and (x) set out requirements in relation to information manufacture and uses; classification and labelling; guidance on safe use; and exposure information required for substances manufactured in quantities of 1-10t. These points, and the more detailed information on requirements set out in Annex VI, are summarised in Table 2.1.

Table 2.1: Annex VI information Requirements

Article 10(a)	Annex VI
(iii) information on the manufacture and use(s) of the substance as specified in section 3 of Annex VI; this information shall represent all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories;	3.1. Overall manufacture, quantities used for production of an article that is subject to registration, and/or imports in tonnes per registrant per year in: the calendar year of the registration (estimated quantity)
	3.2. In the case of a manufacturer or producer of articles: brief description of the technological process used in manufacture or production of articles. Precise details of the process, particularly those of a commercially sensitive nature, are not required.
	3.3. An indication of the tonnage used for his own use(s)
	3.4. Form (substance, mixture or article) and/or physical state under which the substance is made available to downstream users. Concentration or concentration range of the substance in mixtures made available to downstream users and quantities of the substance in articles made available to downstream users.
	3.5. Brief general description of the identified use(s)
	3.6. Information on waste quantities and composition of waste resulting from manufacture of the substance, the use in articles and identified uses
	3.7. Uses advised against (see Section 1 of the safety data sheet) Where applicable, an indication of the uses which the registrant advises against and why (i.e. non-statutory recommendations by supplier). This need not be an exhaustive list.
(iv) the classification and labelling of the substance as specified in section 4 of Annex VI;	4.1 The hazard classification of the substance(s), resulting from the application of Title I and II of Regulation (EC) No 1272/2008 for all hazard classes and categories in that Regulation, In addition, for each entry, the reasons why no classification is given for a hazard class or differentiation of a hazard class should be provided (i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification),
	4.2 The resulting hazard label for the substance(s), resulting from the application of Title III of Regulation (EC) No 1272/2008,
	4.3 Specific concentration limits, where applicable, resulting from the application of Article 10 of Regulation (EC) No 1272/2008 and Articles 4 to 7 of Directive 1999/45/EC.

(v) guidance on safe use of the substance as specified in Section 5 of Annex VI;	This information shall be consistent with that in the Safety Data Sheet, where such a Safety Data Sheet is required according to Article 31.
	5.1. First-aid measures (Safety Data Sheet heading 4)
	5.2. Fire-fighting measures (Safety Data Sheet heading 5)
	5.3. Accidental release measures (Safety Data Sheet heading 6)
	5.4. Handling and storage (Safety Data Sheet heading 7)
	5.5. Transport information (Safety Data Sheet heading 14)
	Where a Chemical Safety Report is not required, the following additional information is required:
	5.6. Exposure controls/personal protection (Safety Data Sheet heading 8)
	5.7. Stability and reactivity (Safety Data Sheet heading 10)
	5.8. Disposal considerations 5.8.1. Disposal considerations (Safety Data Sheet heading 13) 5.8.2. Information on recycling and methods of disposal for industry 5.8.3. Information on recycling and methods of disposal for the public.
(x) for substances in quantities of 1 to 10 tonnes, exposure information as specified in section 6 of Annex VI;	6.1. Main use category: 6.1.1. (a) industrial use; and/or (b) professional use; and/or (c) consumer use. 6.1.2. Specification for industrial and professional use: (a) used in closed system; and/or (b) use resulting in inclusion into or onto matrix; and/or (c) non-dispersive use; and/or (d) dispersive use.
	6.2. Significant route(s) of exposure: 6.2.1. Human exposure: (a) oral; and/or (b) dermal; and/or (c) inhalatory. 6.2.2. Environmental exposure: (a) water; and/or (b) air; and/or (c) solid waste; and/or (d) soil.
	6.3. Pattern of exposure: (a) accidental/infrequent; and/or (b) occasional; and/or (c) continuous/frequent.

The remaining points refer to (vi) the provision of study summaries for information derived by the application of Annexes VII to XI (vi); (vii) robust study summaries in cases where one is required by Annex I requirements for CSAs (which do not apply to 1-10t substances); (viii) an indication as to the appropriate experience of assessors; (ix) proposals for testing for test endpoints listed in Annexes IX and X; and (xi) concerning the availability of information on the internet.

As such, most of these points mainly refer to the information to be submitted depending on tonnage (discussed below).

2.2.2 Article 12 - Information to be Submitted Depending on Tonnage

The information to be submitted depending on tonnage is defined in Article 12 of the Regulation in combination with the Annex relevant to the tonnage band; Annex VII in the case of the 1-10t substances. Annex VII is, itself, divided into two types of information:

- **information on physicochemical properties** – where this is required for all 1-10t substances;
- **information on toxicological and ecotoxicological properties** – where this is only required for certain types of 1-10t substances.

In relation to which 1-10t substances must provide toxicological and ecotoxicological information (in addition to physicochemical information), Article 12 identifies that the technical dossier:

"shall include all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant and as a minimum the following:

a) the information specified in Annex VII for non-phase-in substances, and for phase-in substances meeting one or both of the criteria specified in Annex III, manufactured or imported in quantities of one tonne or more per year per manufacturer or importer;

b) *the information on physicochemical properties specified in Annex VII, section 7 for phase-in substances manufactured or imported in quantities of one tonne or more per year per manufacturer or importer which do not meet either of the criteria specified in Annex III.*"

The criteria in Annex III (as amended[7]) that are referred to (and which trigger the need to provide information on all the Annex VII endpoints[8]) are:

"*(a) 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 category 1A or 1B classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity or the criteria in Annex XIII;*

(b) substances:

i. with dispersive or diffuse use(s) particularly where such substances are used in consumer mixtures or incorporated into consumer articles; and

ii. *for which it is predicted (i.e. by application of (Q)SARs or other evidence) that they are likely to meet the classification criteria for any health or environmental hazard classes or differentiations under Regulation (EC) No 1272/2008*".

In relation to the question of extending the CSA/CSR obligation to CMRs 1A/1B, clearly, only those substances that are or will be identified as meeting classification as C, M or R 1A/1B will be subject to any such extension. The only means by which these substances will be identifiable as CMR 1A/1B is either:

- in the course of completing the full Annex VII information (i.e. including all toxicological and ecotoxicological endpoints in Annex VII); or
- if the substance is already a known CMR 1A/1B (and, as such, the information is at least equivalent to that required for the above).

[7] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance) - Official Journal L 353 , 31/12/2008 P. 0001 - 1355

[8] And in this case, further testing may then be required to fulfil the data gaps; where animal testing is required to meet Annex VII a testing proposal would be submitted to ECHA.

Considering the requirements of Article 12 and Annex III, there are three sets of substances that would be identifiable as C, M, or R 1A/1B, all of which would have had to gather full data set out in Annex VII (or would already have equivalent data):

A. **those that are already known to be CMR 1A/1B:** Article 23(1)(a) of REACH requires that all phase-in CMRs 1A/1B (either for which there is already a harmonised classification or self-classified) above 1tpa had to be registered by 1 December 2010. ECHA's records suggest that 46 unique substances were fully registered with such properties in the 1-10t band;

B. **those with as yet unknown properties "*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 C, M or R 1A/1B:** Substances that are identified as such will proceed to the full dataset for Annex VII that, in turn, should verify whether such a classification is applicable and eliminate those where it is not;

C. **those substances with as yet unknown properties that, for reasons other than the above must supply full Annex VII data and these data subsequently identify classification as C, M or R 1A/1B:** Owing to the criteria in Annex III(b), the only substances (other than those in B) for which full Annex VII information would have to be generated are those which have both a dispersive/diffuse use and which have or are predicted *"by application (Q)SARs and other evidence*" to have any human health or environmental classification.

Figure 2.1 summarises these groups of C, M, or R 1A/1B substances.

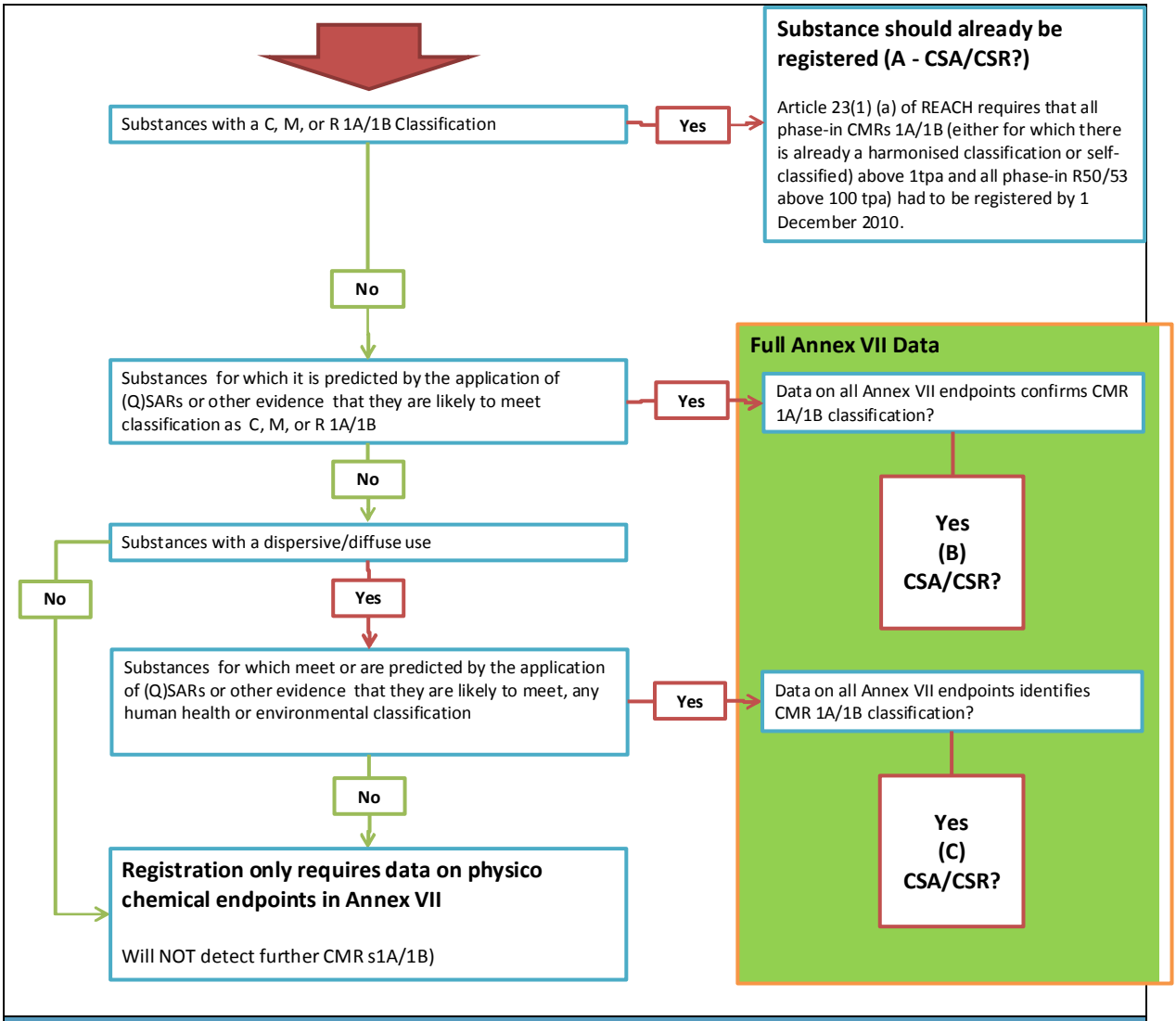


Figure 2.1: CMR 1A/1B Substances within the Scope of an Extended CSA/CSR Obligation

2.2.3 Annex VII – Physicochemical, Toxicological and Ecotoxicological Information to be Submitted

As is identified, above, all 1-10t substances that will, in the course of registration, be identified as meeting classification as 'CMR 1A/1B' will have been required to supply the full data set according to the requirements of Annex VII (groups B and C in Figure 2.1). The toxicological and ecotoxicological information required under Annex VII is summarised in Table 2.2.

Any substances with currently unknown 'CMR 1A/1B' properties that are not required to supply full Annex VII information (because they do not meet Annex III criteria) will remain unidentified (at least under REACH).

Any substances which are already known 'CMRs 1A/1B' must supply all relevant information regardless of tonnage band where this will be, as a minimum, the same information as that for the substances described above.

Table 2.2: 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 need where: 1) and 2) indicates classification as corrosive to the skin or irritating to eyes; the substance is flammable in air at room temperature[2]; 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 need where: 1) and 2) indicates classification as corrosive to the skin or irritating to eyes[3]; or the substance is flammable in air at room temperature[2]
8.3 Skin sensitisation	Following consecutive steps: (1) an assessment of the available human, animal and alternative data; (2) *In vivo* testing (The Murine Local Lymph Node Assay (LLNA) is the first-choice method for *in vivo* testing	Step 2 is not need where: (1) the available information indicates classification for skin sensitisation or corrosivity; (2) the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5); or the substance is flammable in air at room temperature[2]
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 2.2: 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 membranes4; 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

In terms of those substances with (as yet) unknown 'CMR 1A/1B' properties and completing full Annex VII requirements, as can be seen from Table 2.2, the only endpoint that provides information of (direct) relevance to the identification of 'CMR' properties is that in point 8.4 and the *in vitro* gene mutation study in bacteria.

As such, for a substance with no known C, M, or R properties to be identified as possibly meeting classification for C, M or R 1A/1B, the substance must first test positive for this endpoint as a negative result leads to the conclusion that the substance is non-genotoxic (and the substance is not, therefore a 'CMR').

In the event of a positive result in the *in vitro* gene mutation study in bacteria the Regulation identifies that "*further testing shall be considered*". What this means in practice is expanded upon in detail in ECHA's "*Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.7a: Endpoint Specific Guidance*[9]". This clearly identifies that, in the event of a positive result for the mutagenicity endpoint in Annex VII for a 1-10t substance, further testing progressing up through Annex VIII and above is required to establish whether a substance is:

- genotoxic to somatic cells only and hence meets classification as a category 2 mutagen); or

[9] Latest version is #2.4 of February 2014 but this is currently being revised. This report is based upon the revisions set out in the Draft version 3.0 February 2014 for consultation with ECHA's Committees in relation to mutagenicity combined with those set out in #2.4 of February for carcinogenicity and reproductive toxicity (requirements for which are not part of the abovementioned revision).

- is genotoxic to somatic and germ cells and hence meets classification as a category 1B mutagen.

2.2.4 Annex VIII and Above – Information to be Submitted Progressing through Annex VIII and above.

Overview

The ECHA "*Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.7a: Endpoint Specific Guidance*" sets 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*[10]".

The general route followed by ECHA guidance is one of undertaking relevant mutagenicity testing progressing up through Annex VIII and above. If the conclusion of this testing is that the substance is genotoxic to somatic cells this triggers consideration of whether the substance is also toxic to germ cells. Positive conclusions in relation to either trigger further consideration of carcinogenicity and reproductive toxicity.

It is very important to note early on that the route to the identification of 'CMR' properties for those substances where such properties are (as yet) unknown is through the genotoxicity route. Thus, all 1-10t 'CMRs 1A/1B' identified by the application of information requirements progressing through Annex VII and above will be genotoxic (category 1B mutagens). There is no testing for carcinogenicity (including carcinogenicity mechanisms other than genotoxicity) or reproductive toxicity and, as such, there will be no classification for C or R.

From the perspective of risk management (through CSA or otherwise), this means that all of the 1-10t substances that can be identified based on the testing requirements as possessing 'CMR' properties will be category 1B mutagens which, in turn, makes them 'non-threshold' substances for which risk management to eliminate exposure is the objective (as opposed to risk management to reduce exposure to a certain threshold concentration).

The following sub-sections set out information requirements for 1-10t substances through each of the following stages:

- Identification of genotoxicity;
- Consideration of germ cell mutagenicity;
- Consideration of carcinogenicity and reproductive Effects.

Information Required in Relation to Genotoxicity

A flowchart summarising ECHA's guidance and the testing strategy to establish genotoxicity is provided in Figure 2.2. 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

[10] Structure of Chapter R.7a – page 15

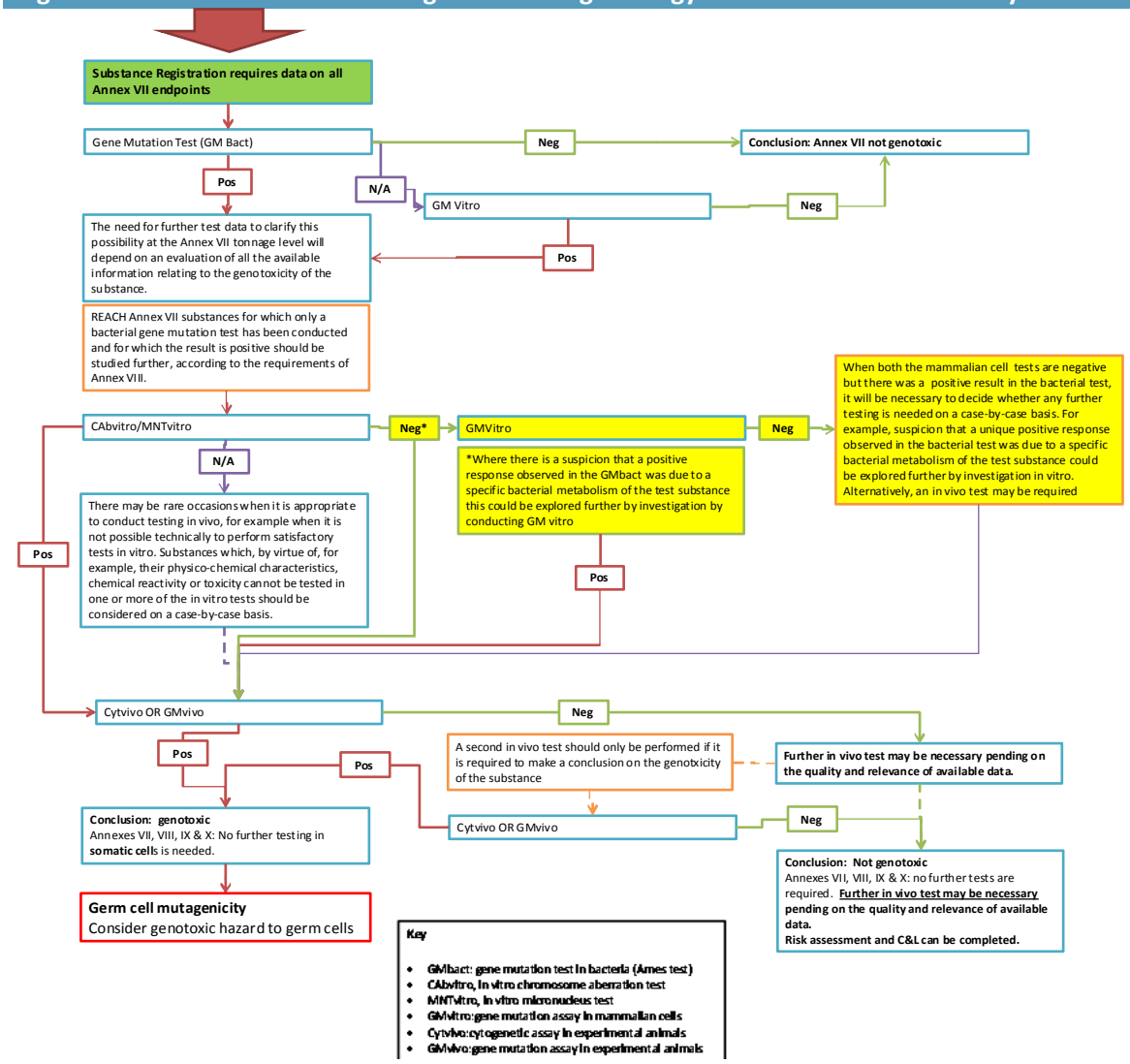
above. Thus, to establish genotoxicity all of the following are required in the event of a positive result for GMBact:

- either or both of CAbvitro/MNT Vitro or GMvitro tests in Annex VIII as appropriate to the ITS;
- Cytvivo or GMvivo[11] *in vivo* tests in Annex IX as appropriate to the ITS.

For a substance presenting negative in the *in vivo* tests it would be concluded that the substance is not genotoxic and no further testing or consideration for carcinogenicity or reproductive toxicity is required. For a substance presenting positive in the *in vivo* tests it would be concluded that the substance was genotoxic and there would be a need to consider mutagenicity to germ cells.

[11] 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

Figure 2.2: ECHA Guidelines – Integrated Testing Strategy in Relation to Genotoxicity



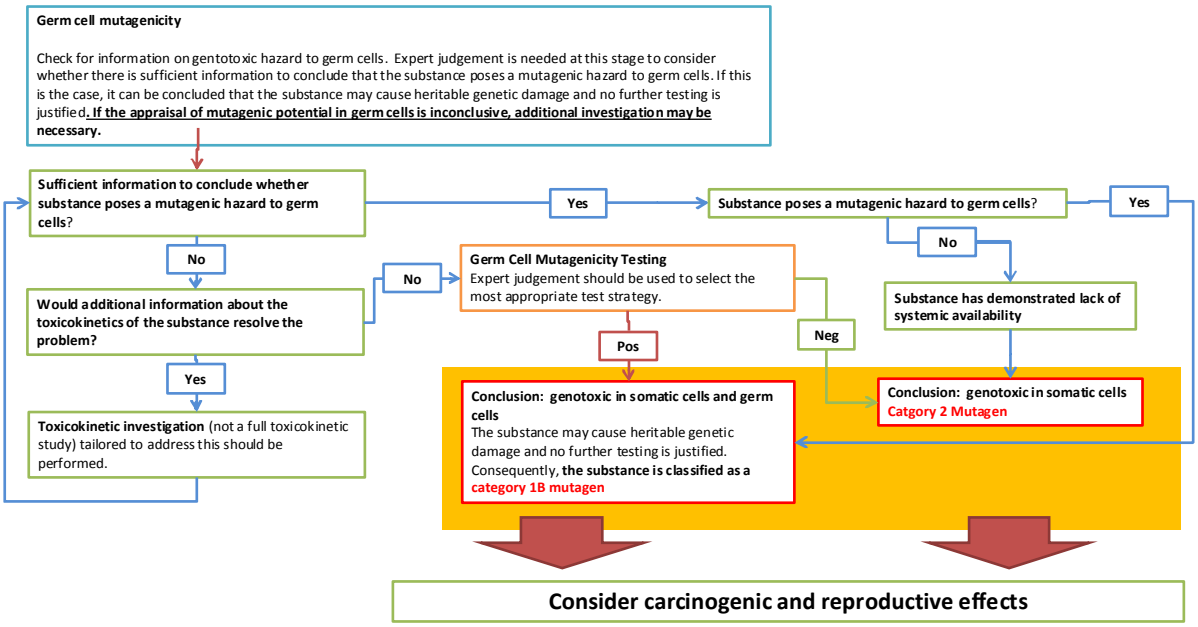
Information Required in Relation to Germ Cell Mutagenicity

Once genotoxicity to somatic cells has been concluded, according to ECHA's ITS, there is a need to check whether there is sufficient information to conclude that a substance poses a mutagenic hazard to germ cells. The steps set out in ECHA's guidance are summarised in Figure 2.3.

If the appraisal of mutagenic potential in germ cells is inconclusive, additional investigation may be necessary. However, if there is sufficient information available to suggest that the substance is not a hazard to germ cells and there is a demonstrated lack of systemic availability then the substance is classified as a category 2 mutagen. If such a conclusion is made no further testing is justified in relation to mutagenicity but further consideration is required in relation to carcinogenicity which, if classification as carcinogen 1A/1B is made (which is very unlikely), this may lead to consideration of reproductive toxicity (but not classification).

If it is concluded that a substance does pose a mutagenic hazard to germ cells, it can be concluded that the substance may cause heritable genetic damage and the substance is subsequently classified as a category 1B mutagen. If such a conclusion is made no further testing is justified in relation to mutagenicity further consideration is required in relation to, first, carcinogenicity and second, reproductive toxicity.

Figure 2.3: Consideration of Germ Cell Mutagenicity



Information Required in Relation to Carcinogenicity

According to the ECHA guidance on carcinogenicity endpoints, "*the minimum information to be provided at the Annex VII, VIII and IX tonnage levels in relation to this endpoint is equivalent to that required for the mutagenicity endpoint* [as described above]*: positive results from in vitro mutagenicity studies provide an alert for possible carcinogenicity, and need confirmation via further testing in vitro and/or in vivo mutagenicity testing. As such, this will not lead to classification of a substance as a carcinogen, but this evidence should be taken into account in risk assessment: substances shown to be in vivo mutagens should be assumed to be potentially carcinogenic…Although the criteria for carcinogenicity classification may not be met in the absence of substance-specific carcinogenicity data, the evidence from the available information alerting to possible carcinogenicity should be taken into account in the risk assessment for this endpoint*[12]"

In terms of actions triggered by classification as a category 1A/1B mutagen or category 2 mutagen, the ECHA guidance identifies that:

[12] Chapter R.7.7.13.3 Testing strategy for carcinogenicity.

- ***For substances identified as category 1A/1B mutagens:*** "Formally, for a substance classified as a category 1A or 1B mutagen, a carcinogenicity study will not normally be required; i.e. it will be regarded as a genotoxic carcinogen. In order to allow an assessment of the magnitude of potential cancer risks associated with the prevailing human exposures, it may well be that available non-testing data (read-across, grouping, (Q)SAR) provide a sufficiently helpful estimate of the carcinogenic potency of the substance (i.e. by read-across) from which risks can be assessed[13]".
- ***For substances identified as category 2 mutagens:*** "For substances classified as category 2 mutagens, and for which there is no carcinogenicity study, there should first be an evaluation of whether classification in category 2 for mutagenicity is possible. If such a classification is made, then the approach described above can be followed with regards to carcinogenicity. Occasionally, it may be established that classification as a category 2 mutagen is not appropriate. In such instances, it should not be assumed automatically that the substance has carcinogenic potential. However, unless there is clear evidence to indicate the contrary, it is expected that these substances will be regarded as genotoxic carcinogens.[13]"

Accordingly, in relation to carcinogenicity it can be concluded that, under the current requirements for 1-10t substances identified with previously unknown genotoxic properties (category 1A/1B/2 mutagens):

- There will be no classification for carcinogenicity;
- Any risk assessment that is carried out should regard the substances as genotoxic carcinogens (non-threshold substances); and
- as no CSA is required for the 1-10t substances, **no such risk assessment under REACH is required to be carried out.**

Information Required in Relation to Reproductive and Developmental toxicity

According to the ECHA guidance on reproductive and developmental toxicity endpoints, "*consistent with the parameters defined within the REACH programme (Annex VII-XI), testing for reproductive toxicity is not required for chemicals produced at tonnage levels <10 tonnes per annum (t/y), although all available information relevant to reproductive toxicity must be evaluated, and classification for this area of toxicity should be considered*[14]".

Accordingly, while classification must be considered for reproductive toxicity for any 1-10t substances identified with previously unknown genotoxic properties the Integrated Testing Strategy (ITS) only applies to substances manufactured or imported in quantities of >10t per year.

However, it is worth noting that the first stage of the ITS for >10t substances asks:

[13] Chapter R.7.7.13.2 Preliminary considerations.

[14] Chapter R.7.6.6.2 Preliminary considerations.

"Is the substance classified as a genotoxic carcinogen (Carcinogen Category 1A/1B and Mutagen Category 2 or Carcinogen Category 2 and Mutagen Category 3) or a germ cell mutagen (Mut. Cat. 1 or Cat. 2)?

If the answer is yes, it is important to establish that appropriate risk management measures addressing potential carcinogenicity, genotoxicity and reproductive toxicity have been implemented and therefore further specific testing for reproductive and/or developmental toxicity will not be necessary[15]*"*.

Accordingly, in relation to reproductive and developmental toxicity it can be concluded that, under the current requirements for 1-10t substances identified with previously unknown genotoxic properties (category 1A/1B/2 mutagens):

- There will be no classification for reproductive and developmental toxicity;
- For substances produced in quantities of >10t per that are Mut. 1A/1B (or Carc. 1A/1B and Mut. 2) it is necessary to establish that appropriate risk management measures addressing potential carcinogenicity, genotoxicity and reproductive toxicity have been implemented; and
- because the CSA obligation does not currently apply to 1- 10 t substances and because the Integrated Testing Strategy (ITS) for reproductive and developmental toxicity does not apply either (because no testing for this endpoint is required under REACH) **no formal risk assessment addressing potential carcinogenicity, genotoxicity and reproductive toxicity is required under REACH.**

2.2.5 Post Registration Information - Evaluation, Authorisation and Restriction under REACH

In the event that a substance is classified as C, M or R 1A or 1B a substance could be subject to other provisions of REACH such as Evaluation, Authorisation and Restriction. These provisions within REACH are aimed at assuring that risks from substances with properties of very high concern are properly controlled.

Given the high level of concern and priority that is attached to CMRs 1A/1B in later titles, it is possible that 1-10t CMRs 1A/1B could, at some point in time, be entered upon the rolling programme for evaluation owing to their hazardous properties. In this event, if sufficient information on risks and exposure has not been provided as part of the registration dossier, then this information is likely to be requested (under the provisions of Article 46) by competent authorities undertaking the evaluation. If the evaluation determines that there is sufficient concern associated with the substance and its uses, risk management measures should be taken.

The substance may be included on Annex XIV (substances subject to authorisation) and a CSA is then required. When making an application for authorisation, an applicant must supply detailed information on uses, analysis of alternatives, risk assessment and management and socioeconomic analysis to justify continued use. The substances may also be subject to restriction.

[15] Chapter R.7.6.6.3 Testing strategy for reproductive toxicity

For the purposes of this analysis, it has been assumed that none of the 1-10t 'C, M, or R 1A/1B' substances would be prioritised for Evaluation, Authorisation and Restriction and would need to produce a CSR anyway at some point in the future.

2.3 Downstream User Obligations

2.3.1 Overview

In addition to information requirements to be supplied in registration dossiers, REACH places duties on manufacturers, importers and downstream users (DUs) to supply information up and down the supply chain. This includes:

- provision of key information on a substance down the supply chain by the production of Safety Data Sheets (SDSs);
- obligations on downstream users in relation to supplying information both up and down the supply chain.

2.3.2 Information to Downstream Users - Safety Data Sheets

The requirement for manufacturers and importers to provide a Safety Data Sheet (SDS) is a requirement for all substances with hazardous properties (including those produced in quantities of 1-10t per year) and is defined in Annex II of REACH. The aim of an SDS is to provide downstream users of a substance with information to enable them to implement controls to address the risks arising from use of a substance. Sections 7 and 8 (Handling and storage; Exposure controls/personal protection) in particular are fed from the exposure scenarios developed for that substance during CSA. For such substances there should be no discrepancies between the information in the SDS and that in the exposure assessment completed as part of CSA and handling and storage advice and exposure control measures should be described with detail in the SDS.

For the 1-10t substances for which no CSA is required, however, only more general advice is required in the SDS. The precautionary statements (P-statements) from CLP will usually provide a starting point for filling in these sections of the SDS. For Carcinogens, Mutagens or Reprotoxins the relevant P-statements are generic and identify phases such as "use special protective equipment as required", "store locked up" or "if exposed or concerned: get medical advice or attention". Without an exposure assessment detailing risk management measures and the technical means to achieve them, manufacturers and importers of the 1-10t substances will have to expand on these based on experience and by applying a good measure of caution but will not have to quantitatively assess exposures and technical risk management measures. Thus, for example for non-threshold substances they may identify that a closed system is required but they will not have to carry out the assessments required to detail technically how this should be achieved.

The "control parameters" sub-section of the SDS is likely only to include any Occupational Exposure Limits (OELs) set at Member State Level where such limits exist. Such OELs will certainly not exist for 1-10t substances not previously identified with C, M, or R properties.

Table 2.3: Content of Safety Data Sheets (SDS) as Required by Annex II of REACH		
Main Section	**Subsections (Required of all substances regardless of CSR)**	**Current source of Information for 1-10t CMRs 1A/1B**
SECTION 1: Identification of the substance/mixture and of the company/undertaking	1.2 Relevant identified uses of the substance or mixture and uses advised against	Annex VI information
SECTION 2: Hazards identification	2.1. Classification of the substance or mixture	Annex VI information and application of Annex VII to XI requirements
	2.2. Label elements	
	2.3. Other hazards Information shall be provided on other hazards which do not result in classification but which may contribute to the overall hazards of the substance or mixture	Information in relation to carcinogenicity and reproductive/developmental toxicity that have been considered by application of Annex VII to XI requirements but cannot be classified owing to data limitations.
SECTION 3: Composition/information on ingredients	3.1. Substances	Annex VI information
	3.2. Mixtures	
SECTION 4: First aid measures	4.1. Description of first aid measures	Annex VI information
	4.2. Most important symptoms and effects, both acute and delayed	
	4.3. Indication of any immediate medical attention and special treatment needed	
SECTION 5: Firefighting measures		
SECTION 6: Accidental release measures	6.1. Personal precautions, protective equipment and emergency procedures	Annex VI information
	6.2. Environmental precautions	
	6.3. Methods and material for containment and cleaning up	
	6.4. Reference to other sections	
SECTION 7: Handling and storage	7.1. Precautions for safe handling	Annex VI information
	7.2. Conditions for safe storage, including any incompatibilities	
	7.3. Specific end use(s)	
SECTION 8: Exposure controls/personal protection	8.1. Control parameters	Annex VI information
	8.2. Exposure controls	
SECTION 9: Physical and chemical	9.1. Information on basic physical and chemical properties	Annex VII information on physicochemical properties

Table 2.3: Content of Safety Data Sheets (SDS) as Required by Annex II of REACH		
Main Section	**Subsections (Required of all substances regardless of CSR)**	**Current source of Information for 1-10t CMRs 1A/1B**
properties	9.2. Other information	
SECTION 10: Stability and reactivity		Annex VII information
SECTION 11: Toxicological information	11.1. Information on toxicological effects	Annex VI information and application of Annex VII to XI requirements
SECTION 12: Ecological information	12.1. Toxicity	Application of Annex VII to XI requirements
	12.2. Persistence and degradability	Results from tests on ready biodegradation in accordance with Section 9.2.1.1 of Annex VII
	12.3. Bioaccumulative potential	Octanol-water partitioning coefficient experimentally determined in accordance with Section 7.8 of Annex VII
	12.4. Mobility in soil	Annex VII information on physicochemical properties
	12.5. Results of PBT and vPvB assessment	Not required
	12.6. Other adverse effects	Application of Annex VII to XI requirements
SECTION 13: Disposal considerations	13.1. Waste treatment methods	Annex VI information
SECTION 14: Transport information		Annex VI information
SECTION 15: Regulatory information	15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture	References to other regulation as appropriate which would 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); • the Carcinogens and Mutagens Directive 2004/37/EC (CMD); • the Pregnant and Breastfeeding Workers Directive 92/85/EEC; • Directive 2001/95/EC on General Product Safety; • Toys Directive 2009/48/EC; • the Drinking Water Directive 98/83/EC; and • The Water Framework (WFD) and EQS Directives.
	15.2. Chemical safety assessment It must be indicated if a CSA has been carried out.	Whilst no CSA is required it must be indicated if a CSA has been carried out.
SECTION 16: Other information		As appropriate
ANNEX	Exposure scenarios from CSA/CSR	Not Required

2.3.3 Obligations on Downstream Users under REACH

REACH also places duties on downstream users to communicate information up and down the supply chain where this includes:

- passing information that identifies particular uses up the supply chain (so that they can be included as uses in the registration dossier);
- a duty to ensure the identification and application of appropriate risk management measures identified in safety data sheets;
- a duty to pass information further down the supply chain in the form of SDS to ensure safe use by downstream users;
- a duty to keep SDS up to date and notify downstream users of any changes (including in relation to Authorisation and Restriction.

A list of the key provisions and their applicability in relation to the 1-10t substances is provided in Table 2.4.

Table 2.4: List of the Key Provisions by Duty-holders, Drivers and Benefits for Information in the Supply Chain			
Article	**Key Provisions**	**Duty-holders**	**Comments**
31(1)	Requirement on a supplier of a substance or a mixture to provide recipient with a SDS compiled in accordance with Annex II.	M, I, DU	
31(2)	Requirement on any actor in the supply chain who has been requested to perform a CSA to ensure that information in the SDS is consistent with the information in the assessment.	M, I, DU	Not currently applicable to 1-10t substances
31(7)	Requirement on actors in the supply chain to place the relevant exposure scenarios in an annex to the SDS.	DU	Not currently applicable to 1-10t substances
	Requirement on a downstream user to include the exposure scenarios in their own SDS for identified uses.	DU	
	Requirement on a distributor to pass on relevant exposure scenarios and use other relevant information from the SDS when compiling his own data sheet.	D	
31(8-9)	The SDS shall be provided free of charge either electronically or on paper.	M, I, DU	
	Requirement on a supplier to update the SDS and provide it free of charge to all former recipients as soon as new information becomes available or once an authorisation has been granted or refused or once a restriction has been imposed.	M, I, DU	
33(1 and 2)	Requirement on a supplier of an article containing a substance meeting the criteria in Article 57 (including CMRs 1A/1B) in a concentration above 0.1 % weight by weight (w/w) to provide the recipient with sufficient information to allow safe use, including as a minimum the name of that substance.	M, I	
	Requirement on a supplier of an article to provide a consumer on request with sufficient information to allow safe use, including as a minimum the name of that substance, free of charge and within 45 days of the request	D	

34	Requirement on every actor (including distributor) in the supply chain to communicate the information on new information or any other information that might call into question the appropriateness of the risk management measures identified in an SDS to the next actor or distributor up the supply chain.	M, I, DU, D	
35	Requirement on an employer to provide workers and their representatives with access to information received in accordance with articles 31 and 32 in relation to substances or mixtures which they may use or be exposed to in the course of their work.	M, I, DU, D	
39	Article 39 states that downstream users shall comply with the Article 37 obligations at the latest 12 months after receiving a registration number.	DU	
37(5)	Requirement on downstream user to identify and apply appropriate measures to adequately control risks identified in (a) an SDS supplied to it: (b) its own chemical safety assessment. Requirement on downstream user to recommend, where suitable, measures to adequately control the risks identified in (a) an SDS supplied to it; (b) its own chemical safety assessment .	DU	References to (b) not currently applicable to 1-10t substances
37(2)	Requirement on a downstream user to have the right to make a use known in writing. Requirements on distributors to pass on such information to the next actor up the supply chain.	DU	
37(4)	Requirement on a downstream user 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. A downstream user need not prepare such a chemical safety report if a chemical safety report is not required to be completed by his supplier in accordance with Article 14;	DU	Not currently applicable to 1-10t substances
37(6)	Requirement on a downstream user to identify and apply appropriate risk management measures needed to ensure that the risks to human health and the environment are adequately controlled. Where a downstream user does not prepare a chemical safety report in accordance with paragraph 4(c), he shall consider the use(s) of the substance and identify and apply any appropriate risk management measures needed to ensure that the risks to human health and the environment are adequately controlled. Where necessary, this information shall be included in any safety data sheet prepared by him.	DU	
37(7)	Requirement on downstream users to keep their chemical safety report up to date and available.	DU	Not currently applicable to 1-10t substances

2.4 Summary of Information Provided under REACH for 1-10t 'CMR 1A/1B' Substances

2.4.1 Known versus unknown 'CMR 1A/1B' Substances

There are two distinct types of substances "*meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, in accordance with Regulation (EC) No 1272/2008*[16]" (to which an extended CSA obligation would apply):

- ***Known C, M or R 1A/1B substances:*** These are 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 records suggest that 46 unique substances were fully registered with such properties in the 1-10t band; and

- ***Substances that will be identified with C, M, or R 1A/1B properties:*** these are substances for which there is little or no toxicological information at present but information that must be gathered as part of meeting registration requirements will identify genotoxic properties that may result in classification as category 1A/1B mutagen or category 2 mutagen.

2.4.2 Information Supplied During Registration

In terms of the information supplied in the registration dossiers, any substances which are already known 'CMRs 1A/1B' must already be registered and must have supplied all relevant information regardless of tonnage band where this will be, as a minimum, the same information as that for other 1-10t substances that will be identified with C, M or R 1A/1B properties. This information includes all of the following:

- **The information stipulated in Article 10(a) and Annex VI on**: the identity of the manufacturer or importer and that of the substance; information on manufacture and uses; classification and labelling; guidance on safe use; exposure information concerning main use category, significant routes of human and environmental exposure and pattern of exposure; study summaries for information derived by the application of Annexes VII to XI;

- **Information in relation to tests and testing strategies applied following Annex VII:** information in respect of all of the physico-chemical, toxicological and eco-toxicological endpoints in Annex VII and associated study summaries; and

- **Information in relation to mutagenicity tests and testing strategies applied following Annexes VIII to XI:** owing to a positive result to the Annex VII test further mutagenicity further information in respect of the *in vitro* and *in vivo* tests from Annexes VIII to X applying both the general rules for adaptation set out in Annex XI and ECHA guidelines and the associated Integrated Testing Strategy (ITS).

[16] Article 138(1) of REACH

2.4.3 Conclusions on Classification by the Application of REACH

For all previously unknown substances that will be identified as "*meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, in accordance with Regulation (EC) No 1272/2008*" the application of Annexes VII to XI and the ECHA guidance will have led to two possible conclusions/outcomes of relevance to this assessment:

- **Conclusion 1 - the substance is genotoxic to germ cells and is classified as a category 1B mutagen:** according to the ECHA guidelines, the substance will not be classified as a carcinogen but any risk assessment should regard the substances as genotoxic carcinogens. The substance will not be classified for reproductive toxicity. However, because the CSA obligation does not currently apply to these substances under REACH, no assessment of the risk of exposure or recommended risk management measures would be provided in the dossier. Owing to classification as category 1B mutagens, these substances would be identified as "*meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, in accordance with Regulation (EC) No 1272/2008"* but only in respect of mutagenicity; or

- **Conclusion 2 - the substance is genotoxic to somatic cells only and is classified as a category 2 mutagen:** as above, the substance will not be classified as a carcinogen but "unless there is clear evidence to indicate the contrary", any risk assessment should regard the substances as genotoxic carcinogens. The substance will not be classified for reproductive toxicity. However, because the CSA obligation does not currently apply to these substances under REACH, no assessment of the risk of exposure or recommended risk management measures would be provided in the dossier. As category 2 mutagens, these substances would **not** be identified as "*meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, in accordance with Regulation (EC) No 1272/2008"*.

2.4.4 Information in the Supply Chain

For the 1-10t substances where no CSA is required only more general advice is required in the Safety Data Sheet (SDS) supplied to downstream users.

The information in Sections 7 and 8 (Handling and storage; Exposure controls/personal protection) of the SDS, will draw from and build on the generic precautionary statements (P-statements) from CLP. Without an exposure assessment detailing risk management measures and the technical means to achieve them, manufacturers and importers of the 1-10t substances will have to expand on these based on experience and by applying a good measure of caution but will not have to quantitatively assess exposures and technical risk management measures. Thus, for example, they may identify that a closed system is required but they will not have to carry out the assessments required to detail technically how this should be achieved and place this as part of the exposure scenario in an Annex to the SDS (as would be the case with substances subject to CSA).

3 Compliance with Parallel Regulation

3.1 Introduction

As the requirement to conduct a CSA does not currently apply for the 1-10t substances, risk management is, at present, achieved via classification under CLP which, in turn, triggers risk management requirements under other community regulation.

In the event that a substance is identified as meeting the criteria for classification as C, M, or R 1A/1B in accordance with Regulation (EC) No 1272/2008, the Classification and Labelling Inventory (CLI) will be updated to reflect the new classification. This change in classification then triggers actions on the part of manufacturers, importers and downstream users to comply with other pieces of community regulation. Key areas of regulation requiring action on the part of manufacturers, importers and downstream users to assess exposure, risks and implement risk management measures are:

- Worker health and safety regulation;
- Product safety requirements; and
- Waste regulation.

3.2 Compliance with Worker Health and Safety Regulation

Several pieces of worker health and safety regulation require action on the part of employers (which would include manufacturers and downstream users of substances) to assess the risk and exposure of workers to substances with C, M or R 1A or 1B properties. Key pieces of regulation here are:

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

3.2.1 Directive 2004/37/EC on Carcinogens and Mutagens

The Carcinogens and Mutagens Directive 2004/37/EC (CMD) sets specific risk management measures for workers exposed to carcinogens and mutagens. The scope of the carcinogens and mutagens Directive is specifically focussed on the carcinogenic and mutagenic properties of substances and associated risks to workers' health. Environmental hazards and risk are outside of the scope, as are impacts on the environment and consumers.

As the Directive applies to all employers where workers may be exposed to carcinogens and/or mutagens its provisions apply to both manufacturers and downstream users as defined by REACH.

Under Article 3(2) manufacturers and downstream users must determine the nature, degree and duration of workers' exposure to carcinogens or mutagens in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken. When assessing the risk, account shall be taken of all routes of exposure, such as absorption into and/or through the

skin. When the risk assessment is carried out, particular attention shall be given to any effects concerning the health or safety of workers at particular risk and shall, inter alia, take account of the desirability of not employing such workers in areas where they may come into contact with carcinogens or mutagens.

Data on workers' exposure to C and M 1A and 1B must be generated at specific workstations in order to inform the risk assessment. In the case of any activity likely to involve a risk of exposure to carcinogens or mutagens, the nature, degree and duration of workers' exposure shall be determined in order to make it possible to assess any risk to the workers' health or safety. There is no requirement under CMD for employers (manufacturers and downstream users) to generate additional data on hazards. As such, the information to complete the assessment is drawn from the SDS. Employers (manufacturers and downstream users) are, however, required to generate new data on the workers exposure to chemical agents on site (i.e. level, type and duration of exposure).

In the case of the 1-10t substances, as there is no obligation to conduct a chemical safety assessment 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. As such, under CMD, all manufacturers and downstream users of these substances will have to conduct their own bespoke assessments of exposure, risk and identification of risk management measures based on the general information provided in the SDS.

In terms of measures, CMD requires that, as a priority, workers' exposure must be prevented through substitution. If not possible, a closed technological system shall be used. Where a closed system is not technically possible, the employer shall reduce exposure to minimum through a number of risk management measures specified in the Directive.

3.2.2 Directive 98/24/EC on Chemical Agents

As with the CMD, Directive 98/24/EC[17] on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD) requires employers 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. As such, the scope of the CAD is broad, covering the assessment and control of all physicochemical and human health risks to workers. Environmental hazards and risk are outside of the scope, as are impacts on the environment, on humans via the environment and on consumers.

As with CMD, site specific data on workers' exposure to chemical agents at specific work stations must be generated. The SDS provided by suppliers under REACH will be the key means to identify and assess hazardous substances in the workplace. This hazard data will be combined with exposure data generated for specific workstations to assess the risk to individual workers.

The Commission has issued a guidance document for employers on controlling risks from chemicals concerning the interface between the Chemicals Agent Directive and REACH at the workplace. [18] It

[17] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), OJ L 131, 5.5.1998, p. 11–23.

[18] Guidance for employers on controlling risks from chemicals, Interface between Chemicals Agents Directive and REACH at the workplace, European Commission, October 2010, link available at: http://ec.europa.eu/social/main.jsp?catId=716&langId=en&intPageId=223

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.

In the case of the 1-10t substances, however, there will be no risk assessment from REACH registration upon which to draw because there is no obligation to conduct a chemical safety assessment and provide exposure scenarios detailing the technical means to achieve risk management in the SDS. As such, as with CMD, all manufacturers and downstream users of these substances will have to conduct their own bespoke assessments of exposure, risk and identification of risk management measures based on the general information provided in the SDS. The assessment performed in relation to CMD should be sufficient for compliance with CAD (and *vice versa*).

3.2.3 Directive 92/85/EEC on Pregnant Workers and Directive 94/33/EC on Young Workers

The Pregnant and Breastfeeding Workers Directive 92/85/EEC requires employers to conduct a risk assessment to the nature, degree and duration of exposure to certain types of chemical agents in so far as it is known that they endanger the health of pregnant women and the unborn child. The risk assessments apply to substances and mixtures, and require assessment of risks to vulnerable workers from substances generated in the workplace. This Directive sets risk management measures to limit the exposure of pregnant workers, workers who have recently given birth and or who are breastfeeding to certain hazardous chemicals. The risk management measures vary depending on whether the exposure is to chemical agents listed in Annex I or to chemical agents listed in Annex II (lead and lead derivatives), with work prohibited in the latter case.

For chemical agents set in Annex I (which would include substances classified as C, M or R 1A/1B) the duties on the employer include that:

- the employer shall assess the nature, degree and duration of exposure;
- he/she shall assess any risks to the safety or health and any possible effects on the pregnancy or breastfeeding of workers; and
- he/she shall then decide what measures should be taken.

The Young Workers Directive 94/33/EC[19] takes a two-tiered approach to protecting young workers from exposure to chemical agents. Firstly, employers are obliged to assess the hazards to young people, involving the identification of chemical hazards with respect to chemical agents in the workplace. They must then generate new site-specific data on the nature, degree and duration of exposure to chemical agents. Employers shall then adopt the measures necessary to protect the safety and health of young people. In particular, work involving the exposure of young people to agents to certain categories of substances is prohibited, namely substances that are toxic, carcinogenic, cause heritable genetic damage or harm to the unborn child or which in any other way chronically affect human health.

[19] Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work, OJ L 216, 20.8.1994, p. 12.

As with CMD and CAD, all manufacturers and downstream users of 1-10t substances identified with C, M or R properties will have to conduct their own bespoke assessments of exposure, risk and identification of risk management measures based on the general information provided in the SDS.

3.3 Compliance with Product Safety Regulation

In addition to worker health and safety requirements, classification as C, M or R 1A/1B under CLP 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 the CLP Regulation. However, currently consumer articles are not in the scope of the entries 28 to 30, but some specific legislation applies to some of these articles.

3.3.1 Directive 2001/95/EC on General Product Safety

The General Product Safety Directive (GPSD) is complementary to specific product safety legislation by sector. It applies in its entirety to consumer products falling outside the scope of sector Directives. In addition, it applies partially to consumer products covered by sector legislation (for example toys or cosmetics). In general specific sector provisions have priority over general provisions although the GPSD for certain aspects may be more detailed than the sector directives.

Under Article 3 of the GPSD producers are obliged to place only safe products on the market where:

- 'product' means any product — including in the context of providing a service — which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them;
- 'producer' means the manufacturer of the product, the manufacturer's representative, when the manufacturer is not established in the Community or the importer of the product or other professionals in the supply chain, insofar as their activities may affect the safety properties of a product; and
- 'safe product' means any product which, under normal or reasonably foreseeable conditions of use does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons including the categories of consumers at risk when using the product, in particular children and the elderly.

In combination with considerations covered by other sector specific regulation, manufacturers, importers and downstream users of 1-10t substances used in products (as defined above) and identified as meeting classification for C, M, or R 1A/1B properties would have to consider the implications of such a classification on the safety of any products containing that substance. To comply with the GPSD, assessment of the risk to consumers from the presence of the substance in a product would be required where this would include consideration of human exposure to the substance from use of the product considering, in the case of the 1-10t 'CMRs', only the general information presented in the SDS will be available for such an assessment where this will not include detailed information on the technical considerations in relation to exposure, risk and safety.

In cases where products may pose a serious risk, the GPSD establishes that Member States are to assess and take appropriate action. Here, under certain conditions, the Commission may adopt a

formal temporary Decision requiring the Member States to ban the marketing of a product, to recall it from consumers or to withdraw it from the market. A Decision of this kind is temporary but it may be renewed and result in permanent legislation. Emergency measures have been taken in the past for: Dimethylfumarate (DMF) and Phthalates.

3.3.2 Other product Safety Regulation - Uses Not Exempted from REACH

In addition to requirements on general product safety, a number of other regulations deal specifically with product safety in uses and applications that are not exempted from REACH. These include Regulation No 305/2011 for the Marketing of Construction Products and the Toys Directive 2009/48/EC.

Regulation No 305/2011 for the Marketing of Construction Products

The Construction Products Regulation (EU) No 305/2011[20] requires the manufacturer to draw up a declaration of performance when placing a product on the market. Where a construction product has been found to present a risk to the basic requirements set out under Annex I of the Regulation, Member States may conduct an evaluation of the product. Point 3 of Annex I deals with risks to hygiene, health and the environment, namely that:

"The construction works must be designed and built in such a way that they will, throughout their life cycle, not be a threat to the hygiene or health and safety of workers, occupants or neighbours, nor have an exceedingly high impact, over their entire life cycle, on the environmental quality or on the climate during their construction, use and demolition, in particular as a result of any of the following:

(a) the giving-off of toxic gas;

(b) the emissions of dangerous substances, volatile organic compounds (VOC), greenhouse gases or dangerous particles into indoor or outdoor air;

(c) the emission of dangerous radiation;

(d) the release of dangerous substances into ground water, marine waters, surface waters or soil;

(e) the release of dangerous substances into drinking water or substances which have an otherwise negative impact on drinking water;

(f) faulty discharge of waste water, emission of flue gases or faulty disposal of solid or liquid waste;

(g) dampness in parts of the construction works or on surfaces within the construction works."

To comply with these requirements, all manufacturers of construction products containing substances identified with C, M or R properties should consider the implications of this in terms of risk and safety of their products. In the case of the 1-10t substances, only the general information presented in the SDS will be available for such an assessment where this will not include detailed information on the technical considerations in relation to exposure, risk and safety.

[20] Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonized conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, OJ L 88, 4.4.2011, p. 5.

Toys Directive 2009/48/EC

Directive 2009/48/EC on the safety of toys[21] lays down rules on the safety of toys and on their free movement within the internal market. 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 toys containing newly identified 1-10t mutagenic 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.

3.4 Compliance with Waste Legislation

3.4.1 Waste Framework Directive 2008/98/EC

Directive 2008/98/EC (the Waste Framework Directive) establishes a legal framework for the treatment of waste within the Community, and aims at protection of the environment and human health by way of preventing or reducing the harmful effects of waste generation and waste management. It 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.

Section 13 of Annex II of REACH on the requirements for the compilation of safety data sheets provides that this section of the safety data sheet must describe information for proper waste management of the substance or mixture and/or its container to assist in the determination of safe and environmentally preferred waste management options, consistent with the requirements in accordance with Directive 2008/98/EC.

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).

[21] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, OJ L 170, 30.6.2009, p.1

4 Changes Introduced by Extension of the CSA/CSR Obligation to 1-10t CMRs 1A/1B

4.1 Introduction

4.1.1 Chemical Safety Assessment (CSA)

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 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.

4.1.2 The Chemical Safety Report (CSR)

The Chemical Safety Report (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*"[22].

The CSR has a set format. This is defined in Annex I of REACH and can be summarised as in Table 4.1. As can be seen from Table 4.1, information to be provided in the registration dossier in relation to Annexes VII to XI is compiled in the appropriate Sections 1 to 7 (and also summarised in the SDS). The PBT/vPvB assessment that forms Section 8 is based upon the relevant data from Sections 4 and 5. Sections 9 and 10 (exposure assessment and risk characterisation) are based upon all of the information in Sections 1 to 8.

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

Table 4.1: Chemical Safety Report Format and Key Sources of Information	
Part A	
Summary Of Risk Management Measures	
Declaration That Risk Management Measures Are Implemented	
Declaration That Risk Management Measures Are Communicated	
Part B	**Sources of Information**
1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES	Annex VI and VII information and summarised in Section 1 of the SDS: Identification of the substance/mixture and of the company/undertaking
2. MANUFACTURE AND USES	Annex VI information summarised in Section 1 of the SDS: Identification of the substance/mixture and of the company/undertaking
2.1. Manufacture	
2.2. Identified uses	
2.3. Uses advised against	
3. CLASSIFICATION AND LABELLING	Annex VI and application of Annexes VII to XI. Summarised in Section 2 of the SDS: Hazards identification
4. ENVIRONMENTAL FATE PROPERTIES	
4.1. Degradation	Application of Annexes VII to XI and summarised in Section 12.2 of the SDS: Persistence and degradability
4.2. Environmental distribution	Characterisation of possible degradation, transformation, or reaction processes and an estimation of environmental distribution and fate based on available data
4.3. Bioaccumulation	Application of Annexes VII to XI and summarised in Section 12.3 of the SDS: Bioaccumulative potential
4.4. Secondary poisoning	Based on analysis of composite information
5. HUMAN HEALTH HAZARD ASSESSMENT	Application of Annex VII to XI and summarised in section 11.1 of the SDS: Information on toxicological effects
5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)	Information from Annex VIII and above
5.2. Acute toxicity	Information from Annex VII
5.3. Irritation	
5.4. Corrosivity	
5.5. Sensitisation	
5.6. Repeated dose toxicity	Information from Annex VIII (not required if relevant human exposure can be excluded in accordance with Annex XI Section 3).
5.7. Germ cell mutagenicity	Application of Annex VII to XI

5.8. Carcinogenicity	
5.9. Toxicity for reproduction	
5.10. Other effects	As appropriate
5.11. Derivation of DNEL(s)	Based on information from Annex VII to XI Note that for some hazard classes, especially germ cell mutagenicity and carcinogenicity, the available information may not enable a toxicological threshold, and therefore a DNEL, to be established.
6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES	
6.1. Explosivity	Annex VII and summarised in Section 10 of the SDS: Stability and reactivity
6.2. Flammability	
6.3. Oxidising potential	
7. ENVIRONMENTAL HAZARD ASSESSMENT	Information from Annex VII to XI and summarised in Section 12 of the SDS: Ecological Information
7.1. Aquatic compartment (including sediment)	Application of Annex VII to XI
7.2. Terrestrial compartment	Information from Annex IX and above
7.3. Atmospheric compartment	Information from Annex IX and above
7.4. Microbiological activity in sewage treatment systems	Information from Annex VIII
8. PBT AND VPVB ASSESSMENT	Based on comparison of information on toxicity, persistence and bioaccumulation with the criteria in Annex XIII
For substances meeting one or more of the criteria in Paragraph 0.6.3 of Annex I (including classification as category 1A/1B C, M or R or PBT/vPvB) the following assessments based on the above information	
9. EXPOSURE ASSESSMENT	
9.1. (Title of exposure scenario 1) 9.1.1. Exposure scenario 9.1.2. Exposure estimation	
10. RISK CHARACTERISATION	
10.1. (Title of exposure scenario 1)	
10.1.1. Human health	
10.1.1.1. Workers	
10.1.1.2. Consumers	
10.1.1.3. Indirect exposure to humans via the environment	
10.1.2. Environment	

10.1.2.1. Aquatic compartment (including sediment)
10.1.2.2. Terrestrial compartment
10.1.2.3. Atmospheric compartment
10.1.2.4. Microbiological activity in sewage treatment systems
10.x Overall Exposure (combined for all relevant emission/release sources)
10.x.1 Human Health (Combined for all Exposure Routes)
10.x.2 Environment (Combined for all Emission Sources)

4.1.3 Safety Data Sheets

As described in Section 2.3, it is a requirement to provide an SDS for all substances and mixtures with hazardous properties (i.e. including those produced in quantities of 1-10t per year). The SDS must be consistent with the information provided 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.

4.2 Changes to Current Requirements for Manufacturers and Importers

4.2.1 Introduction

Extending the CSA/CSR obligation to 1-10t substances classified as C, M or R 1A or 1B would require the completion of both the CSA and the CSR in accordance with Article 14 and Annex I of REACH as set out above, including preparation of an exposure assessment (CSR Section 9) and risk characterisation (CSR Section 10).

Each step of the CSA (and associated section of the CSR) set out in Annex I involves the presentation of information gathered in relation to Annexes VI to X contained in the technical dossier, as well as other available and relevant information.

As such, the information to be considered includes information related to the hazards of the substance, the exposure arising from the manufacture or import, and in the identified uses of the substance, operational conditions and risk management measures applied or recommended to downstream users (including the technical means to achieve them) to be taken into account. Specific actions that would become mandatory for manufacturers and importers of 1-10t substances in relation to each step are described in the sub-sections below.

4.2.2 Information on the Substance, its Uses, Classification and Environmental Fate

Sections 1 to 4 of the CSR are to provide general information on the substance, its manufacture and uses, classification and labelling and environmental fate properties. Table 4.2 describes the sources of the required information in respect of the 1-10t substances.

As can be seen from Table 4.2, much of the information required for these sections of the CSR is already provided according to the requirements of Annexes VI and VII with the exception of there being no specific test information available on long-term aquatic toxicity to allow classification from Annex VII (Section 3). There is no requirement to provide the information for a CSA where it is not required elsewhere, the analysis for 1-10t substances must be based on available information alone.

Table 4.2: CSR Reporting on the Substance, its Uses, Classification and Environmental Fate	
CSR Section	**Availability of information**
1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES	Annex VI and VII information and summarised in Section 1 of the SDS: Identification of the substance/mixture and of the company/undertaking
2. MANUFACTURE AND USES	Annex VI information summarised in Section 1 of the SDS: Identification of the substance/mixture and of the company/undertaking/entity
2.1. Manufacture	
2.2. Identified uses	
2.3. Uses advised against	
3. CLASSIFICATION AND LABELLING	Annex VI and application of Annexes VII to XI. Summarised in Section 2 of the SDS: Hazards identification No specific test information available on long-term aquatic toxicity.
4. ENVIRONMENTAL FATE PROPERTIES	
4.1. Degradation	Results from tests on ready biodegradation in accordance with Section 9.2.1.1 of Annex VII and summarised in Section 12.2 of the SDS: Persistence and degradability
4.2. Environmental distribution	Characterisation of possible degradation, transformation, or reaction processes and an estimation of environmental distribution and fate based on available data
4.3. Bioaccumulation	Results from tests on Octanol-water partitioning coefficient experimentally determined in accordance with Section 7.8 of Annex VII and summarised in Section 12.3 of the SDS: Bioaccumulative potential
4.4. Secondary poisoning	Based on analysis of composite and available information

4.2.3 The Human Health Hazard Assessment

The purpose of the human health hazard assessment is to determine the classification of a substance and to derive levels of exposure to the substance above which humans should not be exposed (the derived no effect level - DNEL) where this can be achieved.

Table 4.3 describes the availability of information in respect of the 1-10t CMR 1A/1B substances and the specifications for CSA/CSR in Annex I. As can be seen from Table 4.3, most of the information would already be required and available for the 1-10t CMRs 1A/1B but there are some gaps in relation to:

- Toxicokinetics - toxicokinetic studies are only required for Annex VIII and above. Some (limited) information may be available from considerations concerning toxicity to germ cells; and
- Repeated dose toxicity - only required under Annex VIII and above. This endpoint is not required anyway under Annex VIII if relevant human exposure can be excluded in accordance with Annex XI Section 3 (which, itself, refers back to demonstration thorough and rigorous exposure assessment in accordance with Section 5 of Annex I).

Table 4.3: CSR Reporting on Human Health Hazard Assessment	
CSR Section	**Availability of information**
5. HUMAN HEALTH HAZARD ASSESSMENT	Application of Annex VII to XI requirements and summarised in section 11.1 of the SDS: Information on toxicological effects
5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)	Not/unlikely to be available - only Annex VIII and above. Some (limited) information may be available from considerations concerning toxicity to germ cells.
5.2. Acute toxicity	Annex VII requirement
5.3. Irritation	Annex VII requirement
5.4. Corrosivity	Annex VII requirement
5.5. Sensitisation	Annex VII requirement
5.6. Repeated dose toxicity	Not available - Annex VIII requirement and, under Annex VIII, not required if relevant human exposure can be excluded in accordance with Annex XI Section 3.
5.7. Germ cell mutagenicity	Application of Annex VII to XI requirement
5.8. Carcinogenicity	Application of Annex VII to XI requirements
5.9. Toxicity for reproduction	Application of Annex VII to XI requirements
5.10. Other effects	-
5.11. Derivation of DNEL(s)	Application of Annex VII to XI requirements/no exposure Step 4: Identification of DNEL(s) As noted in Annex I, para 1.4.1, for some hazard classes, especially germ cell mutagenicity and carcinogenicity, the available information may not enable a toxicological threshold, and therefore a DNEL, to be established.

In relation to filling these gaps, there would be no requirement for 1-10t substances to complete this information under Annex I. Therefore there would be no additional cost burden from introducing the CSA/CSR requirement in terms of the generation of hazard data

In terms of the presentation of information on the appropriate test endpoints in Annexes VII to X, robust study summaries would be required of all key data used in the hazard assessment. For other data, as for substances not subject to CSA/CSR, only a study summary is required. In REACH a study summary is defined as "*a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study*".

For the key endpoints used in the human health hazard assessment, then, five study summaries would need to be upgraded to the level of a robust study summary where, in REACH, this is defined as "*a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report*". **Production of these five robust study summaries for the human health hazard assessment would be an additional requirement and would represent an additional cost for all 1-10t substances identified with C, M, or R 1A/1B properties.**

Considering the levels of a substance which human exposure should not exceed, the existence or non-existence of a threshold effect dictates the approach used in risk assessment. Where there is no threshold, risk assessment and management is geared towards the technical means to eliminate human exposure to the substance at all stages in the lifecycle (closed systems). Where a threshold (DNEL) can be derived, risk assessment and management is geared towards the technical means to reduce exposure to a safe level at all stages in the lifecycle.

As noted in Annex I paragraph 1.4.1 of REACH, for some hazard classes, especially germ cell mutagenicity and carcinogenicity, the available information may not enable a toxicological threshold, and therefore a DNEL, to be established. In practice, if a substance is mutagenic or carcinogenic (or both) it is almost certainly a non-threshold substance as far as risk management is concerned.

In terms of the proportion of non-threshold versus threshold 1-10t C, M or R 1A/1B substances, as noted in Section 2.1, there are two types of 1-10t 'CMRs'. Those that are known and have already been registered (of which there are 46) and those that are, as yet, unknown but will be identified in the course of registering the remaining 1-10t substances.

In terms of the 46 known 1-10t 'CMRs' 1A/1B, ECHA has provided a breakdown of the classifications, with these given in Table 4.4. This suggests that 23 of the 46 (50%) are most likely to be regarded as non-threshold substances for the purpose of exposure and risk assessment and 23 may or may not have a threshold.

Table 4.4: Classification of Known and already Registered 1-10t 'CMRs 1A/1B'

Classification	Number of substances	Threshold or Non-threshold?
only Muta 1A or Muta 1B	0	Non-threshold
only Carc 1A or Carc 1B	17	Non-threshold
only Repr 1A or Repr 1B	23	Potentially threshold - it may be possible to establish a DNEL
only Muta and Carc (1A/1B)	2	Non-threshold
only Muta and Repr (1A/1B)	0	Non-threshold
only Carc and Repr (1A/1B)	1	Non-threshold
Muta and Carc and Repr (1A/1B)	3	Non-threshold

In terms of the substances with, as yet, unknown 'CMR' properties, as noted in Section 2.2 these are all identified through the mutagenicity route. There is no testing for carcinogenicity or reproductive toxicity for the 1-10t substances. As such, all of these substances will be classified as mutagens which, in turn, will be regarded as non-threshold substances for the purposes of exposure and risk assessment.

Accordingly, out of the total set of known and currently unknown 'CMRs 1A/1B', only 23 substances may be able to identify a threshold effect and associated DNEL. These are all substances for which the existence of a classification for reproductive toxicity is already known and these substances are already registered under REACH. Owing to the need to assess the risks to workers under the Chemical Agents Directive and other worker health and safety regulation, manufacturers of these substances are likely to have already established a threshold concentration or DNEL to assess human exposure for their own manufacture and use. As such, there are unlikely to be any additional costs in relation to the human health hazard assessment over and above those required at present under both REACH and parallel regulation **but downstream users may benefit from the communication of the DNEL in the extended SDS.**

4.2.4 The Human Health Hazard Assessment of Physicochemical Properties

The purpose of the human health hazard assessment of physicochemical properties is to determine the classification of a substance in relation to, as a minimum, explosivity, flammability and oxidising potential. For 1-10t CMRs 1A/1B, all of this information is already provided under the current

requirements and is summarised in Section 10 of the SDS (stability and reactivity). As such, no additional work would be required in relation to this section.

4.2.5 The Environmental Hazard Assessment

The purpose of the environmental hazard assessment is to determine the classification of a substance and to identify the Predicted No-Effect Concentration (PNEC). The assessment considers several environmental spheres and associated reporting in the appropriate sections of the CSR, namely:

- Section 7.1: Aquatic compartment (including sediment)
- Section 7.2: Terrestrial compartment
- Section 7.3: Atmospheric compartment
- Section 7.4: Microbiological activity in sewage treatment systems

Of these, for the 1-10t CMRs 1A, only information on the aquatic component (Section 7.1) could be provided for inclusion in a CSA/CSR based on the test endpoints for short-term toxicity to aquatic invertebrates and also algae present in Annex VII.

Owing to differences in information requirements between annexes, submission of data for the terrestrial and atmospheric compartments (Sections 7.2 and 7.3) is only required for >100t substances. Microbiological activity in sewage treatment systems (Section 7.4) is only considered for >10t substances.

Where no hazard information is available for any environmental sphere there is no requirement in Annex I to provide the information and, as such, there is no cost burden stemming from the introduction of a CSA/CSR requirement.

In terms of deriving a PNEC for 1-10t CMRs, the two Annex VII tests are not sufficient and a third species would be needed to establish an acute PNEC for the aquatic compartment. As there is no requirement to undertake a third test in Annex VII or Annex I, it would not be possible to establish a PNEC for the 1-10t CMRs for substances identified as toxic to aquatic life although the information would be sufficient to identify the existence of a risk and likely levels of toxicity for use in the environmental exposure assessment and risk characterisation. Hazard information must already be provided in the SDS and, as such, the Environmental Hazard Assessment does not provide an additional burden other than in terms of the presentation of information.

In terms of presentation of the information on the appropriate test endpoints in Annex VII, as with the human health hazard assessment, robust study summaries would be required of all key data used in the hazard assessment. For other data, as for substances not subject to CSA/CSR, only a study summary is required.

For the key endpoints used in the environmental hazard assessment, then, two study summaries would need to be upgraded to the level of a robust study summary. As in the case of human health, **production of these two robust study summaries would be an additional requirement and would represent an additional cost for all 1-10t substances identified with C, M, or R 1A/1B properties.**

4.2.6 The PBT and vPvB Assessment

The purpose of the PBT/vPvB assessment is to determine if the substance fulfils the criteria for PBT/vPvB given in Annex XIII and, if so, to characterise the potential emissions of the substance.

The procedures for PBT/vPvB assessment are set out in Annex XIII, Section 2.1 which identifies that, for substances with information for Annexes VII and VIII, the first step is a screening for P, B or T properties. If this suggests that the substance may have PBT or vPvB properties there is a requirement to generate the necessary information for assessment.

Examining the Annex XIII requirements in relation to this and the information available for the 1-10t CMRs suggests the following:

- In relation to T: C or M 1A/1B properties are one of the criteria for T. As such, all of the 1-10t 'CMRs 1A/1B' will automatically meet the criteria for T.
- In relation to P and vP: Results from tests on ready biodegradation in accordance with Section 9.2.1.1 of Annex VII is sufficient to provide an indication of P/vP but is insufficient for assessment. Thus, in the event that the screening suggests the possibility of P/vP, additional testing might be required depending on the outcome of considerations in relation to B/vB.
- In relation to B and vB: results from the octanol-water partitioning coefficient experimentally determined in accordance with Section 7.8 of Annex VII is sufficient to provide an indication of B/vB but is insufficient for assessment. Thus, in the event that the screening suggests the possibility of B/vB, additional information might be required depending on the outcome of the screening in relation to P and vP.

If the screening suggests that the substance may have both P and B properties, the following further information would have to be generated under REACH CSA/CSR requirements to enable the assessment to be completed:

- For P: simulation testing on degradation in surface water/soil/sediment; and
- For B: assessment of the toxicokinetic behaviour of the substance or results from a bioconcentration or bioaccumulation study in aquatic species.

As noted above, no further information would be required in relation to T as CMRs 1A/1B automatically fulfil the T criterion.

If the substance fulfils the criteria (or it is considered as if it is a PBT or vPvB in the registration dossier), Annex I requires that an emission characterisation is conducted comprising the relevant parts of the exposure assessment (described below).

In relation to additional burden of PBT/vPvB screening and assessment, there is a need to compare the relevant test results with screening criteria for P and B and T in Annex XIII. No additional information is required to achieve this for the 1-10t CMRs 1A/1B and costs are zero or near zero.

Where the PBT/vPvB screening suggests that the substance meets the criteria in Annex XIII, the following additional information would be required to complete the assessment where this would represent an additional burden on manufacturers and importers:

- **for assessment of P:** simulation testing on degradation in surface water/soil/sediment; and
- **for assessment of B:** assessment of the toxicokinetic behaviour of the substance or results from a bioconcentration or bioaccumulation study in aquatic species.

4.2.7 The Exposure Assessment and Risk Characterisation

Overview

In terms of putting all of the elements together for the management of risks and recommending risk management measures, the exposure assessment and risk characterisation elements of CSA are critical to demonstrating that the risks associated with substances with dangerous properties are controlled and, where they are not, that steps are taken to ensure that they are controlled. In this way, these elements of the CSA are iterative in nature.

Here, as is identified in ECHA guidance on CSA[23], under REACH, risks are regarded as controlled when the exposure levels to the substance are below the threshold levels considered as safe, both for humans and for the environment or, for effects with no threshold levels, emissions and exposures have to be minimised or avoided for risks to be considered to be controlled.

If risks are adequately controlled, the CSA is complete. If risks are not adequately controlled, the CSA must be refined, either by obtaining more data on the properties of the substance, changing the conditions of manufacturing or use, or making more precise exposure estimations. The process continues until the risks are shown to be under control and the conditions of manufacturing and use under which the risks are under control constitute what is then called the final exposure scenario. This, amongst other things, details the risk management measures to be applied for each of the uses and the technical means to achieve them. This is placed in an annex to the SDS and communicated to downstream users to enable them to implement the recommended risk management measures.

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 downstream uses.

The standard approach to exposure assessment and risk characterisation is first to estimate quantitatively or qualitatively the dose/concentration of the substance to which humans and the environment are or may be exposed:

- considering all stages of the life-cycle of the substance resulting from the manufacture and identified uses that may result in exposure to the hazards identified in the hazard and PBT/vPvB assessments; and
- taking account of how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment.

[23] http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/guidance-in-a-nutshell

Quantitative comparison is then made with the DNEL and PNEC derived in the human health and environmental hazard assessments. 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.

Human Health Assessment

In the case of the 1-10t CMRs 1A/1B, as discussed previously, exposure assessment and risk characterisation for human health exposures is strongly influenced by whether or not the substance is a threshold or a non-threshold substance. The emphasis of exposure assessment and risk characterisation for non-threshold substances is on achieving no human exposure via closed systems and detailing the technical means to achieve this using recommended risk management measures.

In terms of the 46 known (and registered) 1-10t 'CMRs' 1A/1B, as noted in Section 4.2.3, 23 of the 46 (50%) are likely to be regarded as non-threshold substances for the purpose of exposure and risk assessment and 23 may or may not have a threshold.

In terms of the substances with, as yet, unknown 'CMR' properties, as noted in Section 2.2 these are all identified through the mutagenicity route. There is no testing for carcinogenicity or reproductive toxicity for the 1-10t substances. As such, all of these substances will be classified as category 1B mutagens and, in turn, will be regarded as non-threshold substances for the purposes of exposure and risk assessment.

In terms of identified uses, the CSA must cover all identified uses of the substance including the manufacturer's own processes/use. In relation to human exposures and risk management measures for the manufacturers own uses, manufacturers are already required to undertake an assessment of exposure and risk under parallel worker health and safety regulations including:

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

Assessments under these pieces of regulation have been described in Section 3.2 and involve:

- determining the nature, degree and duration of workers' exposure to carcinogens or mutagens in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken;
- generating data on workers' exposure at specific workstations in order to inform the risk assessment considering all routes of exposure, such as absorption into and/or through the skin;
- in the case of any activity likely to involve a risk of exposure to carcinogens or mutagens, the nature, degree and duration of workers' exposure shall be determined;
- as a priority, workers' exposure must be prevented through substitution. If this is not possible, a closed technological system shall be used. Where a closed system is not technically possible, the employer shall reduce exposure to minimum through a number of risk management measures.

As such, manufacturers must already apply a CSA style approach to their own uses. The extension of the CSA obligation to the manufacturers' own uses should not, then, be considered as additional to what is already required.

In relation to human exposures and risk management measures for consumer uses via articles, downstream users are already required to undertake an assessment of exposure and risk under Product Safety Regulation including:

- Directive 2001/95/EC on General Product Safety;
- Regulation No 305/2011 for the Marketing of Construction Products; and
- Toys Directive 2009/48/EC.

Assessments under these pieces of regulation have been described in Section 3.3. To comply with Product Safety Regulation, assessment of the risk to consumers from the presence of the substance in a product would be required where this would include consideration of human exposure to the substance from use of the product in question. However, in the case of the 1-10t 'CMRs', only the general information presented in the SDS will be available to downstream users for such an assessment where this will not include detailed information on the technical considerations in relation to exposure, risk and safety.

In relation to other uses, manufacturers and importers would have to consider downstream uses of the substance in the CSA where this would be additional to what is required of them at present. However, where the substance is a non-threshold substance (as will be the case for most of the 1-10t 'CMRs 1A/1B'), the emphasis of the exposure scenarios and risk management measures will be on closed systems and the technical means to achieve them. Thus, the measures and technical means applied for the manufacturers' own uses (as should already be identified under parallel regulation) may be sufficient to cover downstream uses and recommended risk management measures with regards to worker exposure. In this situation there is little or no cost associated with the extension of exposure scenarios to cover downstream uses and human exposure. For consumer exposure via articles, the development of a CSA would represent an additional requirement and cost for manufacturers because there will be no overlap with the manufacturer's own use.

The process for establishing these identified uses is provided under Article 37 of REACH which identifies that a downstream user or distributor may provide information to assist in the preparation of a registration and make a use known in writing to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own or in a mixture with the aim of making this an identified use.

In making a use known, the downstream user must provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario, or if appropriate a use and exposure category, for his use in the manufacturer, importer or downstream user's chemical safety assessment.

Environmental Assessment

Completion of an environmental exposure assessment and risk characterisation as specified in Annex I is not something that is required under parallel regulation other than in relation to waste management. The coverage of the environmental assessment is more limited for the 1-10t substances compared to higher tonnage substances owing to the fact that information is only

available on the aquatic compartment and information from the two tests for aquatic toxicity (aquatic invertebrates and algae) in Annex VII are not sufficient to derive a PNEC (a third species would be needed but is not required under REACH).

Whilst quantitative comparison between environmental exposures and PNECs would be more difficult, exposure estimation can still be carried out considering recommended risk management measures for human health and, by comparison with available data, the need for specific risk management measures in relation to environmental emissions. It could, for example, be demonstrated through exposure assessment that there are no emissions or losses to environmental compartments. Indeed, where a substance is a PBT/vPvB this would have to be demonstrated.

Assessment of environmental exposures for identified uses (including the manufacturers' own uses) is an additional requirement and represents an additional cost burden.

4.2.8 Communication in the Supply Chain

Having completed the CSR, manufacturers and importers would be required to supply an extended SDS (eSDS) to downstream users that is consistent with the information in the CSA, where this will include:

- 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.

Under Article 37, where the manufacturer, importer or downstream user, having assessed the use as part of the CSA, is unable to include it as an identified use for reasons of protection of human health or the environment, he must provide the downstream user with the reason(s) for that decision in writing without delay and must not supply downstream user(s) with the substance without including these reason(s).

The addition of these elements to provide an extended SDS would represent an additional administrative burden on manufacturers and importers.

4.3 Changes in Requirements for Downstream Users

4.3.1 Overview

The changes that would be introduced for downstream users relate to two categories:

- changes in requirements on downstream user obligations under REACH; and
- changes in relation to compliance with other, parallel regulation.

4.3.2 Changes in Requirements on Downstream Users under REACH

For downstream users, a key obligation that would be triggered by the extension of the CSA requirements is that, under Article 37, in making a use known, a downstream user must provide sufficient information to allow the manufacturer, importer or downstream user who has supplied

the substance to prepare an exposure scenario or, if appropriate, a use and exposure category for his use in the manufacturer, importer or downstream user's chemical safety assessment.

As described in Section 3.2, owing to classification of a substance as C, M or R 1A/1B, downstream users would be required to undertake an assessment of exposure under parallel regulation including worker health and safety regulation. For each downstream user this includes generating data on workers' exposure to carcinogens and mutagens at specific workstations considering all routes of exposure, such as absorption into and/or through the skin and determining the nature, degree and duration of workers' exposure. In addition, product safety regulations also require safety assessment of the use of substances.

For the (46) 1-10t substances already registered with known 'CMR' properties, any obligation on downstream users to pass information sufficient for an exposure assessment up the supply chain should not be viewed as a significant additional burden. **However, documentation compiled to comply with the requirements of parallel regulation may need to summarised in a manner that is useful for the exposure assessment and this may require a small amount of additional time.**

For the 1-10t substances for which mutagenic properties are, as yet, unidentified (and the substance is not yet registered), downstream users will not have complied the information necessary to comply with parallel regulation (because, currently, the substance is not classified for mutagenicity). As such, passing information sufficient for an exposure assessment up the supply chain is likely to be less burdensome than carrying out the assessments required by the parallel regulation. Here, the resulting exposure assessments from the CSA will enable compliance with this parallel regulation (see Section 4.3.3). **As such, substituting the complete assessments required under parallel regulation with the requirement to pass a reduced level of information up the supply chain for exposure assessment and CSA is likely to provide a net cost saving (i.e. a benefit) for downstream users of substances with (as yet) unidentified mutagenic properties.**

In terms of other obligations, Table 4.5 lists the key provisions in respect of downstream users and distributors that would be triggered by extension of the CSA/CSR. As can be seen from Table 4.5, the responsibilities on downstream users and distributors triggered by the extension of the obligation mainly relate to ensuring that information in their SDSs is consistent with any CSA for the identified uses and that this information and the appropriate exposure scenario is passed down the supply chain in the same way as is required for the SDS that is currently required.

An additional requirement of note is that in relation to Article 37(4) which requires a downstream user 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[24]. In turn, Annex XII requires that, effectively, the downstream user must provide a CSR for those uses, drawing on information in the extended SDS and covering those areas appropriate to him.

[24] Under the current requirements, a downstream user need not prepare such a chemical safety report because a chemical safety report is not required to be completed by his supplier.

Table 4.5: List of the Key Provisions by Duty-holders, Drivers and Benefits for Information in the Supply Chain in relation to CSAs		
Article	**Key Provisions**	**Duty-holders**
31(2)	Requirement on any actor in the supply chain who has been requested to perform a CSA to ensure that information in the SDS is consistent with the information in the assessment.	M, I, DU
31(7)	Requirement on actors in the supply chain to place the relevant exposure scenarios in an annex to the SDS.	DU
	Requirement on a downstream user to include the exposure scenarios in their own SDS for identified uses.	DU
	Requirement on a distributor to pass on relevant exposure scenarios and use other relevant information from the SDS when compiling his own data sheet.	D
37(4)	Requirement on a downstream user 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. A downstream user need not prepare such a chemical safety report if a chemical safety report is not required to be completed by his supplier in accordance with Article 14;	DU
37(5)	Requirement on downstream user to identify and apply appropriate measures to adequately control risks identified in (a) an SDS supplied to it: (b) its own chemical safety assessment. Requirement on downstream user to recommend, where suitable, measures to adequately control the risks identified in (a) an SDS supplied to it; (b) its own chemical safety assessment.	DU
37(7)	Requirement on downstream users to keep their chemical safety report up to date and available.	DU

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, as noted in Section 3.2 (and above), downstream users are already required to undertake assessments of their own uses under several pieces of parallel regulation including worker health and safety and product safety regulation. Thus, the requirement to provide a CSA for a use not covered in a manufacturer/importer CSR, however unlikely, should be considered in the light of what is already required under existing regulation for such uses. In terms of human exposure and risk assessment, any additional requirement from extending the CSA obligation is small in relation to human health exposures but **some additional work might be required in relation to environmental risk and exposure in these (probably few) cases**.

4.3.3 Changes in Requirements on Downstream Users under Parallel Regulation

An important change that would be brought about by the extension of CSA requirements to 1-10t substances classified as C, M or R 1A/1B is that the resulting exposure scenarios for the identified uses and other information in extended SDSs would facilitate compliance with the many regulatory instruments that are triggered by classification in accordance with Regulation (EC) No 1272/2008.

These regulatory requirements have been described in Section 3.2 and include:

- the Carcinogens and Mutagens Directive 2004/37/EC (CMD);
- Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD);
- the Pregnant and Breastfeeding Workers Directive 92/85/EEC;
- Directive 94/33/EC on Young Workers;
- Directive 2001/95/EC on General Product Safety;
- Regulation No 305/2011 for the Marketing of Construction Products;
- Toys Directive 2009/48/EC; and
- Waste Framework Directive 2008/98/EC

In relation to the worker health and safety regulation, at present manufacturers and downstream users of C, M or R 1A/1B substances must conduct and document their own bespoke assessments of exposure, risk and identification of risk management measures based on the general information provided in the SDS. As there are, at the very least, as many downstream uses as there are substances and, in turn, multiple downstream users for each use there is, at present significant potential for duplication of effort in relation to identifying and implementing appropriate risk management measures for worker exposure and in relation to waste and product safety. In addition, owing to the general nature of the information that must currently be provided in SDSs, downstream users do not have access to exposure scenarios detailing the technical means to achieve risk management and detailed information on safe use at present. As such, the task of compliance with existing parallel regulation is made more difficult for downstream users by a paucity of information in the current, general, SDSs.

Concerning the interface between the Chemicals Agent Directive and REACH at the workplace, the Commission has issued guidance[25]. 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. As such, **if the CSA obligation were to be extended, this may provide for compliance with other regulation or, at the very least, greatly facilitate compliance. Both could reduce the costs of compliance with worker health and safety regulation.** However, existing downstream users of 1-10t substances with already known C, M, or R 1A/1B properties are unlikely to benefit significantly as they must already be compliant with existing regulatory requirements. In contrast, new downstream users may experience these benefits and there is the potential for more consistent implementation of robust risk management measures (with associated human health benefits).

[25] Guidance for employers on controlling risks from chemicals, Interface between Chemicals Agents Directive and REACH at the workplace, European Commission, October 2010, https://osha.europa.eu/en/topics/ds/materials/reach-guidance-employers.pdf

In relation to other regulation on downstream users, any safety assessments required under, for example, the General Product Safety Directive (or other product specific regulation) are likely to be both more robust and easier to complete with the benefit of a more detailed extended SDS. The same is also true in relation to the provisions of the Waste Framework Directive and compliance in relation to the determination of safe and environmentally preferred waste management options, all of which should be set out in some detail in an extended SDS (but in only general terms in an SDS). **Thus, extension of the CSA obligation could reduce the costs of compliance with waste and product safety regulation for downstream users.** As noted above, existing downstream users of 1-10t substances with already known C, M, or R 1A/1B properties are unlikely to benefit significantly as they must already be compliant with existing regulatory requirements. However, new downstream users may experience these benefits and there is the potential for more consistent implementation of robust measures (with associated human health benefits).

5 Analysis of Costs and Benefits

5.1 Overview

Section 4 has discussed the changes that would be brought about by the extension of the CSA obligation to 1-10t 'CMRs' given existing requirements on manufacturers, importers and downstream users under both REACH and parallel regulation that is triggered by classification as C, M, or R 1A/1B in accordance with Regulation (EC) No 1272/2008.

The general conclusion of this analysis is that, for many of the components of CSA/CSR required under REACH, the obligation would simply shift some of the work required to comply with existing parallel regulation under the general heading of CSA/CSR under REACH. To some extent this places some additional burden on manufacturers and importers in relation to completing some the elements that are unique to CSA/CSR under REACH (such as robust study summaries or PBT/vPvB assessment). In addition, manufacturers and importers would have to consider the exposure, risk management measures and the technical means to achieve them on behalf of their downstream users for the identified uses. However, this shift of responsibilities from downstream user to manufacturer/importer is likely to benefit multiple downstream users of each substance because the CSA/CSR process and the exposure assessments provided in the resulting extended SDSs will enable downstream user to comply with their obligations under parallel regulation.

The costs and benefits identified in Section 4 of this report are summarised and assessed in the following sub-sections. When considering these costs and benefits there is a need to consider impacts on the various actors differently for the following types of substances:

- 1-10t substances as yet unregistered because their mutagenic properties are yet to be identified; and
- 1-10t substances already registered owing to known C, M, or R 1A/1B properties.

This is because manufacturers and downstream users of substances already registered owing to known properties must already be compliant with existing parallel regulation. Conversely, manufacturers and importers of substances with (as yet) unidentified mutagenic properties will not yet complied with parallel regulation because the substances are not yet classified for mutagenicity.

Numbers of 1-10t 'CMRs 1A/1B'

In terms of the estimated numbers of each type of substance, Annex I to this report provides a detailed estimation of the numbers of each type. This suggests that:

For the 1-10t substances with properties as yet unidentified:

- 106 substances are likely to be classified as Mut. 1B and, hence, would be required to undertake a CSA under any extended obligation;
- 46 substances would be classified as Mut. 2. Assuming a small percentage (~5%) of those would also be classified as Carc 1A/1B (which is expected to be a rare/unlikely event) this suggests an additional 2 substances might be required to undertake a CSA under any extended obligation; and

- assuming that all of these substances proceed with registration (and do not withdraw from the market), a total of around 108 previously unknown 1-10t substances would be required to undertake a CSA under any extended obligations. These would all be mutagenic and, thus, non-threshold substances for the purposes of exposure assessment and risk characterisation (hence technical measures to implement closed systems are the starting point for risk management measures.

For the 46 substances already registered owing to known 'CMR 1A/1B' properties:

ECHA have provided a breakdown of the classifications. These are provided in Table 5.1. These data suggest that 23 of the 46 (50%) are most likely to be regarded as non-threshold substances for the purpose of exposure and risk assessment and 23 may or may not have a threshold (owing to classification as R 1A/1B only).

Table 5.1: Classification of Known and already Registered 1-10t 'CMRs 1A/1B'		
Classification	**Number of substances**	**Threshold or Non-threshold?**
only Muta 1A or Muta 1B	0	Non-threshold
only Carc 1A or Carc 1B	17	Non-threshold
only Repr 1A or Repr 1B	23	Potentially threshold - it may be possible to establish a DNEL
only Muta and Carc (1A/1B)	2	Non-threshold
only Muta and Repr (1A/1B)	0	Non-threshold
only Carc and Repr (1A/1B)	1	Non-threshold
Muta and Carc and Repr (1A/1B)	3	Non-threshold

Accordingly, out of the total set of known and currently unknown 'CMRs 1A/1B', only 23 substances may be able to identify a threshold effect and associated DNEL. These are all substances for which the existence of a classification for reproductive toxicity is already known and these substances are already registered under REACH. For the remainder, the focus of CSA should be on the achievement of closed systems.

Approach to estimation of Costs and Benefits

The estimation of costs and benefits takes a scenario approach. Three scenarios have been developed to cover the costs of the various elements, the numbers of uses and downstream users and other factors. Estimates for all three scenarios (low, medium and high) are provided in Annex II and this section provides results in relation to the medium scenario but any differences across scenarios are highlighted in this section where these change the outcome and conclusions.

5.2 Costs to Manufacturers and Importers

5.2.1 Human Health and Environmental Hazard Assessment

Description of Costs

In relation to manufacturers and importers, the following costs have been identified in Section 4 in relation to each registration of each substance:

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

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

Estimation of Costs

Table 5.2 provides estimates for the cost of producing Robust Study Summaries. Costs are based on an estimated €350 for each endpoint for Robust Study Summaries and €150 for Study Summaries making an additional €200 for substances not yet registered. Substances already registered owing to their known 'CMR 1A/1B' properties have already provided Study Summaries and so it has been assumed that they would have to produce entirely new Robust Study Summaries (at a cost of €350 per endpoint). This is likely to be a slight exaggeration of the costs to substances already registered.

Table 5.2: Cost of Producing Robust Study Summaries		
	Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Number of studies to summarise (HH and ENV)	7	7
Cost of producing a Study Summary	€ 150	€ 150
Cost of producing a Robust Study Summary	€ 350	€ 350
Additional cost of producing Robust Study Summaries for a CSA	€ 200	€ 350
Overall cost of producing Robust Study Summaries per substance	€ 1,400	€ 2,450
Total Cost of Robust Study Summaries for all substances	**€ 151,200**	**€ 112,700**
Total	**€ 263,900**	

5.2.2 PBT/vPvB Assessment

Description of Costs

No additional information is required to achieve carry out a screening for PBT/vPvB properties and costs should be regarded as zero or near zero.

However, where the PBT/vPvB screening suggests that the substance meets the criteria in Annex XIII, the following additional information would be required to complete the assessment where this would represent an additional burden on manufacturers and importers:

- **for assessment of P:** simulation testing on degradation in surface water/soil/sediment; and
- **for assessment of B:** assessment of the toxicokinetic behaviour of the substance or results from a bioconcentration or bioaccumulation study in aquatic species.

Estimation of Costs

Table 5.3 provides estimates for the costs of generating information for the assessment based on an overall cost of €20,000 per substance for additional studies on toxicokinetics and expert assessment plus other follow up studies. The high scenario uses full testing costs from the CEFIC testing catalogue. However, it is considered unlikely that all substances would undertake such tests and,

indeed, many might seek to demonstrate no environmental exposure to avoid the costs of testing (and, as such, the additional costs of information would be zero or near zero).

Table 5.3: Cost of PBT/vPvB Assessment		
	Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Number of possible PBTs identified by screening	10	4
Cost of additional 54information for assessment of P:	€ 10,000	€ 10,000
Cost of additional 54information for assessment of B:	€ 10,000	€ 10,000
Overall cost of PBT Assessment per substance	€ 20,000	€ 20,000
Total Cost of PBT assessment for all substances	**€ 2,160,000**	**€ 920,000**
Total	**€ 3,080,000**	

5.2.3 Exposure Assessment and Risk Characterisation

Human Health Exposure Assessment and Risk Characterisation

Manufacturers and importers 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 substance (as will be the case for 108 of the 154 substances -70%), 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 should not be automatically assumed that a different exposure scenario will be required for each use (including the manufacturer's 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 use may not cover the other uses where this includes the assessment of consumer exposures for identified uses. For the purpose of this 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 is perhaps 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 to manufacturers and importers.

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 5.4. These assume that the exposure scenario for a manufacturer's own use also covers downstream uses for 50% of substances. For the other 50%, the manufacturer must generate separate assessments for each use at a cost of €5,000 each. Two uses are assumed for each substance and 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 5.4: Cost of Human Health and Environmental Exposure Assessments and Risk Characterisation		
	Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Percentage of substances where the exposure scenarios for the manufacturer's own use also covers downstream uses	50%	50%
Number of substances where the exposure scenarios for the manufacturer's own use also covers downstream uses	54	24
Number of substances where the exposure scenarios for the manufacturer's own use DOES NOT also covers downstream uses	54	22
Number of uses per substance	2	2
Cost of Human Health Exposure Assess and Risk Characterisation per use	€ 3,000	€ 3,000
Cost of Environmental Exposure Assess and Risk Characterisation per use	€ 2,000	€ 2,000
Overall manufacturer cost per substance across all uses	€ 10,000	€ 10,000
Total Costs to manufacturers across all substances	**€ 540,000**	**€ 220,000**
Total	**€ 760,000**	

5.2.4 Communication in the Supply Chain

Description of Costs

The addition of the following elements to provide an extended SDS would represent a small additional administrative burden on manufacturers and importers:

- 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.

Estimation of Costs

Estimated costs of communication in the supply chain are provided in Table 5.5. 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 5.5: Costs of Communication in the Supply Chain		
	Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Cost of adding the results of the PBT/vPvB assessment to the SDS per substance	€ 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
Cost of including the relevant exposure scenario(s) in an annex to the SDS per use	€ 300	€ 300
Percentage of substances where translation of eSDS will be needed	50%	50%
Number of languages to translate into	3	3
Cost of translation per language	€ 150	€ 150
Total cost of translation (where required) per use	€ 450	€ 450
Total cost of producing and translating eSDS for all substances	**€ 125,280**	**€ 53,560**
Total	**€ 178,840**	

5.2.5 Overall Costs to Manufacturers and Importers

The overall costs to manufacturers and importers are summarised in Table 5.6. The estimates suggest costs of €3 million for manufacturers and importers of substances with (as yet) unknown 'CMR 1A/1B' properties and €1.3 million for known 'CMRs 1A/1B'. Total costs for both are around €4.3 million.

Table 5.6: Overall Costs to Manufacturers and Importers			
	Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'	All 'CMRs 1A/1B'
Overall Costs to Manufacturers and Importers	€ 2,976,480	€ 1,306,260	**€ 4,282,740**

5.3 Costs and Benefits to Downstream Users

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

Description of Costs

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. This requires an amount of additional time.

Estimation of Cost

Table 5.7 provides an estimate of costs to downstream users for passing information up the supply chain. These assume a cost of €700 for each downstream user.

Table 5.7: Cost of Passing Information up the Supply Chain		
	Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Number of 'CMRs 1A/1B'	108	46
Cost for DU to provide information to Human Health Exposure Scenario	€ 350	€ 350
Cost for DU to provide information to Environmental Exposure Scenario	€ 350	€ 350
Overall DU costs per substance	€ 70,000	€ 70,000
Total DU costs for all substances	**€ 7,560,000**	**€ 3,220,000**
Total	**€ 10,780,000**	

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

Description of Costs

Article 37(4) requires a downstream user 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 assessments of their own uses under several pieces of parallel regulation including worker health and safety and product safety regulation.

However, some additional work might 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.

Estimation of Costs

Table 5.8 provides estimated costs for Article 37(4) provisions. The provisions are assumed to apply to 5% of substances, requiring production of an Annex XII CSA for an additional use not covered by the estimates set out above.

Table 5.8: Cost of CSAs under Article 37(4)		
	Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Number of 'CMRs 1A/1B'	108	46
Percentage of substances where Article 37(4) might apply	5%	5%
Cost of Environmental Exposure Assess and Risk Characterisation per use	€ 2,000	€ 2,000
Cost of communication in the supply chain (averaged from manufacturers' above)	€ 590	€ 590
Cost per DU completing an Article 37(4) CSA	€ 2,590	€ 2,590
Total costs of Article 37(4) requirements	**€ 13,986**	**€ 5,957**
Total	**€ 19,943**	

5.3.3 Reduced Costs of Compliance with Parallel Regulation

Description of Benefits

As is discussed in Section 4.3.3, an important change that would be brought about by the extension of CSA requirements to 1-10t substances classified as C, M or R 1A/1B is that the resulting exposure scenarios for the identified uses and other information in extended SDSs would facilitate compliance with the many regulatory instruments that are triggered by classification in accordance with Regulation (EC) No 1272/2008.

These regulatory requirements have been described in Section 3.2 and include:

- the Carcinogens and Mutagens Directive 2004/37/EC (CMD);
- Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD);
- the Pregnant and Breastfeeding Workers Directive 92/85/EEC;
- Directive 94/33/EC on Young Workers;
- Directive 2001/95/EC on General Product Safety;
- Regulation No 305/2011 for the Marketing of Construction Products;
- Toys Directive 2009/48/EC; and
- Waste Framework Directive 2008/98/EC

For the (108) 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 outcome of the CSA/CSR that would be required by extending the obligation to 1-10t 'CMRs 1A/1B' is that this should provide compliance with other parallel regulation or, at the very least, greatly facilitate that compliance. Shifting responsibilities

from downstream user to manufacturer/importer in this way is likely to benefit multiple downstream users of each substance.

Estimation of Benefits

Estimates of the reduced cost of compliance with parallel regulation are provided in Table 5.9. These assume that the assessments based on the general information currently provided in the SDS would cost downstream users €2,500 in the case of the 108 substances with (as yet) unidentified 'CMR 1A/1B' properties. For known 'CMRs 1A/1B' it is assumed that all downstream users have already complied with requirements under parallel regulation and, as such, there is no reduction in any cost of compliance via the extension of the CSA obligation.

Table 5.9: Reduced Costs of Compliance with Parallel Regulation		
	Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Cost for a DU to conduct assessments to comply with parallel regulation	€ 2,500	€ 0
Overall DU cost per 'CMR 1A/1B' substance	€ 250,000	€ 0
Total DU cost for all 'CMR 1A/1B' substances	**€ 27,000,000**	**€ 0**
Total	**€ 27,000,000**	

5.3.4 Net Costs to Downstream Users

The overall net costs to downstream users are provided in Table 5.10 where, here, a negative value indicates a net benefit. In the case of the 108 substances with (as yet) unidentified 'CMR 1A/1B' properties, there is a substantial net benefit of around €19.4 million associated with the extension of the CSA obligation to 1-10t 'CMRs1A/1B'.

In contrast, for known 'CMRs 1A/1B' there is a cost of around €3.2 million as downstream users will have already complied with requirements under parallel regulation.

Table 5.10: Net Costs to Downstream Users		
	All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Overall Costs to Downstream Users	€ 7,573,986	€ 3,225,957
Savings to Downstream Users (compliance costs avoided)	€ 27,000,000	€ 0
Net costs to Downstream Users (a negative cost is a benefit)	**-€ 19,426,014**	**€ 3,225,957**

5.4 Human Health Benefits

5.4.1 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 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.**

5.4.2 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).

5.5 Control of Environmental Risks

5.5.1 Identification of PBT/vPvB Substances

Extending the CSA/CSR obligation to 1-10t 'CMRs 1A/1B' would permit the detection and control of 1-10t CMRs 1A/1B that are also PBTs. Such substances would not be identified under current requirements.

Annex I provides the estimates of numbers of 1-10t substances identified. **This identifies that the following numbers are likely to be confirmed as PBT by extension of the CSA obligation**:

- 2 of the 108 previously unknown 1-10t CMRs 1A/1B; and
- 1 of the 46 known and already registered 1-10t CMRs 1A/1B (if the CSA/CSR obligation were to act retrospectively);
- 3 PBTs would be identified by the extension of the CSA obligation to 1-10t 'CMRs 1A/1B'.

5.5.2 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 the three PBT/vPvB substances it would have to be demonstrated through exposure assessment that there are no emissions or losses to environmental compartments.

As is identified in Section 4.2, quantitative comparison between environmental exposures and an established PNEC is unlikely to be possible because the two Annex VII tests are not sufficient 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 Annex VII or Annex I but if an adjustment were made to undertake one then this is likely to enhance the robustness of the environmental assessments. It should be noted that this is not possible within the scope of reporting in relation to Article 138(1) on the extension of the CSA obligation to 1-10t CMRs 1A/1B.

However, Article 138(3) of REACH identifies that the Commission may present legislative proposals to modify the information requirements for substances manufactured or imported in quantities of 1-10t per year. The Commission must report on Article 138(3) by November 2014. The inclusion of a third test in Annex VII is currently being considered as one of the options.

5.6 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.

As outlined in Sections 4.2.3 (Human Health Assessment) and 4.2.5 (Environmental Health Assessment), the extended 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).

5.7 Competitiveness and Innovation

Extending the CSA obligation to 1-10t 'CMRs 1A/1B' would promote the consistent application of recommended risk management measures across downstream users. Harmonising the regulatory framework in this way is likely to provide benefits in terms of consistency and competition.

Regarding innovation impacts and product withdrawal, the extension of the CSA obligation is, in itself, unlikely to lead to further product withdrawals. By far the most significant factor in relation to product withdrawal is the cost of generating information in relation to classification for mutagenicity (which is estimated to cost around €42,300 per substance – see Annex I). Thus, if product withdrawal is to occur, it will have occurred before the need to conduct a CSA has been established owing to classification as a category 1B mutagen.

Even in the event that some small level of product withdrawal occurred (which as noted is unlikely), owing to the fact that the estimated 154 1-10t 'CMRs 1A/1B' represent around 0.6% of the total number of 1-10t substances (20,000), any impacts on innovation of the EU chemicals market could be expected to be insignificant.

6 Conclusions

The net costs for manufacturers, importers and downstream users are provided in Table 6.1. Costs are given for both currently unknown and known 1-10t 'CMRs 1A/1B' as well as the total across both.

For the 108 1-10t substances with, as yet, unknown 'CMR 1A/1B' properties the estimates suggest that:

- there is a net benefit of around €19.4 million to downstream users in relation to compliance with parallel regulation on CMRs that is triggered by classification as C, M, or R 1A/1B in accordance with Regulation (EC) No 1272/2008;
- the CSA obligation would cost manufacturers and importers a total of around €3 million;
- as a result, across all actors and costs, there is a total net benefit of around €16.4 million; and
- on the basis of costs alone, extending the CSA obligation to CMRs 1A/1B that are, as yet, unknown and unregistered, the extension is likely to be justified.

For the 46 1-10t substances with known 'CMR 1A/1B' properties, downstream users are likely to have already complied with the parallel regulation on CMRs that is triggered by classification as C, M, or R 1A/1B in accordance with Regulation (EC) No 1272/2008. As such, there are no/few benefits to downstream users of these substances in relation to compliance with parallel regulation and the estimated costs of extending the CSA obligation are around €1.3 million for manufacturers/importers and €3.2 million for downstream users.

Table 6.1: Net Costs of Extending the CSA Obligation to 1-10t 'CMRs 1A/1B'

	Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'	All 'CMRs 1A/1B'
Overall Costs to Manufacturers and Importers	€ 2,976,480	€ 1,306,260	**€ 4,282,740**
Overall Costs to Downstream Users	€ 7,573,986	€ 3,225,957	**€ 10,799,943**
Savings to Downstream Users (compliance costs avoided)	€ 27,000,000	€ 0	**€ 27,000,000**
Net costs to Downstream Users (a negative cost is a benefit)	-€ 19,426,014	€ 3,225,957	**-€ 16,200,057**
Net Costs of extending the CSA obligation to 1-10t 'CMRs 1A/1B' (a negative cost is a benefit)	**-€ 16,449,534**	**€ 4,532,217**	**-€ 11,917,317**

Viewed across all of the 154 1-10t substances known and yet to be identified with 'CMR 1A/1B' properties, there is a net benefit of around €11.9 million for the extension of the CSA obligation. This suggests that the extension of the CSA obligation to all 1-10t 'CMRs 1A/1B' is justified by the cost savings to downstream users alone[26]. In addition to the benefits to downstream users,

[26] It should be noted that all of the costing scenarios presented in Annex II suggest that extending the CSA obligation to all substances is likely to be justified on the basis of the cost savings to downstream users.

extending the obligation will deliver a number of other benefits where these are summarised in Table 6.2.

Table 6.2: Benefits of Extending the CSA Obligation to 1-10t 'CMRs 1A/1B'	
Benefit	**Description**
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.
Adequate Risk Management Measures in Relation to Articles	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.
Identification of PBT/vPvB Substances	Extending the CSA/CSR obligation to 1-10t 'CMRs 1A/1B' is likely to permit the detection and control of around three PBT/vPvB substances that would not otherwise be identified.
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.
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. The extended 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).

Estimation of the magnitude of each these benefits in economic terms is complicated by a number of confounding factors. However, ultimately one of the main objectives of extending the obligation would be the avoidance of cancer and cancer fatalities.

A cancer fatality is valued at €2 million per case, based on the value of a statistical life. The value of avoiding a non-fatal cancer is based on a willingness to pay estimate to avoid a non-fatal cancer case

of €450,000[27]. For the purposes of example, a benefit of, say, €10 million would be achievable if extending the CSA obligation:

- prevented five cancer fatalities; or
- prevented 22 non-fatal cancers.

Concerning innovation and competitiveness, extending the CSA obligation to 1-10t 'CMRs 1A/1B' would promote the consistent application of recommended risk management measures across downstream users. Harmonising the regulatory framework in this way is likely to provide benefits in terms of consistency and competition. There are no significant impacts on innovation in the EU chemicals industry.

[27] See ECHA's Guidance on Socio-Economic Analysis under Restrictions, 2009

Annex 1 Estimation of Numbers of Substances meeting a CMR 1A/1B Criterion

A1.1 Numbers of 1-10t Substances

A1.1.1 Starting Point

It is estimated by ECHA that full registration for 20,000 unique substances will be submitted in the 1-10t band. A proportion of these will have to submit full data for Annex VII and, in the process of generating the data for Annex VII, it is expected that a proportion of these will be identified with 'CMR 1A/1B' properties that were previously unknown[28].

In terms of the currently unknown 1-10t 'CMRs 1A/1B', a review of the regulation combined with ECHA's "*Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.7a: Endpoint Specific Guidance*[29]" suggests that these substances are restricted in the first instance to those that:

1. require full Annex VII information; AND
2. present positive for the Annex VII gene mutation test (Annex VII); AND
3. present positive OR negative for either or both of CAbvitro/MNT Vitro or GMvitro (Annex VIII); AND
4. present positive for either or both of Cytvivo or GMVivo[30] (Annex IX).

Substances meeting the above criteria would be identified as genotoxic and would be considered as follows:

A. **if expert judgment on available data or further mutagenicity testing suggests there is a mutagenic hazard to germ cells:** substances are subsequently classified as genotoxic in germ cells (Mut. 1B). By virtue of this classification, under the ECHA guidance, they would also be regarded in the genotoxic carcinogens (even though actual classification for carcinogenicity is unlikely). Owing to a Mut. 1B classification (or Carc. a 1A/1B if made), under the ECHA guidance, consideration of toxicity to reproduction is also required. It must be established "*that appropriate risk management measures addressing potential carcinogenicity, genotoxicity and reproductive toxicity have been implemented*"; or

[28] 1-10t Substances with already known 'CMR 1A/1B' properties are already registered and hence are not included in the 20,000 figure above.

[29] Latest version is #2.4 of February 2014 but this is currently being revised. This report is based upon the revisions set out in the Draft version 3.0 February 2014 for consultation with ECHA's Committees in relation to mutagenicity combined with those set out in #2.4 of February for carcinogenicity and reproductive toxicity (requirements for which are not part of the abovementioned revision).

[30] 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

B. **if expert judgment on available data or further mutagenicity testing suggests that the substance has a demonstrated lack of systemic availability and there is NO mutagenic hazard to germ cells:** substances are subsequently classified as genotoxic in somatic cells (Mut. 2). By virtue of this classification, under the ECHA guidance, in the absence of clear evidence to the contrary they would also be considered to be genotoxic carcinogens. However, the ECHA guidance notes that actual classification for carcinogenicity is unlikely. As such, unless the substances were classified as Carc. 1A/1B (which as noted is unlikely) there would be no need to consider toxicity to reproduction (and hence no classification or need to establish "*that appropriate risk management measures addressing potential carcinogenicity, genotoxicity and reproductive toxicity have been implemented*").

As a result, the only substances that might be identified as C, M, or R 1A/1B are those that:

- Conform to the conditions in A (above) and are thus classified as Mut. 1B (or 1A);
- Conform to the conditions in B (above) and, although only classified as Mut. 2, consideration for carcinogenicity results in a classification as Carc. 1A/1B. According to the ECHA guidelines this is expected to be unlikely (and hence rare).

Substances that do not meet these criteria would be considered as non-genotoxic and would not be considered further in relation to carcinogenicity or reproductive toxicity.

A1.1.2 *In Vivo* versus *In Vitro* Testing

In relation to the *in vitro* and *in vivo* tests required by the application of Annexes VII-XI it is worth noting that the ultimate determinant of whether a substance is or is not genotoxic is the *in vivo* testing (Cytvivo and/or GMVivo) described in Annex IX.

The information requirements set out in REACH have been developed in a way that limits *in vivo* testing to the extent possible so as to reduce both costs of testing and also animal welfare issues. As such, batteries of *in vitro* studies must be carried out first and, where these signal that a substance may have mutagenic properties, *in vivo* testing is required to establish for certain whether or not the substance is or is not genotoxic.

However, *in vitro* studies (and QSARs) 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).

The UK Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM)[31] recently reviewed the literature in relation to the sensitivity and specificity of different *in vitro* tests and testing batteries. Table A1.1 summarises these data.

Table A1.1: Genotoxicity Tests *(in vitro)* in Relation to Rodent Carcinogenicity			
Method	**Sensitivity[a]**	**Specificity[b]**	**Comments/references**
Ames	59%	74%	541 chemicals (Kirkland et al., 2005a)
Ames	52%	72%	3711 chemicals including tests with *Salmonella* and *Escherichia* (Matthews et al., 2006a)
Micronucleus *(in vitro)*	79%	31%	89 chemicals (Kirkland et al., 2005a)
Micronucleus *(in vitro)*	88%	23%	182 chemicals (Matthews et al., 2006a)
Chromosomal aberrations *(in vitro)*	66%	45%	352 chemicals (Kirkland et al., 2005a)
Chromosomal aberrations *(in vitro)*	55%	63%	1391 chemicals (Matthews et al., 2006a)
Mouse lymphoma assay	73%	39%	245 chemicals (Kirkland et al., 2005a)
Mouse lymphoma assay	71%	44%	827 chemicals (Kirkland et al., 2005a; Matthews et al., 2006a)
Ames + Micronucleus* combined	94%	12%	372 chemicals. Positive results in at least one test.(Kirkland et al., 2005a)
Ames + mouse lymphoma* combined	89%	32%	436 chemicals (Kirkland et al., 2005a)
Ames+ mouse lymphoma +Chromosomal aberrations combined	84%	23%	202 chemicals (Kirkland et al., 2005a)
Ames + mouse lymphoma + micronucleus* combined	91%	5%	54 chemicals (Kirkland et al., 2005a)
*Positive results in at least one test a: accurate prediction of rodent carcinogenicity b: accurate prediction of rodent non-carcinogenicity			

In terms of interpretation of such data, using the example of the Ames test in Table A1.1, the sensitivity values suggest that this *in vitro* test is able to correctly identify 52% of *in vivo* rodent carcinogens. As such, 48% of the *in vivo* rodent carcinogens will not be identified with these properties.

In terms of specificity, the values for the Ames test suggest that this *in vitro* test is able to correctly identify 72% of *in vivo* rodent non-carcinogens. Importantly, this means that this *in vitro* test will falsely identify that 28% of the *in vivo* rodent non-carcinogens are likely to be *in vivo* rodent carcinogens.

[31] 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

In relation to the application of Annex VII to the 1-10t substances, this means that around 28% of the 1-10t substances that are not mutagenic are likely to be falsely identified as potential *in vivo* mutagens. Application of the REACH Annexes and the Integrated Testing Strategy (ITS) means that these substances will be required to generate test information for the endpoints including both of the *in vivo* tests (Cytvivo and GMVivo) in Annex IX before their non-mutagenic status can be established and a non-genotoxic conclusion can be reached. Whilst these substances will not be classified as genotoxic (and hence will not meet a CMR 1A/1B criterion) they will incur costs of testing similar in magnitude to those substances that are subsequently classified as mutagenic.

The following subsections consider the numbers of 1-10t substances that will undergo testing and the number of substances that will be classified for mutagenicity (and will reach the CMR 1A/1B criterion).

A1.2 Estimating Numbers of Substances undergoing Testing

In order to estimate the numbers of mutagenic and mutagenic and non-mutagenic substances that will undergo full testing for mutagenicity concluding in *in vivo* testing it is necessary to estimate the expected number of mutagens and non-mutagens in the population of 20,000 1-10t substances expected to register.

The starting point for the estimation is the total number substances likely to possess properties that would result in classification as Mut. 1A, 1B or 2 if *in vivo* testing were applied. The only source of information on the numbers of actual mutagens likely to be identified is statistical information on the current percentage of substances with classification for mutagenicity within the overall population of substances for which there is information (and hence properties are known). Data in the Classification and Labelling Inventory (CLI) suggests that there are currently 2,177 substances meeting these criteria out of a total of 117,371 substances with classifications on the on the CLI (i.e 1.85%).

In terms of the 1-10t substances, as noted above, it is assumed that there are 20,000 unique substances that will be registered in the 1 to 10 tonnage band. Applying the 1.85% value to this figure suggests that 370 of the 1-10t substances could be expected to be *in vivo* mutagens and thus meet the criteria for Mut. 1A/1B or 2.

By extension, 19,630 of the 1-10t substances are not *in vivo* mutagens.

A1.2.1 Substances Required to Submit Full Annex VII Data

According to Article 12 and Annex III of REACH, only the following substances are required to submit the full Annex VII data:

- those "*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 CMRs 1A/1B; and
- those substances that have both a dispersive/diffuse use and which have or are predicted *"by application (Q)SARs and other evidence*" to have any human health or environmental classification.

Substances Predicted as likely to meet the CMR 1A/1B Criterion

In relation to the former (numbers predicted by (Q)SARs), Table A1.2 provides information on the sensitivity of different (Q)SAR models in terms of the correct identification of mutagens or rodent carcinogens (sensitivity) and non-mutagens or rodent non-carcinogens (specificity) (UKCOM, 2011[32]). These data, in combination with discussions with ECHA (pers. comm. 2014), suggest that:

- around 70% of the 370 currently unknown Mut. 1A/1B or 2 might be correctly identified as being "*likely to meet the criteria*" for CMRs 1A/1B by the application of (Q)SAR or other evidence[33]; and

- around 75% of the 19,630 non-Mut. 1A/1B or 2 would be correctly identified as **NOT** being "*likely to meet the criteria*" for CMRs 1A/1B by the application of (Q)SAR or other evidence.

Thus, 70% of the 370 mutagenic substances (259) would be required to submit full Annex VII data because they meet this Annex III criterion (and 111 would not be identified).

In addition, 25% of the 19,630 non-mutagenic substances (4,908) would be falsely identified as potentially mutagenic and would have to submit full Annex VII data because they meet this Annex III criterion (and 15,092 would not).

Table A1.2: Sensitivity of Different (Q)SAR Models in terms of the Correct Identification of (known) Mutagens or Rodent Carcinogens

Method	Sensitivity Identification of mutagens or rodent carcinogens	Specificity Identification of non-mutagens or rodent non-carcinogens	Comments/references
MDL QSAR	81%	76%	3338 compounds tested in bacterial mutagenicity tests (Contrera et al., 2005)
MultiCASE (MC4PC)	71% (bacterial) 63% (mouse lymphoma) 44% (clastogenicity in vitro) 53% (clastogenicity)	88% (bacterial) 74% (mouse lymphoma) 92% (clastogenicity in vitro) 75% (clastogenicity)	1485 compounds, bacterial. 328 compounds for mouse lymphoma. 556 compounds for clastogenicity (Matthews et al., 2006). 679 compounds (Roithfuss et al., 2006)
Toxtree (version 1.50)	74% (rodent carcinogenicity) 85% (bacterial mutagenicity	64% (rodent carcinogenicity) 72% (bacterial mutagenicity)	878 chemicals with carcinogenicity data, 698 chemicals with mutagenicity data (Benigni and Bossa, 2008)

[32] 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

[33] Assuming that (Q)SAR or other evidence is gathered where it is missing and is reliable. Here, unlike other areas of the Regulation, no specific requirements as to the reliability of the models are stipulated in Annex III nor does Annex III specifically identify that (Q)SAR data should be generated where it is missing.

Substances predicted to have any Human Health or Environmental Classification and a Diffuse Use

In relation to substances having both dispersive/diffuse use and any human health/environmental classification), of the 111 mutagenic substances not identified as being "*likely to meet the criteria*" for CMRs 1A/1B by the application of (Q)SAR or other evidence, a proportion will still be required to submit full Annex VII data owing to their having both a dispersive/diffuse use and having (or being predicted *"by application (Q)SARs and other evidence*" to have) any human health or environmental classification.

In previous studies it has been 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) resulting in the overall assumption that around 30% of substances have one or more dispersive/diffuse uses.

Applying this value of 30% would suggest that around 33 of the 111 substances with actual (but, as yet, unidentified) Mut. 1A/1B or 2 properties would have one or more diffuse/dispersive uses. If it is (conservatively) assumed that all of these 33 substances have (or would be predicted *"by application (Q)SARs and other evidence*" to have) any human health or environmental classification, then full Annex VII data would have to be submitted for a further 33 substances.

In terms of the 15,092 non-mutagenic substances not identified as being likely to meet the CMR 1A/1B criterion in Annex III, 4,528 (30%) may have one or more diffuse/dispersive uses. If it is assumed that 70% of these are predicted to also have one or more human health or environmental classifications, then a further 3,170 non-mutagenic substances would have to submit full Annex VII data.

Total Substances Submitting full Annex VII Data

Combining the above, the following numbers of substances would be required to submit full Annex VII data:

- 292 mutagenic substances (whose mutagenic properties are yet to be identified but are suspected for 259 of those substances by the application of QSARs and a further 33 for which no mutagenic properties are suspected through QSARs but other human health or environmental classifications are predicted and there are one or more a dispersive/diffuse uses); and

- 8,078 non-mutagenic substances (whose non-mutagenic properties are yet to be established but 4,908 have been falsely identified with potential mutagenic properties by QSARs and a further 3,170 for which no mutagenic properties are suspected through QSARs but other human health or environmental classifications are predicted and there are one or more a dispersive/diffuse uses).

A1.3 Genotoxic Substances Identified by Collection of Full Annex VII Data

All substances submitting full Annex VII data are required to gather data in relation to the Annex VII gene mutation test (GMBact). In the event of a positive result, substances are required to gather additional data as appropriate to the Integrated Testing Strategy (ITS) established by the ECHA endpoint specific guidelines. Thus, in addition to information on GMBact the following would be required in the event of a positive result for GMBact:

- either or both of CAbvitro/MNT Vitro or GMvitro in vitro tests in Annex VIII as appropriate to the ITS; and
- Cytvivo or GMvivo[34] in vivo tests in Annex IX as appropriate to the ITS.

Note that, according to the ITS set out in ECHA's guidance[29] (see for example Figure R.7.7-1 Flow chart of the mutagenicity 1 testing strategy) *in vivo* testing is required to finally establish the genotoxicity conclusion after a positive result for GMBact.

For those substances presenting negative for GMBact it would be concluded that the substance was not genotoxic and no further testing would be required in relation to mutagenicity.

As has been discussed earlier, *in vitro* tests are not 100% accurate in their predictions. Rather, tests differ in terms of their ability to correctly identify mutagens as mutagens (sensitivity) and non-mutagens as non-mutagens (specificity). Table A1.1 provided data on the specificity and sensitivity of different tests.

Drawing on these values, Table A1.3 sets out the assumptions applied in this analysis in relation to each of the tests. As can be seen from Table 3, for example, the Annex VII test endpoint (GMBact) has a sensitivity of around 52%, meaning that a test will:

- correctly record a positive result for 52% of mutagens; and
- conversely, incorrectly record a negative result for 48% of mutagens.

This, in turn, means that, of the 292 substances with currently unknown Mut. 1A/1B or 2 properties providing full Annex VII data:

- 152 (52%) will be identified as needing further data from endpoints in Annexes VIII, IX and X; and
- 140 (48%) will be identified as non-genotoxic and no further testing will be required.

In relation to the same test endpoint, 72% of the 8,078 non-mutagenic substances submitting full Annex VII data will be correctly identified as being non-mutagenic. However, 28% (2,262) will be incorrectly identified as potentially mutagenic and will need to gather data for relevant endpoints in Annexes VIII, IX and X.

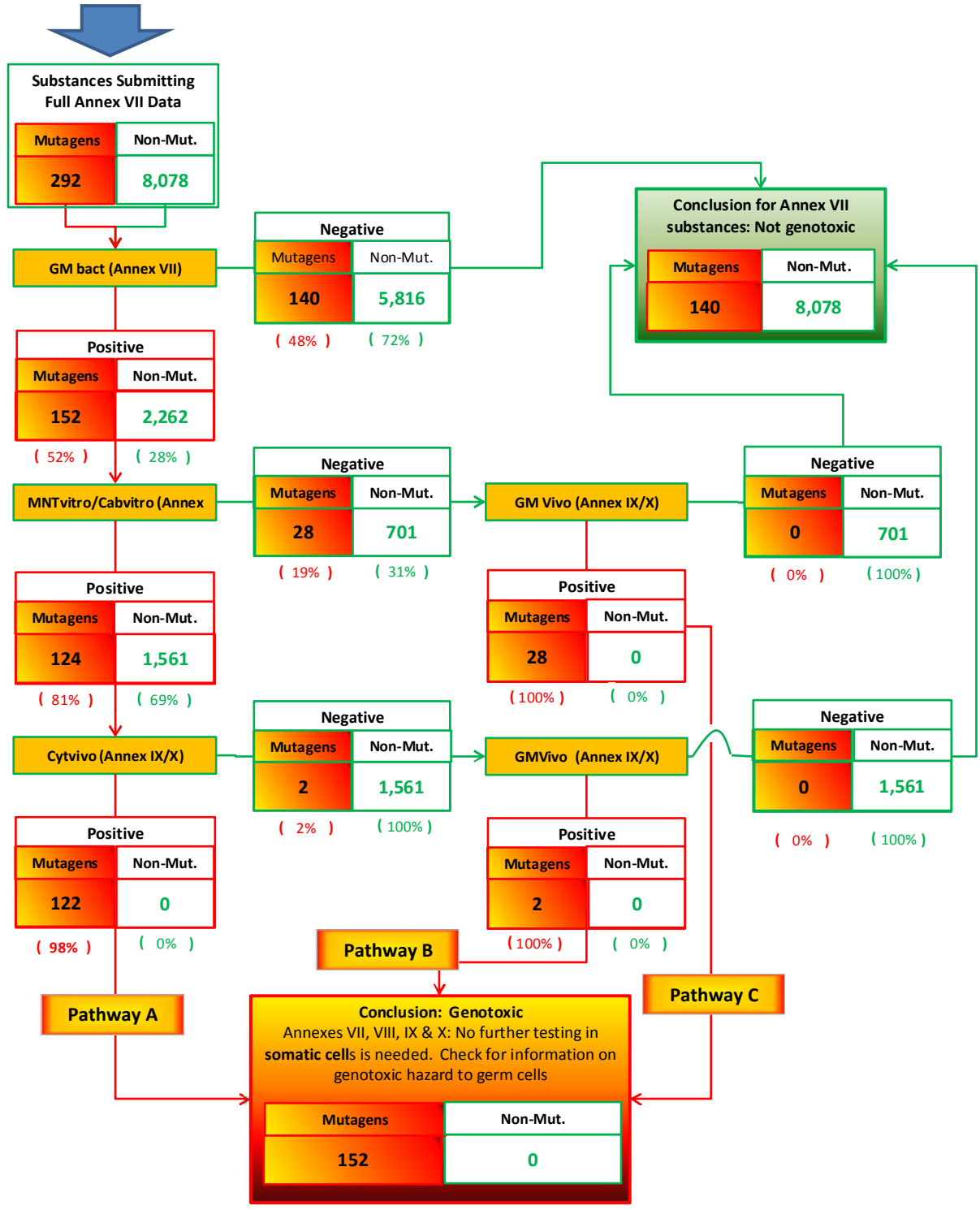
[34] GMbact: gene mutation test in bacteria (Ames test); CAbvitro, in vitro chromosome aberration test; MNTvitro, in vitro micronucleus test; GMvitro:gene mutation assay in mammalian cells; Cytvivo:cytogenetic assay in experimental animals; GMvivo:gene mutation assay in experimental animals

Table A1.3: Sensitivity and Specificity Data Applied in the Analysis			
Test	**Sensitivity**	**Specificity**	**Comments/references**
GMBact	52%	72%	3711 chemicals including tests with *Salmonella* and *Escherichia* (Matthews et al., 2006a)
MNTvitro	88%	23%	182 chemicals (Matthews et al., 2006a)
CAbvitro	55%	63%	1391 chemicals (Matthews et al., 2006a)
MNTvitro/CAbvitro	81.4%	31%	Based on 80% undertaking MNTvitro and 20% Cabvitro
GMvitro	71.0%	44%	827 chemicals (Kirkland et al., 2005a; Matthews et al., 2006a)
Cytvivo combined with GMvivo	100%[35]	100%	The battery of *in vivo* tests are the ultimate determinant of substances are or are not regarded as mutagenic and hence the battery of *in vivo* tests are, by definition, 100% sensitive and 100% specific.

Applying the sensitivity and specificity values in Table A1.3, Figure A1.1 summarises the numbers of substances providing different levels of information and the associated conclusions in relation to genotoxicity (as noted above).

[35] The combined sensitivity of both tests is 100%. However, to capture the possibility that the Cytvivo test might fail to detect a positive result and require a further GMvivo test to detect the positive (with associated costs), in the calculations, 98% sensitivity has been applied for Cytvivo and 100% for GMvivo.

Figure A1.1: Outcome of Testing in Accordance with the Integrated Testing Strategy

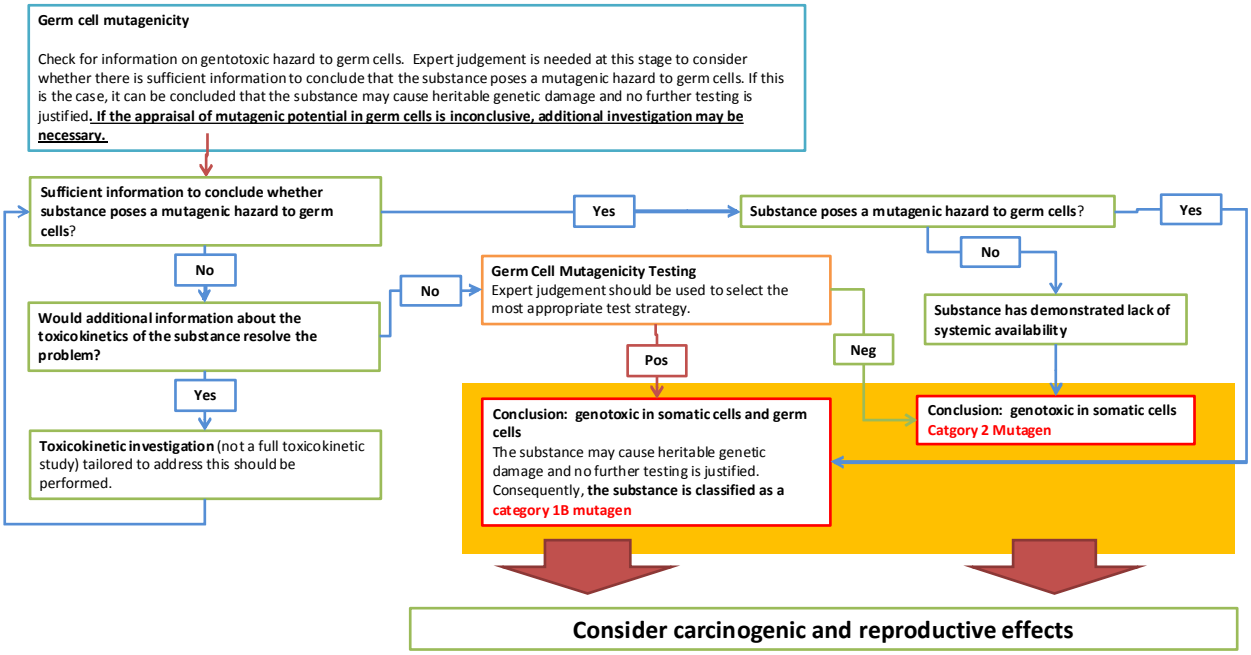


As can be seen from Figure A1.1, the analysis suggests that around 152 substances are likely to be identified as being genotoxic in (at least) somatic cells. Once genotoxicity to somatic cells has been concluded, according to ECHA's ITS, there is a need to check whether there is sufficient information

to conclude that a substance poses a mutagenic hazard to germ cells. If this is the case, it can be concluded that the substance may cause heritable genetic damage, the substance is classified as a category 1B mutagen and no further testing is justified. If the appraisal of mutagenic potential in germ cells is inconclusive, additional investigation may be necessary. If there is sufficient information available to suggest that the substance is not a hazard to germ cells and there is a demonstrated lack of systemic availability then the substance is classified as a category 2 mutagen.

The steps are summarised in Figure A1.2.

Figure A1.2: Consideration of Germ Cell Mutagenicity



In terms of the division of the 152 substances identified as genotoxic into those that are hazardous to germ cells (category 1B mutagens) and those that are not (category 2 mutagens) there is little information on which to base a quantitative prediction. However, it is thought likely that 70% of these will be identified as germ cell mutagens and the remainder as somatic cell mutagens producing the following numbers of each:

- category 1B mutagens (germ cell mutagens) = 106
- category 2 mutagens (somatic cell mutagens) = 46

The identification of these 152 mutagenic substances is also accompanied by the need for further testing on the 2,262 non-mutagens incorrectly identified as being potentially mutagenic by mutagenicity testing in Annex VII. Both sets of substances (mutagenic and non-mutagenic) follow one of three pathways to the appropriate conclusion (genotoxic or non-genotoxic). Drawing on Figure A1.1, Table A1.4 summarises the numbers of each type of substance going through each testing pathway and the associated costs (based on testing costs in the 2012 CEFIC testing catalogue).

From Table A1.4, it can be seen that the total costs of further mutagenicity testing (i.e. Annex VIII and above and hence additional to the Annex VII testing costs) for all mutagenic substances (152) are around €6.4 million (making an average cost per substance of around €42.4 thousand).

For the 2,262 non-mutagenic substances the total costs are much higher (mainly owing to the larger number of them compared with mutagenic substances). Here the total costs for all 2,262 substances are around €111 million (making an average of around €49 thousand per substance).

Table A1.4: Pathways and Estimated Costs of 'Further Mutagenicity Testing'				
	Annex	Pathways (see Figure A1.1)		
		A	B	C
In vitro mutagenicity tests	**Annex VII**	GMBact	GMBact	GMBact
	Annex VIII	Cytvitro	Cytvitro	Cytvitro
In vivo mutagenicity tests	**Annexes IX/X**	Cytvivo	Cytvivo	GMvivo
			GMvivo	
Cost of further In vitro mutagenicity testing	**Annex VIII**	€17,231	€17,231	€17,231
Cost of further in vivo mutagenicity testing	**Annexes IX/X**	€27,730	€40,350	€12,620
Total cost of further testing	**Annexes VIII to X**	**€44,961**	**€57,581**	**€29,851**
Number of Genotoxic Substances through each Pathway		122	2	28
Number of Non-genotoxic Substances through each Pathway		0	1,561	701
Total costs for genotoxic substances		**€ 5,485,198**	**€115,162**	**€835,826**
Total costs for non-genotoxic substances		**€0**	**€89,883,847**	**€20,925,509**

A1.4 Numbers of 1-10t Substances meeting CMR 1A/1B Criterion

As noted in Section A1.1, the only substances that might be identified as C, M, or R 1A/1B are those that are:

- classified as Mut. 1B (or 1A);
- classified as Mut. 2 but consideration for carcinogenicity triggered by this classification results in a classification as Carc. 1A/1B. According to the ECHA guidelines this is expected to be unlikely (and hence rare).

As noted above, the analysis suggests that 106 substances are likely to be classified as Mut. 1B and, hence, would be required to undertake a CSA under any extended obligations. Assuming a small percentage (~5%) of those 46 substances classified as Mut. 2 would also be classified as Carc 1A/1B (which, as noted, is expected to be rare) suggests an additional 2 substances meeting the CMR 1A/1B criteria for any extended CSA obligation.

As such, assuming that all substances proceed with registration, a total of around 108 substances with previously unknown mutagenic properties would be identified as meeting a CMRs 1A/1B criterion.

A1.5 Final Estimates of 1-10t CMRs 1A/1B

The final estimates of the numbers of substances that would be affected by any extended CSA/CSR obligations are:

- **108 previously unknown 1-10t CMRs 1A/1B; and**
- **46 known and already registered 1-10t CMRs 1A/1B (if the CSA/CSR obligation were to act retrospectively).**

A1.6 Estimation of 1-10t CMRs that are also PBT/vPvB

Based on the work of Strempel *et al* (2012)[36] and others, screening for P, B and T is likely to identify that 2% of substances exhibit PBT characteristics. However, based on ECB (2002)[37], it is also estimated that around 20% of the substances with potential PBT characteristics are actual PBT substances (i.e. 0.4% overall).

From Strempel *et al* (2012), the combined probability that P, B and T is met (PBT3) is 'around 2%' and also the probability that none of the criteria are met (PBT0) is 60%. Using these data and an overall probability of a possible T classification of around 0.21 (21%), one can back-calculate to derive probabilities that fit broadly with Strempel *et al* findings in relation to scores for PBT. These are provided in Table A1.5.

Table A1.5: Calculated Probabilities for P, B and T

Variable	Calculated Probability Values
T - Probability of T	0.210
B - Probability of B	0.168
P1 - For substance meeting B, probability of P	0.567
P0 - For substance NOT meeting B, probability of P	0.083

Applying these probabilities to calculate values for PBT outcomes provides a means to cross check values with the estimates of Strempel *et al* (2012). Figure A1.3 provides a tree diagram describing all combinations and associated combined probabilities and Table A1.6 compares calculated values with those of Strempel *et al* (2012).

[36] Strempel et al (2012): *Screening for PBT Chemicals among the "Existing" and "New" Chemicals of the EU*, Environ. Sci. Technol. 2012, 46, 5680−5687.

[37] ECB (2002): Identification of Potential PBTs or vPvBs Among the IUCLID High Production Volume Chemicals (ECB 4/14/02 (PBT strategy – report).

Figure A1.3: Tree diagram with associated combined probabilities for PBT outcomes

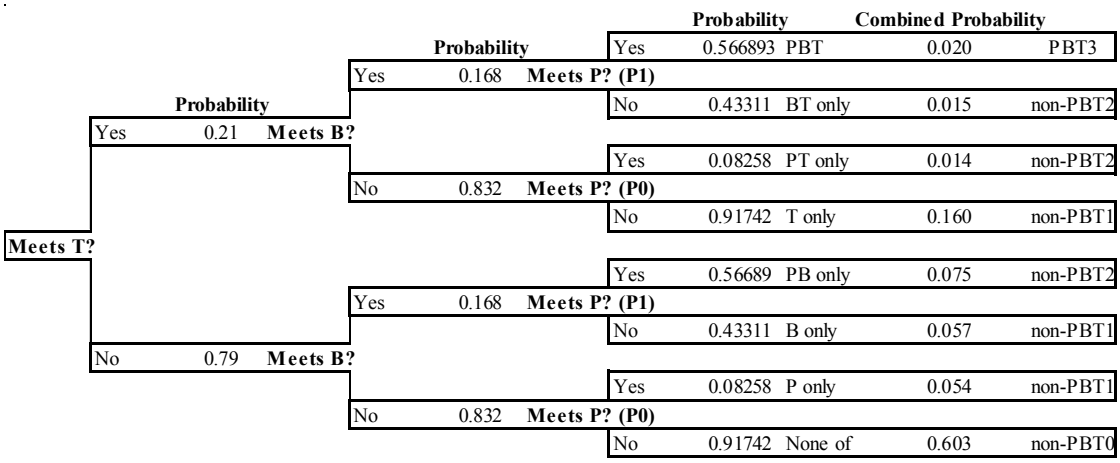
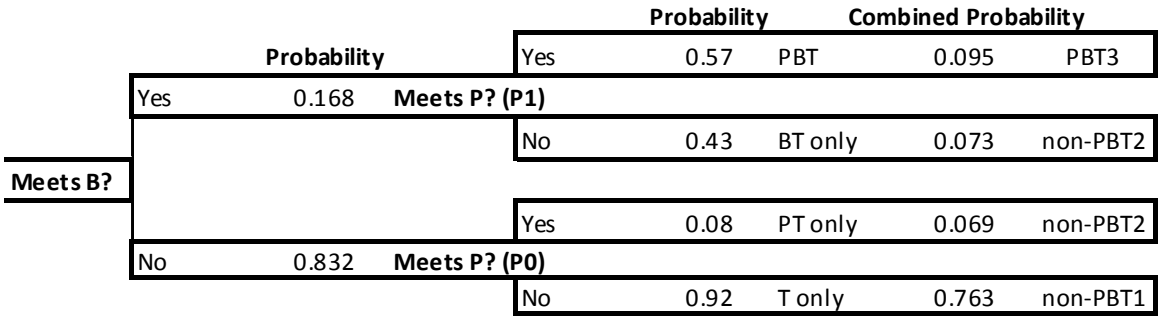


Table A1.6: Comparison of Calculated Probability Values with Those of Scheringer *et al* (2012)		
Outcome	**Calculated Combined Probability**	**Estimates from Strempel *et al* (2012)**
PBT3	2.00%	3.5% or "around 2%"
non-PBT2	10.49%	10.10%
non-PBT1	27.21%	26.10%
non-PBT0	60.30%	60.30%

As can be seen from Table A1.6, the calculated probabilities provide a reasonable approximation of the outcome of screening and of the numbers of substances likely to be identified by screening as potentially being PBT.

Applying this to the situation for 1-10t CMRs 1A/1B, such substances automatically reach the criteria for T (and as such the probability of T in this case is 1 or 100%). Applying the probabilities for P and B set out above provides a prediction of the combined probability that a CMRs 1A/1B will be identified as PBT by screening where this is provided in the tree diagram in Figure A1.4.

Figure A1.4: Tree diagram with associated combined probabilities for PBT outcomes for CMRs 1A/1B



As can be seen from Figure A1.4, the analysis suggests that around 9.5% of the CMRs 1A/1B are likely to be identified as potential PBTs by screening. As such, the numbers of substances that would be required to gather further data to complete the PBT assessment as part of a CSA/CSR are:

- **10 of the 108 previously unknown 1-10t CMRs 1A/1B; and**
- **4 of the 46 known and already registered 1-10t CMRs 1A/1B (if the CSA/CSR obligation were to act retrospectively).**

As noted earlier, however, screening will tend to overestimate the number of actual PBT substances and, based on ECB (2002), it is further estimated that around 20% of the substances with potential PBT characteristics are actual PBT substances.

As such, in terms of actual PBTs identified by a PBT assessment required by a CSA/CSR, the following numbers are likely to be confirmed as PBT:

- **2 of the 108 previously unknown 1-10t CMRs 1A/1B; and**
- **1 of the 46 known and already registered 1-10t CMRs 1A/1B (if the CSA/CSR obligation were to act retrospectively).**

Annex 2 Cost Estimates under Different Costing Scenarios

This Annex provides estimates of costs based on low, medium and high scenarios. The medium scenarios have been reported on in the main text of the report.

Table A2.1 (overleaf) provides an overview of the estimates and assumptions applied in each case along with brief notes on reasoning behind the numbers used. As with previous assessments of the impacts on REACH and substances not yet registered, there remains a paucity of information on markets for substances and also on other aspects. This is why a scenario based approach has been used to cover the range of possibilities.

Tables A2.2, A2.3, and A2.4 provide the cost estimates for the low, medium and high scenarios respectively.

Table A2.1: Summary of Assumptions and Estimates for Scenario Modelling

		Low	Med	High	
		All 1-10t 'CMRs 1A/1B'	All 1-10t 'CMRs 1A/1B'	All 1-10t 'CMRs 1A/1B'	Notes
	Number of uses per substance	1	2	5	The 2006 revised BIA and the Commission's Extended Impact Assessment assumed 1 use per substance in addition to manufacturer's own use and 20 downstream users per
	Number of Downstream Users (DUs) per use	20	50	200	
Robust Study Summaries	Number of studies to summarise (HH and ENV)	7	7	7	Derived in the main report.
	Cost of producing a Study Summary	€ 100	€ 150	€ 250	Representing a spread of possibilities
	Cost of producing a Robust Study Summary	€ 200	€ 350	€ 500	Costs of producing summaries in the revised BIA were assumed to be €500-750 in total for all summaries produced. This is considered to be an underestimate and has been adjusted upwards.
PBT/vPvB Assessment	Cost of additional informtion for assessment of P:	€ 2,000	€ 10,000	€ 60,000	The medium scenario assumes assessment based on an overall cost of €20,000 per substance for additional studies on toxicokinetics and expert assessment plus other follow up studies. The high scenario uses full testing costs from the CEFIC testing catalogue. The low assumes some additional information combined with accepting the results of the screening
	Cost of additional informtion for assessment of B:	€ 2,500	€ 10,000	€ 70,000	
Costs of producing CSA (Manufacturers)	Percentage of substances where the exposure scenarios for the manufacturer's own use also covers downstream uses	90%	50%	20%	Estimates based on a range of possibilities.
	Cost of Human Health Exposure Assess and Risk Characterisation per use	€ 1,500	€ 3,000	€ 5,000	Medium and high scenarios based on consultancy costs of producing exposure scenarios for the Authorisations that RPA is working on.
	Cost of Environmental Exposure Assess and Risk Characterisation per use	€ 1,000	€ 2,000	€ 3,000	
Communication in the Supply chain	Cost of adding the results of the PBT/vPvB assessment to the SDS per substance	€ 10	€ 10	€ 10	Estimate
	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	Estimate
	Cost of including the relevant exposure scenario(s) in an annex to the SDS per use	€ 200	€ 300	€ 500	Estimate covering a range of possibilities
	Percentage of substances where translation of eSDS will be needed	30%	50%	70%	Estimate covering a range of possibilities
	Number of languages to translate into	3	3	3	Estimate
	Cost of translation per language	€ 100	€ 150	€ 200	Estimate
Duty to Pass Information Sufficient for an Exposure Assessment up the Supply Chain	Cost for DU to provide information to Human Health Exposure Scenario	€ 200	€ 350	€ 500	Estimate covering a range of possibilities
	Cost for DU to provide information to Environmental Exposure Scenario	€ 200	€ 350	€ 500	Estimate covering a range of possibilities
Article 37(4) - Duty to prepare a CSR in Accordance with Annex XII	Percentage of substances where Article 37(4) might apply	5%	5%	5%	Estimate

			Currently Unknown 'CMRs 1A/1B' - Non-threshold	
Reduced Costs of Compliance with Parallel Regulation	Cost for a DU to conduct assessments to comply with parallel regulation	Low	€ 1,500	Estimates covering a range of possibilities and based on likely time to complete assessments and associated costs.
		Med	€ 2,500	
		High	€ 3,500	

Table A2.2: Cost Estimates - Low Scenario

Numbers and types of 'CMRs 1A/1B'		All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
	Number of 'CMRs 1A/1B'	108	46
	Number of possible PBTs identified by screening	10	4
	Number of uses per substance	1	1
	Number of Downstream Users (DUs) per use	20	20
Robust Study Summaries	Number of studies to summarise (HH and ENV)	7	7
	Cost of producing a Study Summary	€ 100	€ 100
	Cost of producing a Robust Study Summary	€ 200	€ 200
	Additional cost of producing Robust Study Summaries for a CSA	€ 100	€ 200
	Overall cost of producing Robust Study Summaries per substance	€ 700	€ 1,400
	Total Cost of Robust Study Summaries for all substances	**€ 75,600**	**€ 64,400**
PBT/vPvB Assessment			
	Number of possible PBTs identified by screening	10	4
	Cost of additional informtion for assessment of P:	€ 2,000	€ 2,000
	Cost of additional informtion for assessment of B:	€ 2,500	€ 2,500
	Overall cost of PBT Assessment per substance	€ 4,500	€ 4,500
	Total Cost of PBT assessment for all substances	**€ 486,000**	**€ 207,000**

Costs of producing CSA (Manufacturers)		All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
	Percentage of substances where the exposure scenarios for the manufacturer's own use also covers downstream uses	90%	90%
	Number of substances where the exposure scenarios for the manufacturer's own use also covers downstream uses	97	42
	Number of substances where the exposure scenarios for the manufacturer's own use DOES NOT also covers downstream uses	11	4
	Number of uses per substance	1	1
	Number of Downstream Users (DUs) per use	20	20
	Cost of Human Health Exposure Assess and Risk Characterisation per use	€ 1,500	€ 1,500
	Cost of Environmental Exposure Assess and Risk Characterisation per use	€ 1,000	€ 1,000
	Overall manufacturer cost per substance across all uses	€ 2,500	€ 2,500
	Total Costs to manufacturers across all substances	**€ 27,500**	**€ 10,000**

Communication in the Supply chain		All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
	Cost of adding the results of the PBT/vPvB assessment to the SDS per substance	€ 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
	Cost of including the relevant exposure scenario(s) in an annex to the SDS per use	€ 200	€ 200
	Percentage of substances where translation of eSDS will be needed	30%	30%
	Number of languages to translate into	3	3
	Cost of translation per language	€ 100	€ 100
	Total cost of translation (where required) per use	€ 300	€ 300
For CSAs where uses overlap with manufacturer uses	Number of substances where the exposure scenarios for the manufacturer's own use also covers downstream uses	97	42
	Number of substances requiring translation	29	12
	Number of uses covered in CSAs	1	1
	Overall cost of producing eSDS per substance	€ 260	€ 260
	Total cost of producing eSDS for all substances	**€ 25,220**	**€ 10,920**
	Overall cost of translation per substance (when required)	€ 300	€ 300
	Overall cost of producing eSDS per substance - where no translation	€ 260	€ 260
	Overall cost of producing eSDS per substance - where translation required	€ 560	€ 560
	Total cost of producing and translating eSDS for all substances	**€ 33,920**	**€ 14,520**
Uses NOT overlapping with Manufacturer uses	Number of substances where the exposure scenarios for the manufacturer's own use DOES NOT also covers downstream uses	11	4
	Number of substances requiring translation	3	2
	Number of uses covered in CSAs	2	2
	Overall cost of producing eSDS per substance	€ 510	€ 510
	Total cost of producing eSDS for all substances	€ 5,610	€ 2,040
	Overall cost of translation per substance (when required)	€ 600	€ 600
	Overall cost of producing eSDS per substance - where no translation	€ 510	€ 510
	Overall cost of producing eSDS per substance - where translation required	€ 1,110	€ 1,110
	Total cost of producing and translating eSDS for all substances	**€ 7,410**	**€ 3,240**
	Total cost of producing and translating eSDS for all substances	**€ 41,330**	**€ 17,760**

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

	All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Number of 'CMRs 1A/1B'	108	46
Cost for DU to provide information to Human Health Exposure Scenario	€ 200	€ 200
Cost for DU to provide information to Environmental Exposure Scenario	€ 200	€ 200
Number of uses per substance	1	1
Number of Downstream Users (DUs) per use	20	20
Overall DU costs per substance	€ 8,000	€ 8,000
Total DU costs for all substances	**€ 864,000**	**€ 368,000**

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	All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Number of 'CMRs 1A/1B'	108	46
Percentage of substances where Article 37(4) might apply	5%	5%
Cost of Environmental Exposure Assess and Risk Characterisation per use	€ 1,000	€ 1,000
Cost of communication in the supply chain (averaged from manufacturers' above)	€ 350	€ 350
Cost per DU completing an Article 37(4) CSA	€ 1,350	€ 1,350
Cost for all DUs completing an Article 37(4) CSA	**€ 7,290**	**€ 3,105**
Total costs of Article 37(4) requirements	**€ 7,290**	**€ 3,105**

Reduced Costs of Compliance with Parallel Regulation

	All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Cost for a DU to conduct assessments to comply with parallel regulation	€ 1,500	€ 0
Overall DU cost per 'CMR 1A/1B' substance	€ 30,000	€ 0
Total DU cost for all 'CMR 1A/1B' substances	**€ 3,240,000**	**€ 0**

Overall Costs

	All Currently Unknown 'CMRs 1A/1B'	All known 'CMRs 1A/1B'	All 1-10t 'CMRs 1A/1B' (known plus unknown)
Total costs to Manufacturers/Importers	**€ 630,430**	**€ 299,160**	€ 929,590
Total costs to Downstream Users	**€ 871,290**	**€ 371,105**	€ 1,242,395
Total Costs to all actors	**€ 1,501,720**	**€ 670,265**	**€ 2,171,985**
Savings to Downstream Users (compliance costs avoided)	**€ 3,240,000**	**€ 0**	**€ 3,240,000**
Net costs to Downstream Users (a negative cost is a benefit)	**-€ 2,368,710**	**€ 371,105**	**-€ 1,997,605**
Net Costs of extending the CSA obligation to 1-10t 'CMRs 1A/1B' (a negative cost is a benefit)	**-€ 1,738,280**	**€ 670,265**	**-€ 1,068,015**

Table A2.3: Cost Estimates - Medium Scenario

Numbers and types of 'CMRs 1A/1B'		All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
	Number of 'CMRs 1A/1B'	108	46
	Number of possible PBTs identified by screening	10	4
	Number of uses per substance	2	2
	Number of Downstream Users (DUs) per use	50	50
Robust Study Summaries	Number of studies to summarise (HH and ENV)	7	7
	Cost of producing a Study Summary	€ 150	€ 150
	Cost of producing a Robust Study Summary	€ 350	€ 350
	Additional cost of producing Robust Study Summaries for a CSA	€ 200	€ 350
	Overall cost of producing Robust Study Summaries per substance	€ 1,400	€ 2,450
	Total Cost of Robust Study Summaries for all substances	**€ 151,200**	**€ 112,700**
PBT/vPvB Assessment			
	Number of possible PBTs identified by screening	10	4
	Cost of additional informtion for assessment of P:	€ 10,000	€ 10,000
	Cost of additional informtion for assessment of B:	€ 10,000	€ 10,000
	Overall cost of PBT Assessment per substance	€ 20,000	€ 20,000
	Total Cost of PBT assessment for all substances	**€ 2,160,000**	**€ 920,000**

Costs of producing CSA (Manufacturers)		All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
	Percentage of substances where the exposure scenarios for the manufacturer's own use also covers downstream uses	50%	50%
	Number of substances where the exposure scenarios for the manufacturer's own use also covers downstream uses	54	24
	Number of substances where the exposure scenarios for the manufacturer's own use DOES NOT also covers downstream uses	54	22
	Number of uses per substance	2	2
	Number of Downstream Users (DUs) per use	50	50
	Cost of Human Health Exposure Assess and Risk Characterisation per use	€ 3,000	€ 3,000
	Cost of Environmental Exposure Assess and Risk Characterisation per use	€ 2,000	€ 2,000
	Overall manufacturer cost per substance across all uses	€ 10,000	€ 10,000
	Total Costs to manufacturers across all substances	**€ 540,000**	**€ 220,000**

Communication in the Supply chain		All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
	Cost of adding the results of the PBT/vPvB assessment to the SDS per substance	€ 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
	Cost of including the relevant exposure scenario(s) in an annex to the SDS per use	€ 300	€ 300
	Percentage of substances where translation of eSDS will be needed	50%	50%
	Number of languages to translate into	3	3
	Cost of translation per language	€ 150	€ 150
	Total cost of translation (where required) per use	€ 450	€ 450
For CSAs where uses overlap with manufacturer uses	Number of substances where the exposure scenarios for the manufacturer's own use also covers downstream uses	54	24
	Number of substances requiring translation	27	12
	Number of uses covered in CSAs	1	1
	Overall cost of producing eSDS per substance	€ 360	€ 360
	Total cost of producing eSDS for all substances	**€ 19,440**	**€ 8,640**
	Overall cost of translation per substance (when required)	€ 450	€ 450
	Overall cost of producing eSDS per substance - where no translation	€ 360	€ 360
	Overall cost of producing eSDS per substance - where translation required	€ 810	€ 810
	Total cost of producing and translating eSDS for all substances	**€ 31,590**	**€ 14,040**
Uses NOT overlapping with Manufacturer uses	Number of substances where the exposure scenarios for the manufacturer's own use DOES NOT also covers downstream uses	54	22
	Number of substances requiring translation	27	12
	Number of uses covered in CSAs	3	3
	Overall cost of producing eSDS per substance	€ 1,060	€ 1,060
	Total cost of producing eSDS for all substances	€ 57,240	€ 23,320
	Overall cost of translation per substance (when required)	€ 1,350	€ 1,350
	Overall cost of producing eSDS per substance - where no translation	€ 1,060	€ 1,060
	Overall cost of producing eSDS per substance - where translation required	€ 2,410	€ 2,410
	Total cost of producing and translating eSDS for all substances	**€ 93,690**	**€ 39,520**
	Total cost of producing and translating eSDS for all substances	**€ 125,280**	**€ 53,560**

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

	All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Number of 'CMRs 1A/1B'	108	46
Cost for DU to provide information to Human Health Exposure Scenario	€ 350	€ 350
Cost for DU to provide information to Environmental Exposure Scenario	€ 350	€ 350
Number of uses per substance	2	2
Number of Downstream Users (DUs) per use	50	50
Overall DU costs per substance	€ 70,000	€ 70,000
Total DU costs for all substances	**€ 7,560,000**	**€ 3,220,000**

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	All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Number of 'CMRs 1A/1B'	108	46
Percentage of substances where Article 37(4) might apply	5%	5%
Cost of Environmental Exposure Assess and Risk Characterisation per use	€ 2,000	€ 2,000
Cost of communication in the supply chain (averaged from manufacturers' above)	€ 590	€ 590
Cost per DU completing an Article 37(4) CSA	€ 2,590	€ 2,590
Cost for all DUs completing an Article 37(4) CSA	**€ 13,986**	**€ 5,957**
Total costs of Article 37(4) requirements	**€ 13,986**	**€ 5,957**

Reduced Costs of Compliance with Parallel Regulation

	All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Cost for a DU to conduct assessments to comply with parallel regulation	€ 2,500	€ 0
Overall DU cost per 'CMR 1A/1B' substance	€ 250,000	€ 0
Total DU cost for all 'CMR 1A/1B' substances	**€ 27,000,000**	**€ 0**

Overall Costs

	All Currently Unknown 'CMRs 1A/1B'	All known 'CMRs 1A/1B'	All 1-10t 'CMRs 1A/1B' (known plus unknown)
Total costs to Manufacturers/Importers	**€ 2,976,480**	**€ 1,306,260**	€ 4,282,740
Total costs to Downstream Users	**€ 7,573,986**	**€ 3,225,957**	€ 10,799,943
Total Costs to all actors	**€ 10,550,466**	**€ 4,532,217**	**€ 15,082,683**
Savings to Downstream Users (compliance costs avoided)	**€ 27,000,000**	**€ 0**	**€ 27,000,000**
Net costs to Downstream Users (a negative cost is a benefit)	**-€ 19,426,014**	**€ 3,225,957**	**-€ 16,200,057**
Net Costs of extending the CSA obligation to 1-10t 'CMRs 1A/1B' (a negative cost is a benefit)	**-€ 16,449,534**	**€ 4,532,217**	**-€ 11,917,317**

Table A2.4: Cost Estimates - High Scenario

Numbers and types of 'CMRs 1A/1B'		All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
	Number of 'CMRs 1A/1B'	108	46
	Number of possible PBTs identified by screening	10	4
	Number of uses per substance	5	5
	Number of Downstream Users (DUs) per use	200	200
Robust Study Summaries	Number of studies to summarise (HH and ENV)	7	7
	Cost of producing a Study Summary	€ 250	€ 250
	Cost of producing a Robust Study Summary	€ 500	€ 500
	Additional cost of producing Robust Study Summaries for a CSA	€ 250	€ 500
	Overall cost of producing Robust Study Summaries per substance	€ 1,750	€ 3,500
	Total Cost of Robust Study Summaries for all substances	**€ 189,000**	**€ 161,000**
PBT/vPvB Assessment			
	Number of possible PBTs identified by screening	10	4
	Cost of additional informtion for assessment of P:	€ 60,000	€ 60,000
	Cost of additional informtion for assessment of B:	€ 70,000	€ 70,000
	Overall cost of PBT Assessment per substance	€ 130,000	€ 130,000
	Total Cost of PBT assessment for all substances	**€ 14,040,000**	**€ 5,980,000**

Costs of producing CSA (Manufacturers)		All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
	Percentage of substances where the exposure scenarios for the manufacturer's own use also covers downstream uses	20%	20%
	Number of substances where the exposure scenarios for the manufacturer's own use also covers downstream uses	22	10
	Number of substances where the exposure scenarios for the manufacturer's own use DOES NOT also covers downstream uses	86	36
	Number of uses per substance	5	5
	Number of Downstream Users (DUs) per use	200	200
	Cost of Human Health Exposure Assess and Risk Characterisation per use	€ 5,000	€ 5,000
	Cost of Environmental Exposure Assess and Risk Characterisation per use	€ 3,000	€ 3,000
	Overall manufacturer cost per substance across all uses	€ 40,000	€ 40,000
	Total Costs to manufacturers across all substances	**€ 3,440,000**	**€ 1,440,000**

Communication in the Supply chain		All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
	Cost of adding the results of the PBT/vPvB assessment to the SDS per substance	€ 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
	Cost of including the relevant exposure scenario(s) in an annex to the SDS per use	€ 500	€ 500
	Percentage of substances where translation of eSDS will be needed	70%	70%
	Number of languages to translate into	3	3
	Cost of translation per language	€ 200	€ 200
	Total cost of translation (where required) per use	€ 600	€ 600
For CSAs where uses overlap with manufacturer uses	Number of substances where the exposure scenarios for the manufacturer's own use also covers downstream uses	22	10
	Number of substances requiring translation	15	8
	Number of uses covered in CSAs	1	1
	Overall cost of producing eSDS per substance	€ 560	€ 560
	Total cost of producing eSDS for all substances	**€ 12,320**	**€ 5,600**
	Overall cost of translation per substance (when required)	€ 600	€ 600
	Overall cost of producing eSDS per substance - where no translation	€ 560	€ 560
	Overall cost of producing eSDS per substance - where translation required	€ 1,160	€ 1,160
	Total cost of producing and translating eSDS for all substances	**€ 21,320**	**€ 10,400**
Uses NOT overlapping with Manufacturer uses	Number of substances where the exposure scenarios for the manufacturer's own use DOES NOT also covers downstream uses	86	36
	Number of substances requiring translation	60	26
	Number of uses covered in CSAs	6	6
	Overall cost of producing eSDS per substance	€ 3,310	€ 3,310
	Total cost of producing eSDS for all substances	€ 284,660	€ 119,160
	Overall cost of translation per substance (when required)	€ 3,600	€ 3,600
	Overall cost of producing eSDS per substance - where no translation	€ 3,310	€ 3,310
	Overall cost of producing eSDS per substance - where translation required	€ 6,910	€ 6,910
	Total cost of producing and translating eSDS for all substances	**€ 500,660**	**€ 212,760**
	Total cost of producing and translating eSDS for all substances	**€ 521,980**	**€ 223,160**

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

	All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Number of 'CMRs 1A/1B'	108	46
Cost for DU to provide information to Human Health Exposure Scenario	€ 500	€ 500
Cost for DU to provide information to Environmental Exposure Scenario	€ 500	€ 500
Number of uses per substance	5	5
Number of Downstream Users (DUs) per use	200	200
Overall DU costs per substance	€ 1,000,000	€ 1,000,000
Total DU costs for all substances	**€ 108,000,000**	**€ 46,000,000**

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

	All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Number of 'CMRs 1A/1B'	108	46
Percentage of substances where Article 37(4) might apply	5%	5%
Cost of Environmental Exposure Assess and Risk Characterisation per use	€ 3,000	€ 3,000
Cost of communication in the supply chain (averaged from manufacturers' above)	€ 970	€ 970
Cost per DU completing an Article 37(4) CSA	€ 3,970	€ 3,970
Cost for all DUs completing an Article 37(4) CSA	**€ 21,438**	**€ 9,131**
Total costs of Article 37(4) requirements	**€ 21,438**	**€ 9,131**

Reduced Costs of Compliance with Parallel Regulation

	All Currently Unknown 'CMRs 1A/1B'	Known 'CMRs 1A/1B'
Cost for a DU to conduct assessments to comply with parallel regulation	€ 3,500	€ 0
Overall DU cost per 'CMR 1A/1B' substance	€ 3,500,000	€ 0
Total DU cost for all 'CMR 1A/1B' substances	**€ 378,000,000**	**€ 0**

Overall Costs

	All Currently Unknown 'CMRs 1A/1B'	All known 'CMRs 1A/1B'	All 1-10t 'CMRs 1A/1B' (known plus unknown)
Total costs to Manufacturers/Importers	**€ 18,190,980**	**€ 7,804,160**	€ 25,995,140
Total costs to Downstream Users	**€ 108,021,438**	**€ 46,009,131**	€ 154,030,569
Total Costs to all actors	**€ 126,212,418**	**€ 53,813,291**	**€ 180,025,709**
Savings to Downstream Users (compliance costs avoided)	**€ 378,000,000**	**€ 0**	**€ 378,000,000**
Net costs to Downstream Users (a negative cost is a benefit)	**-€ 269,978,562**	**€ 46,009,131**	**-€ 223,969,431**
Net Costs of extending the CSA obligation to 1-10t 'CMRs 1A/1B' (a negative cost is a benefit)	**-€ 251,787,582**	**€ 53,813,291**	**-€ 197,974,291**

Risk & Policy Analysts Limited
Farthing Green House, 1 Beccles Road
Loddon, Norfolk, NR14 6LT, United Kingdom

Tel: +44 1508 528465
Fax: +44 1508 520758
E-mail: post@rpaltd.co.uk
Website: www.rpaltd.co.uk