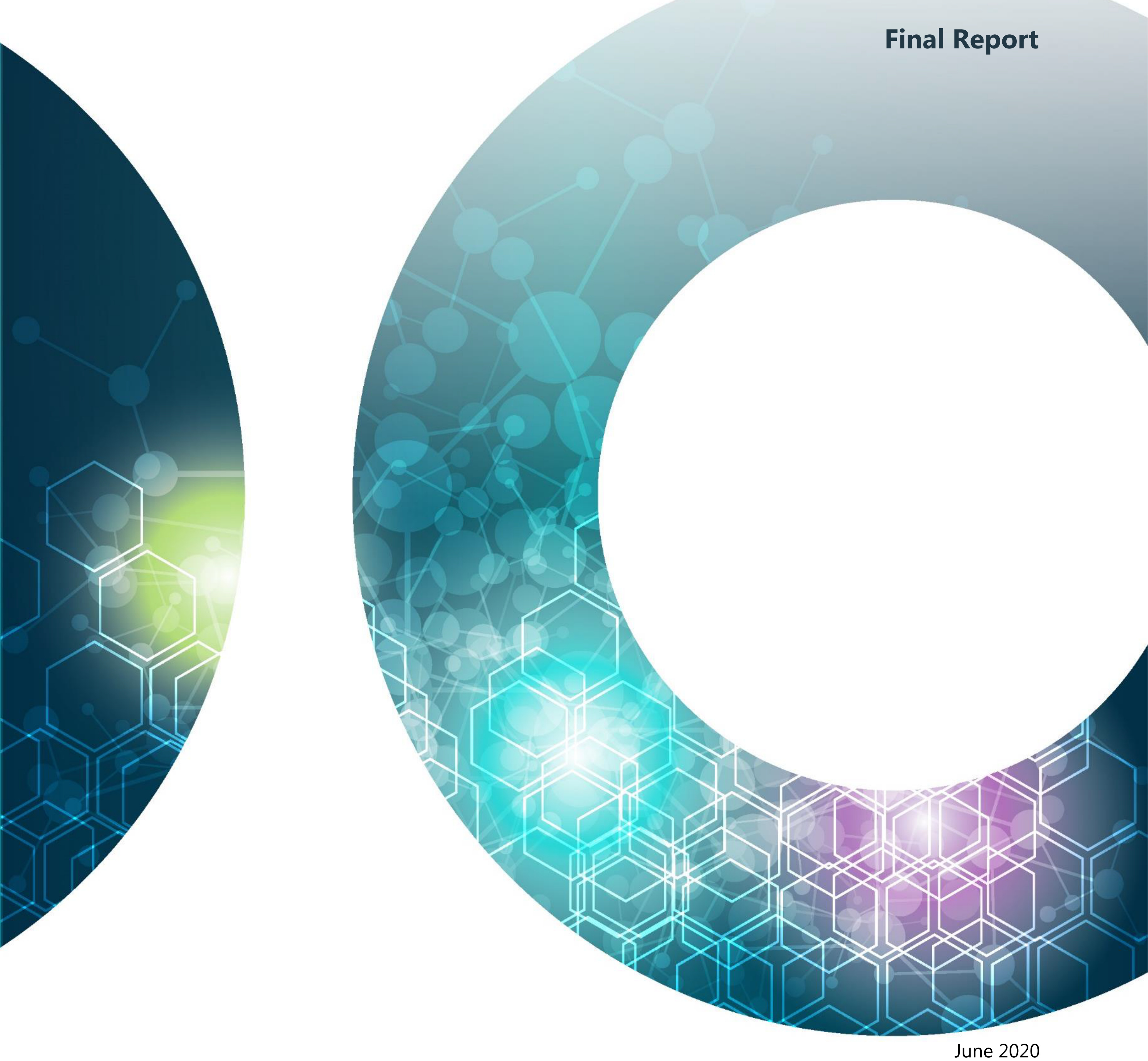
European Commission, ENV.B.2 – Sustainable Chemicals

Scientific and technical support for the development of criteria to identify and group polymers for Registration/ Evaluation under REACH and their impact assessment

Final Report



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Report for

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Document revisions

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2	Final report (issue 2) 40867-WOOD-XX-XX-RP-OP-0002_S3_P03.2	07/05/2020
3	Final report (issue 3) 40867-WOOD-XX-XX-RP-OP-0002_S3_P03.3	02/06/2020
4	Final report (issue 4) 40867-WOOD-XX-XX-RP-OP-0002_S3_P03.4	16/06/2020
5	Final report (issue 5) 40867-WOOD-XX-XX-RP-OP-0002_S3_P03.5	29/06/2020

Abstract

This report proposes criteria for the identification of polymers requiring registration (PRR) under REACH. It sets out possible registration requirements and assesses costs and benefits of registering PRRs. The evidence base was built up through a review of the literature; an online survey; in-depth interviews including with an Advisory Group; a workshop; and additional ad-hoc contributions from numerous stakeholders. Comprehensive information on the hazardous properties of polymers was generally not readily available. However, polymer types for which a requirement for registration is likely to have most merit have been identified. The report also sets out proposals for adapting the REACH registration information requirements to be more suitable for polymers. These proposals deal with polymeric substances in a way which is consistent with the non-polymeric substances, but which is proportionate to their relative hazards and risks. Data gaps make it difficult to draw direct, statistically robust comparisons between the costs and benefits of registering PRRs. Quantified estimates of health and environmental benefits through registration of PRRs amount to around €30 billion over 40 years (range €14 to €52 billion), while costs are estimated at €2.5 billion (range €0.8 to €5.2 billion), though several important costs and benefits could not be quantified.

Executive summary

Purpose of this report

This is the final report for a contract to provide 'scientific and technical support for the development of criteria to identify and group polymers for Registration/Evaluation under REACH and their impact assessment'. The term 'polymers requiring registration' (PRR) is used to indicate those polymers that could be candidates for future registration under the REACH regulation.

Wood E&IS GmbH ('Wood'), together with Peter Fisk Associates ('PFA'), were contracted by the European Commission (DG ENV unit B2) to:

- Propose criteria for the identification of PRRs, including the possibility of grouping PRRs, based on physicochemical properties and/or indication of hazard;
- Estimate the potential risks to human health and the environment posed by PRRs in comparison with other substances;
- Test and validate assumptions in a workshop; and
- Provide a detailed cost-benefit analysis of the registration requirements that could be used by the Commission in a subsequent impact assessment.

Chapter 1: Background context

Polymers are exempted from the provisions on registration of Title II of REACH (Article 2(9)). However, Article 138(2) of the REACH regulation requires a further review of polymers and comparison of the risks compared to other substances. Two previous studies were completed for the European Commission on the issue, in 2012 and 2015. Additionally, at international level, the OECD completed its own review in 2009, intended to define criteria and approaches for polymers of low concern (PLC).

The three previous studies have highlighted the challenges in identifying which polymers should be subject to registration, largely due to scarcity of public data. While the previous reports provide a good foundation for the identification of PLC polymers and a mechanism for addressing PLC within EU policy, the other end of the spectrum is not well described (i.e. which non-PLC polymers might warrant registration). The 2012 report makes clear that the difference in cost burden between medium (<10 t REACH registration requirements) and high tier (>1000 t REACH requirements) registration is significant. Therefore, there is a need to better understand and manage polymers in a cost-effective way that limits the burden on industry but which provides a higher level of protection for human health and the environment than occurs today.

Chapter 2: Scope and methodology

Substances already covered by REACH are not in the scope of this study. Chapter 2 also sets out various other clarifications on which polymers are in scope.

The evidence base for this project was built as follows:

- A **review of existing literature** helped gather additional information and background (secondary data).
- An **Advisory Group** was set up in October 2018 to ensure a good understanding of the state of the art in the field and gain access to relevant stakeholders. This group included the European Commission, ECHA, BAUA (DE), RIVM (NL), KEMI (SE) PETA, EEB, CEFIC, ECETOC, Plastics Europe, OECD, Australian and Canadian authorities and the Norwegian Environment Agency.

- **A targeted survey** was conducted between March and April 2019: in total, 47 stakeholders responded to the study questionnaire. The survey targeted all stakeholders (i.e. industry, public authorities, NGOs, academia). However, 75% of respondents were from industry trade associations and company representatives.
- A **workshop** took place on 21-22 May 2019, attended by 59 participants.
- A total of 17 **in-depth targeted interviews** were conducted to ask more in-depth questions of certain stakeholders, based on their input to the survey. Various other ad-hoc discussions took place with stakeholders throughout the course of the study.
- In addition, 31 additional inputs were submitted during an **extended consultation period** between May 2019 and mid-January 2020, and various follow-up discussions were held.

Chapter 3: Develop criteria to identify and group Polymers Requiring Registration

The objectives of this chapter were to propose criteria to characterise polymers requiring registration with justification for the selected criteria; to propose solutions for the grouping of PRRs; and to compare the potential risks posed by PRRs to other chemicals based on the available scientific evidence on their hazards and risks.

Information on the hazardous properties of polymers, or other basic information on polymer properties such as molecular weights and water solubility, was generally not readily available. An analysis of 57 safety data sheets (SDS) found that the SDS are of variable quality and are not always clear as to which constituents the data refer to. Similarly, it was not clear if the CLP classification relates to the polymer itself, or to other constituents or components. Information on polymers notified under the former dangerous substances directive, as well as information from several regimes internationally was also reviewed.

A number of polymer types for which a requirement for registration is likely to have most merit have been identified, through the literature review and the consultation activities. Further criteria are elaborated in the report to cover these polymer types, which include:

- Cationic polymers;
- Anionic polymers;
- Amphoteric polymers;
- Nonionic polymers with surface-active properties;
- Low molecular weight polymers;
- Polymers containing low molecular weight oligomers;
- Polymers with reactive functional groups; and
- Some types of degradable polymers.

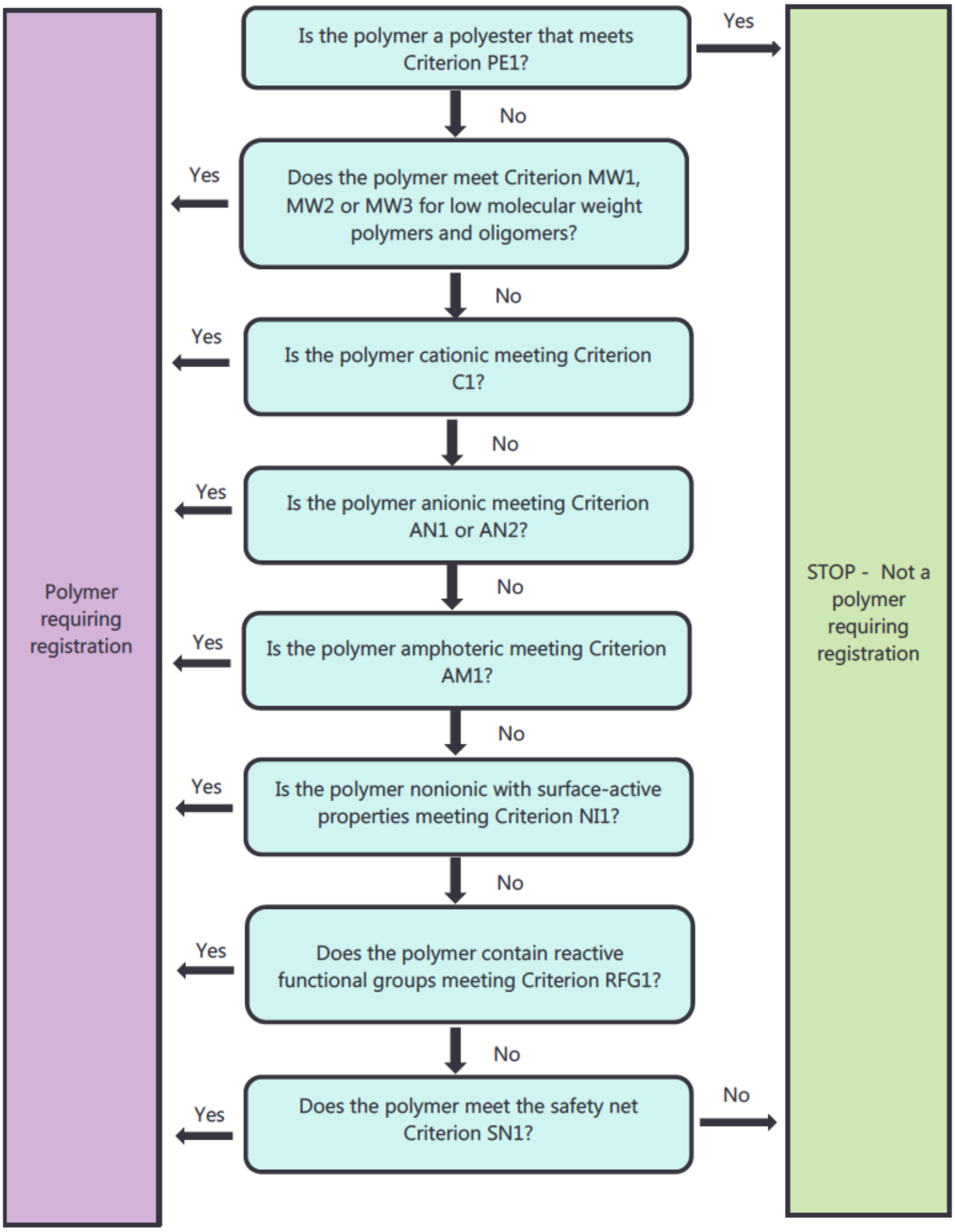
The report sets out a possible approach to grouping of polymers. Most current approaches to grouping are based on similarity of hazards and similarity of exposure or use. The estimation of the risks posed by polymers requiring registration in comparison with other chemicals is currently limited in its extent owing to the lack of useable data. In this report, two main types of grouping of polymers are identified:

- Grouping to identify which polymers meet the criteria for ‘polymers requiring registration’, and to allow the manufacturers/importers of similar types of PRR to consider future collaboration on registration; and

- Grouping of polymers in relation to the specific registration requirements, in order to facilitate cost-effective registration of PRR in line with the 'one substance, one registration' principle and to reduce testing costs and avoid unnecessary testing (e.g. through read-across of data).

The analysis carried out in this report suggests that, in terms of numbers and types of classification and labelling, polymers meeting the criteria for PRR may present similar hazards as other chemicals but there are large uncertainties associated with the available data. In particular, although the overall risk of polymers in general is expected to be lower than that of non-polymer substances (already subject to REACH registration), this is likely to be balanced by the fact that the registration process considered in this study excludes polymers that would be of low or no concern (PLCs and other polymers that do not meet the PRR criteria) and instead focuses on selecting only those with a greater potential to have associated health and environmental hazards.

Figure 1 Suggested criteria for identifying polymers requiring registration



Chapter 4: Propose registration requirements for PRRs

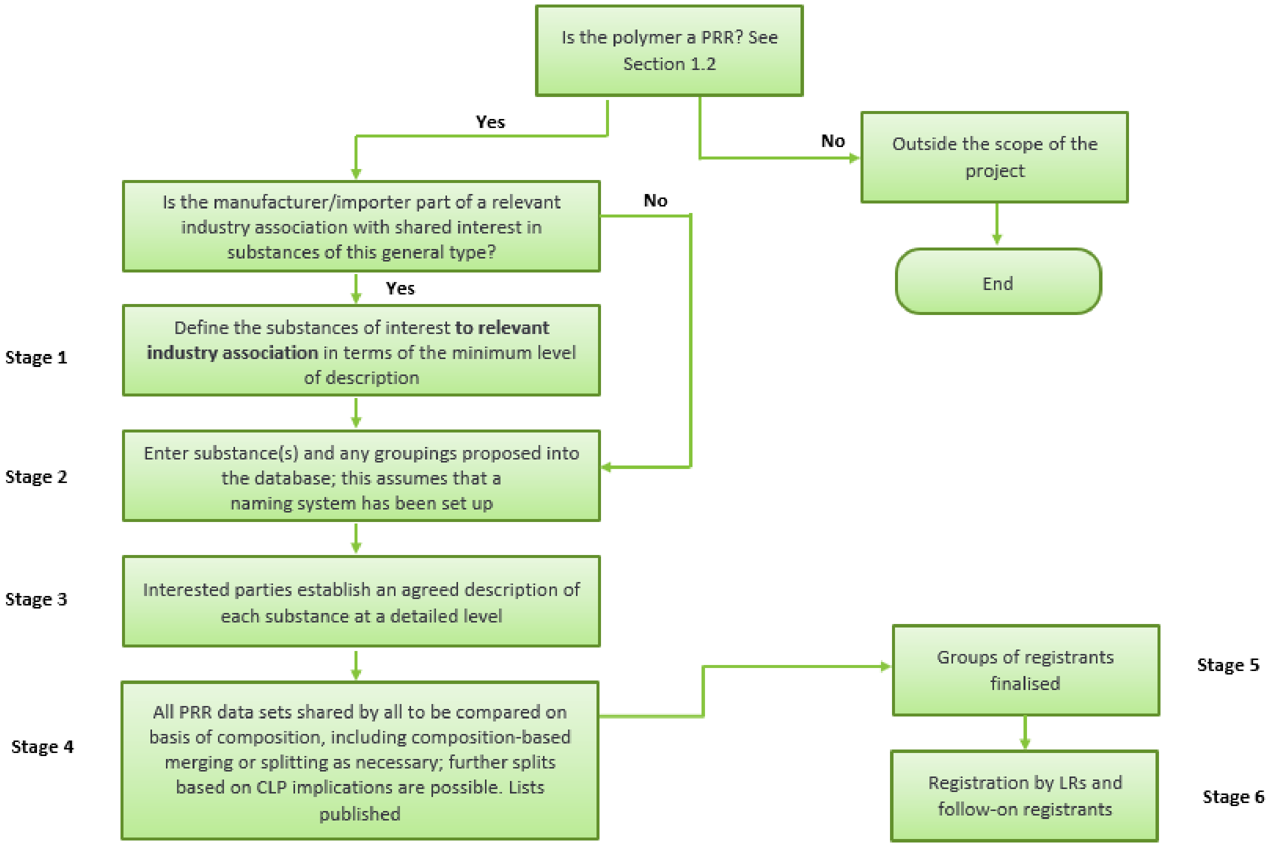
This chapter presents possible registration requirements for PRRs and the possible mechanisms for their implementation. The report sets out proposals for adapting the REACH registration information requirements to be more suitable for polymers; specific requirements necessary for PRRs; and possible information needs based on quantities on the market.

These proposals deal with polymeric substances in a way which is consistent with the non-polymeric substances, but which is proportionate to the relative level of concern for polymers.

Rational hazard-based proposals have been put forward for possible future requirements under a registration system for polymers. Bioavailability is a critical issue under these approaches, as was the case under the legislation that existed for polymers prior to the introduction of REACH (dangerous substances directive). Quantities placed on the market are also relevant.

The diagram below shows the considerations a potential registrant might go through, once it has been established that their substance meets the criteria to become a PRR. Just as in REACH to date, it is very important to establish that joint registrations are valid in respect of composition and hazard. The 'stages' (described below) are those where compositional/sameness issues may apply.

Figure 2 Registration stages for PRR

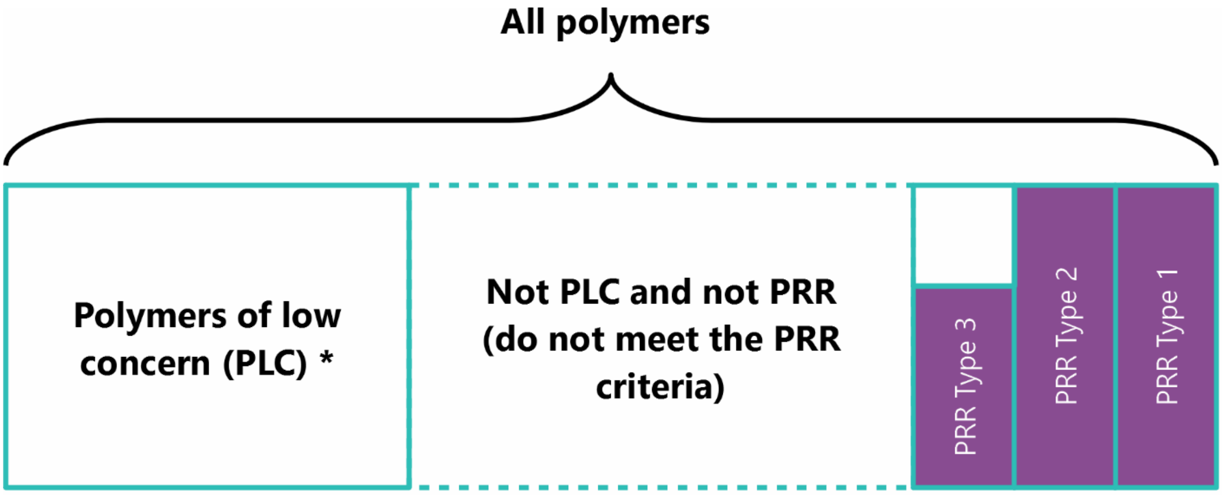


Testing requirements are proposed for each type of PRR, based on physical availability and bioavailability as expressed by molecular weight distribution, and other scientific information. This builds upon the PRR criteria. This is considered to be a proportionate proposal in that uptake by organisms is, in general, lower for higher molecular weight polymers. Firstly, it is proposed that the PRR criteria identified in Task 1 be applied, followed by consideration of the polymers identified as PRR using those criteria in three broad types, based on the dominant number average molecular weight:

- PRR Type 1: < 1000 Da;
- PRR Type 2: 1000-10,000 Da; and
- PRR Type 3: >10,000 Da.

The figure below highlights which polymers are included in the proposed approach for selection of polymers requiring registration. It also highlights the different approaches to selection of PRR of each type, and indicates proposed reduced information requirements in certain cases. Note that the figure is illustrative and does not provide a quantitative estimate of the fraction of polymers that are PRR.

Figure 3 PLC, PRR and other polymers



Only purple-shaded areas are polymers requiring registration (PRR)
Type 1: < 1000 Da – Data as for non-polymers
Type 2: 1000-10,000 Da – Testing strategy (reduced testing)
Type 3: > 10,000 Da – Only PRR if include certain structural features e.g. cationicity or reactive functional groups
* Criteria to identify PLC are considered to be already well accepted (e.g. EC 2015, OECD 2009)

Chapter 5: Carry out a cost and benefit assessment

This chapter provides a detailed analysis of costs and benefits of the possible registration requirements (set out in chapter 4) for PRRs (as defined in chapter 3), that could further feed into a possible Impact Assessment carried out by the European Commission.

The suggested criteria for identification of polymers for registration and the associated registration requirements and considerations in the approach to grouping are intended to provide a proportionate and appropriate means of ensuring information is available to allow safe use of certain polymers, while not imposing potentially significant burdens where there is little benefit to be gained.

There is a significant lack of data on costs and benefits from the various consultations undertaken for this project and within the literature reviewed. Hence, there is significant uncertainty around data points that are key to the analysis of costs and benefits. In this context, a Monte Carlo simulation model has been used to enable the impacts of this uncertainty to be explored. In addition:

- Costs and benefits have been quantified and monetised where possible, based on the best available data at the time of writing. As with any impact assessment, it has been necessary to rely on a number of assumptions, in cases where reliable data do not exist. . Where quantification was not possible, a qualitative analysis is provided. Impacts that have only been assessed qualitatively may be as important as those that have been quantified.

- In cases where no information was provided by stakeholders through the various consultation activities, assumptions from previous studies in the field were used. Where applicable, these assumptions were adjusted (based on data available for polymers in other regimes or for other substances) to reflect the specific characteristics of polymers versus non-polymer substances. A detailed list of assumptions is provided in the main report.
- In cases where no information was available, the expert judgement of the authors, taking into account discussions with industry and authorities, has been applied to estimate certain data points.

Key assumptions are as follows:

- When polymers undergo registration, there will be a process for identifying which endpoints are relevant and hence what test data are needed. In particular, given the physicochemical and other properties of many polymers, it is assumed that many of the vertebrate tests (which are typically required for non-polymer substances) would not be required for most polymers. This would reduce the potential for extensive animal testing as well as reducing costs for industry.
- Grouping of similar polymers together for registration (and read-across) would reduce the number of registrations required, and would also reduce the number of new tests required for the endpoints set out in the REACH annexes[1].
- It should be noted that certain key elements of the potential registration requirements for polymers are yet to be determined. In particular, following completion of this study, a pilot trial of approaches to grouping of polymers for registration will be carried out, involving industry and the European Chemicals Agency. The extent to which this potential for grouping of polymers for registration is realised will affect the costs of registration (and the relative benefits in comparison to those costs). The estimates provided in this report represent a best estimation of the extent to which polymers could be grouped for registration. However, the results of the pilot trial should ideally be taken into account in revising these estimates within the possible future Impact Assessment.

In order to explore the potential implications on the costs and benefits of different registration requirements for polymers, a number of alternative scenarios have been analysed for the cost assessment, including:

- Scenario 1: This is the main scenario for registration of PRR described in this report. Only polymers meeting the criteria for PRR would be registered, and there would be significant waiving of vertebrate tests.
- Scenario 2: This would include registration of all polymers that do not meet the PLC criteria (i.e. not just those identified as PRR in this study; see Figure 3). The same degree of testing (and waiving of testing) as in scenario 1 is assumed.
- Scenario 3: This would include registration of all polymers that do not meet the PLC criteria like scenario 2 but the waiving of tests would not apply in this case.
- Scenario 4: This would include registration of all polymers, also including those that meet the PLC criteria. Again, the waiving of tests would not apply.

It is assumed that the additional benefits from registration of any polymers that are not PRR (i.e. those represented by the non-shaded areas in the figure above) would be marginal. Therefore, it is assumed that,

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[1] It should be noted that key elements of the potential registration requirements for polymers are yet to be determined. In particular, following completion of this study, a pilot trial of approaches to grouping of polymers for registration will be carried out, involving industry and the .European Chemicals Agency. The extent to which this potential for grouping of polymers for registration is realised has a major effect on the costs of registration (and on the relative benefits in comparison to those costs). The estimates provided in this chapter represent a best estimation of the extent to which polymers could be grouped for registration. However, the results of the pilot trial should ideally be taken into account in revising these estimates within the possible future Impact Assessment.

for scenarios 2, 3, and 4, the level of benefits from registration would be broadly the same as for scenario 1 i.e. there would be very little additional benefit and hence little merit from an environmental or health perspective in extending the registration requirements. This is because the selection of PRR should identify those most likely to have relevant hazards.

Data gaps, and the resultant need to make various assumptions in the calculations, make it difficult to draw direct, statistically robust comparisons between the costs and benefits that would arise from registering PRRs. Importantly, various costs and benefits could not be estimated quantitatively. Quantified estimates of health and environmental benefits through registration of PRRs amount to around €30 billion over 40 years (range €14 to €52 billion), while costs are estimated at €2.5 billion (range €0.8 to €5.2 billion under scenario 1). Based on these figures, there would be merit in registering certain polymers.

Conclusion

The available data supporting the proposed criteria for PRRs set out in Chapter 3 are variable, and the scientific basis behind some of these criteria is sometimes unclear. Further information to substantiate the assumptions behind these criteria and to identify whether any further criteria would be useful to reliably identify polymers requiring registration, and in particular how polymers should be grouped, is needed.

As far as validation is concerned, some useful information was made available by industry and these data were compatible with the testing and registration proposals made in Chapter 4. However, the data overall on properties of polymers and the nature and scale of the market potentially affected is far more limited than that which was available for non-polymeric substances prior to the introduction of REACH. A process to test the proposed approach and to improve the understanding of the impacts may yield additional insights to help shape a future registration system. However, the system is already well established for non-polymer substances, some of which are, in practical terms, very similar to certain polymers.

In this context, the ratio of *quantified* benefits to costs is calculated to be greater than 1 for scenario 1, even though the assessment is based on a more conservative approach to estimation of environmental benefits than has been applied in similar previous assessments for the REACH regulation (i.e. the environmental benefits are lower than in those previous assessments).

Note that as in every cost-benefit assessment of future measures, the quantified elements rely on assumptions and are an approximation. There are various important benefits and costs that could not be quantified[2]. However, taking into account the various non-quantified benefits and costs, and the fact that the majority of the costs of registration were quantified[3], these results still suggest that there would be merit in introducing a registration requirement for a subset of polymers i.e. those identified as PRR in this study.

The benefit to cost ratio is highly dependent on the ability to apply grouping approaches to polymers, and to ensuring a process of waiving of test data where it would clearly not be relevant to a polymer (e.g. given physicochemical properties) and of ensuring that approaches to read-across data from one polymer to another are well used.

The selection of polymers for registration (PRR) in this study is expected to capture many or most of those polymers with potential for adverse effects on health or the environment. Some of these polymers will already be well-managed in their uses (in terms of health/environmental effects), while others may require additional risk management measures as a result of the new information generated through registration. As described above, based on current knowledge, there would be little merit in requiring registration for other

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[2] Benefits that were not quantified include reduced health/environmental impacts for avoided hazards/risks that are not covered in this assessment (only a selection of adverse effects were covered in the benefits assessment), and impacts on innovation, including developing safer alternatives. Costs that were not quantified include the cost of market withdrawal due to registration requirements, the costs of keeping the registration dossier updated and enhanced risk management measures.

[3] As set out in the REACH review (COM, 2018d), the main costs associated with REACH are understood to be in compiling registration dossiers and the associated fees that are payable. Both of these have been quantified in the present analysis..

(non-PRR) polymers. As such the benefits of requiring registration for a wider set of polymers may well be outweighed by the corresponding costs, as highlighted by the benefit-to-cost ratios above.

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1. Introduction

1.1 Purpose of this report

This is the **final report** for the contract on '***Scientific and technical support for the development of criteria to identify and group polymers for Registration/Evaluation under REACH and their impact assessment***'. The term 'polymers requiring registration' (PRR) is used to indicate those polymers that could be candidates for future registration under the REACH regulation.

Wood E&IS GmbH ('Wood'), together with Peter Fisk Associates ('PFA') were contracted by the European Commission (DG ENV unit B2) to:

- Propose criteria for the identification of PRRs, including the possibility of grouping PRRs, based on physicochemical properties and/or indication of hazard;
- Estimate the potential risks to human health and the environment posed by PRRs in comparison with other substances;
- Test and validate assumptions in a workshop; and
- Provide a detailed cost-benefit analysis of the registration requirements that could be used by the Commission in a subsequent impact assessment.

Reminder

Polymers are exempted from the provisions on registration of Title II of REACH (Article 2(9)). However, Article 138(2) of the REACH regulation placed an obligation for a further review of polymers and comparison of the risks compared to other substances. Two previous studies were completed in 2012 and 2015 for the European Commission on the issue; additionally, at international level the OECD completed its own review in 2009 intended to define criteria and approaches for polymers of low concern (PLC).

The three previous studies have highlighted the challenges in identifying 'polymers requiring registration' largely due to scarcity of public data. While the previous reports provide a good foundation for the identification of PLC polymers and a mechanism for implementation within EU policy, the other end of the spectrum is not well described.

The 2012 report makes clear that the cost burden between medium (<10 t REACH registration requirements) and high tier (>1000 t REACH requirements) notification is significant and therefore there is an imperative need to better understand and manage PRR in a cost-effective way that limits the burden on industry but provides a high level of protection for human health and the environment.

1.2 Structure of the report

This report is organised as follows:

- **Section 2** provides details of the methodology, data collection and information management, including the literature review and consultations (survey, interviews, workshop)
- **Section 3** presents the findings from Task 1 (defining criteria and grouping for PRRs)
- **Section 4** presents the results of Task 2 (proposing registration requirements for PRRs)

Section 5 presents the findings from Task 4 (carry out a cost-benefit analysis)

2. Overall methodology

2.1 Scope

Substances already covered currently by REACH are not in the scope of this study. The table below describes substances which are to be included in the study and those which are out of scope (e.g. already covered by REACH).

Table 2.1 Substances covered by the scope of the study and those which are not to be included

Substance	Coverage under REACH	Included in the study?
Monomer	Covered under REACH article 6(3).	No
Polymer	Exempted from REACH registration.	Yes
Additives / stabilisers in the manufacturing process	These stabilisers are considered to be part of the substance (article 3(1)) and do not have to be registered separately.	Yes
Additives / stabilisers, not necessary for preserving the stability of the polymer	When a polymeric material contains such substances, it should be considered as a mixture or an article. For such substances normal registration requirements apply.	No
Impurities	These impurities are considered to be part of the substance and do not have to be registered separately.	Yes
Unreacted monomers	Both the reacted monomers and unreacted monomer should be covered in the same registration dossier for that monomer substance.	No
Mixture / article	When a polymeric material contains such substances it should be considered as a mixture or an article, as the case may be. For such substances normal registration requirements apply.	No
Imported polymers		Yes for polymers No for monomers Yes for additives, stabilisers added during the manufacturing process.
Microplastics		There will not be an approach specific to microplastics, i.e. no specific considerations will be developed in relation to particle size when developing the requirements for PRR. Therefore, polymers produced in microparticle size will be in the scope but microplastics generated through the breakdown in the environment of larger plastics are outside the scope of the report.

2.2 Literature review

The project team undertook a review of existing literature to provide additional information and background (secondary data). Further to this literature review, sources that were provided by stakeholders during various stages of the consultation process were also reviewed. An overview of sources consulted in this project is provided in the bibliography at the end of this report.

2.3 Consultation

2.3.1 Consultation phases

The objectives of the consultation were to:

- Ensure that the project team was aware of the state of the art in the field, e.g. gathering the most relevant literature sources in the public domain and collection of data on polymers (on properties, hazards, etc.);
- Obtain stakeholders' feedback as well as facts, assumptions and options relevant to this study; and
- Involve key stakeholders who either have an interest or who would potentially be impacted by any new requirements for PRRs under REACH.

A consultation strategy was circulated and agreed with the Commission in October 2018. The project team consulted with a range of stakeholders from industry, NGOs, regulators and trade associations on the following areas:

Table 2.2 Areas covered in the consultation

Task	Areas
Under Task 1	Relevant and available literature to be considered for this study. Feedback on criteria to identify PRRs. Feedback on criteria to group PRRs. Data on hazard and risk from PRRs compared to other substances.
Under Task 2	Feedback on possible information requirements for PRRs under REACH.
Under Task 4	Assumptions and estimates for the cost assessment Assumptions and estimates for the benefit assessment Cost drivers Benefit drivers Cost and benefit differences (locational, product type, company size related)

The initial consultation for the study took place between October 2018 and April 2019. Following the workshop held on 21-22 May 2019 as part of this study (entitled 'Polymers requiring registration under REACH'), an additional consultation period was used in order to collect further information. This initially ran until June 2019 but was extended to mid-September 2019 in order to incorporate further feedback from stakeholders, particularly related to costs and benefits. This allowed stakeholders to provide further inputs which were more informed after attending the workshop, while also allowing more time for companies to gather useful information. All extra information and literature sources provided in the post-workshop stage of the consultation was reviewed by the project team.

2.3.2 Survey

A targeted survey was conducted in English between March and April 2019, with both open and closed questions. In total, 47 stakeholders responded to the questionnaire [4]. The questionnaire used is provided in Annex A of this report. It should be noted that respondents to this survey were dominated by industry trade associations and company representatives (75%). In addition, 31 additional inputs were submitted during the extended consultation period between May and mid-January 2020.

The following tools were used to disseminate the various consultation methods:

- Diffusion through the 'Advisory Group' (further information below);
- Diffusion through sectoral trade associations (e.g. CEFIC, Plastics Europe);
- Diffusion through national trade associations (e.g. Chimie France); and
- Dedicated support contacts within the project team were provided in case of questions or feedback.

2.3.3 Interviews

A total of 17 **in-depth targeted interviews** were conducted with those stakeholders whom the project team wanted to ask more in-depth questions to, based on their input to the survey. Most interviews were '*gap-fillers interviews*' conducted with stakeholders in order to provide more information on gaps identified throughout the data gathering process. Interviews were run in English.

2.3.4 Advisory group

An Advisory Group was set up in October 2018. The aim was to ensure a good understanding of the state of the art in the field and gain access to relevant stakeholders; gather information on previous assessments/surveys; test draft assumptions and options through Tasks 1-4; pilot targeted surveys and check that they can realistically be completed by stakeholders; and, lastly, gain insights into who the relevant stakeholders in the field are. Members of the Advisory Group were as follows:

- European Commission;
- ECHA;
- BAUA (DE);
- RIVM (NL);
- PETA;
- EEB;
- CEFIC;
- ECETOC;
- Plastics Europe;
- OECD;
- Australian authorities;

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[4] The online survey was conducted in compliance with the General Data Protection Regulation, highlighting for instance, which data is being collected, who processes the data, the storage period of data, the purpose of processing, etc.

- Canadian authorities;
- Kemi; and
- Norwegian Environment Agency.

Calls with the Advisory Group took place on 14 December 2018 and 2 April 2019. A discussion note was sent to all experts ahead of both calls to support the discussion. Desired outcomes for this call were to:

- First call:
  - Provide an overview of the key objectives of the project and the participants' role, as Advisory Group experts;
  - Point to sources of information in order to ensure a good understanding of the state of the art in the field; and
  - Get insights into who the relevant stakeholders in the field are.
- Second call:
  - Issues related to sameness of PRRs;
  - Issues related to grouping of PRRs; and
  - Properties of PRRs.

2.3.5 Workshop

Purpose of the workshop

The workshop on PRR was conducted as part of Task 3 of the study. The workshop was an integral part of the overall consultation process. The objective of the workshop was to gather expert stakeholder inputs on how to develop criteria to identify and group polymers potentially requiring Registration under REACH; to discuss what the proposed Registration requirements may comprise; and to get a better idea of the costs and benefits of doing so.

A Thought Starter was circulated to all participants ahead of the workshop as a means of encouraging discussion. The Thought Starter provided:

- An overview of preliminary findings of the study;
- A list of discussion points to be covered during the workshop;
- A detailed Annex on possible criteria for the identification of Polymers Requiring Registration; and
- A detailed Annex on costs data obtained so far.

Desired outcomes from this workshop were:

- To review and refine the proposed criteria for the identification of PRR;
- To review potential Registration requirements for PRR, including testing strategies;
- To consider the potential for grouping approaches, including the approach to be followed for substance identification of polymers;
- To contribute ideas about systems for handling information, sharing data on PRR, including Confidential Business Information; and

- To confirm or gather new evidence in terms of costs and benefits from registering PRR.

A summary of the workshop report, which includes the results of the discussions from the day, is included in Annex B of this report.

Workshop participants

Overall, 59 stakeholders attended the workshop. Stakeholders were admitted to the workshop based on type (i.e. authority, industry, NGO, trade association) to ensure a good representation of different perspectives on the day. An indicative breakdown of the stakeholders who attended is included in the table below.

Table 2.3 Breakdown of workshop participants by stakeholder type

Breakdown of participants by stakeholder type	%
Industry	37%
Authorities	18%
Project team	10%
Trade Association	17%
NGO	10%
European Commission and agencies (i.e. ECHA)	8%
Total	**N=59**

3. Task 1 – Develop criteria to identify and group Polymers Requiring Registration

The objectives of Task 1 of the project were to:

- Propose criteria to characterise polymers requiring registration (PRRs) with justification for the selected criteria;
- Propose solutions for the grouping of PRRs; and
- Compare the potential risks posed by PRRs to other known chemicals based on the known and available scientific evidence of their hazards.

In order to achieve these objectives, four sub-tasks have been carried out for the project. This section reports the main findings from the work carried out on these sub-tasks.

3.1 Task 1.1 – Gather background information

The purpose of this sub-task was to complete the preliminary steps in the development of the criteria for PRR. This subsection reports the results and findings of the literature review. The literature review consisted of the following.

- A comparison of existing definitions and policy frameworks for polymers against the criteria for polymers of low concern that were proposed in the COM (2015) study; and
- A literature review of data available on the hazardous properties of polymers and possible risks from polymers.

The information from the literature review has been supplemented with information obtained during the various consultations and the workshop (see Task 3) that have been carried out as a part of this project. Some of this information is confidential; where this is the case the data have been suitably anonymised, and a non-confidential summary has been included.

3.1.1 Definition of a polymer from the REACH Regulation

The relevant definitions from Article 3 of the REACH Regulation are reproduced below.

- Polymer: means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

  (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

  (b) less than a simple weight majority of molecules of the same molecular weight.

  In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer.
- Monomer: means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the process.

The terms “sequence” and “other reactant” are not defined in the REACH Regulation itself but ECHA Guidance for monomers and polymers (ECHA, 2012) gives the following further clarification.

- A "sequence" is a continuous string of monomer units within the molecule that are covalently bonded to one another and are uninterrupted by units other than monomer units. This continuous string of monomer units can possibly follow any network within the polymer structure.
- "Other reactant" refers to a molecule that can be linked to one or more sequences of monomer units, but which cannot be regarded as a monomer under the relevant reaction conditions used for the polymer formation process.

These definitions in REACH are consistent with the OECD definition of a polymer[5], monomer unit, monomer, sequence and other reactant.

3.1.2 Information from the COM (2015) study

A previous study (COM, 2015) developed possible criteria for identifying polymers of low concern in relation to the REACH Regulation. These were based on a review of polymer registration schemes and requirements worldwide. The proposed criteria developed in COM (2015) are outlined briefly below. It should be noted that the study did not clearly differentiate the contribution of residual monomer to the whole product polymer.

A polymer of low concern was based on the OECD Polymer Working group definition (OECD, 2009).

- Polymers of low concern are those deemed to have insignificant environmental and human health impacts. Therefore, these polymers should have reduced regulatory requirements.

The criteria given in Table 3.1 were suggested in COM (2015) for identifying polymers of low concern. The rationale for these criteria and a comparison with other approaches world-wide is given in Annex C.

Table 3.1 Criteria proposed in COM (2015) for identifying polymers of low concern

Area	Criteria
Discrimination using hazard information available in REACH and CLP dossiers[Note 1]	
Hazard information (H)	H 1 - for candidate polymers for which information on hazard classification under the EU CLP Regulation [Note 2] is available: the candidate polymer should not be classified as any of the following classes. Acute toxicity (Acute Tox. 1 to Acute Tox. 4); Germ cell mutagenicity (Muta. 1A, Muta. 1B and Muta. 2); Carcinogenicity (Carc. 1A, Carc. 1B and Carc. 2); Reproductive toxicity (Repr. 1A, Repr. 1B, Repr. 2, Lact.); Aspiration hazard (Asp. Tox. 1); Respiratory/skin sensitisation (Resp. Sens. 1 and Skin Sens. 1); Specific target organ toxicity – single exposure (STOT SE1 to SE3); Specific target organ toxicity – repeated exposure (STOT RE 1 and STOT RE 2); Hazardous to the aquatic environment (Aquatic Acute 1, Aquatic Chronic 1 to 4); Hazardous for the ozone layer (Ozone); Furthermore, the polymer should not be identified as PBT or vPvB [Note 3] and If no information is available on hazard classification, then the criterion H 1 does not apply.
	H2 - One or more monomers or other substances in the candidate polymer should not be classified or thought likely to be classified, on the basis of its REACH Registration dossier, as any of the following classes: Acute toxicity (Acute Tox. 1 to Acute Tox. 4); Germ cell mutagenicity (Muta. 1A, Muta. 1B and Muta. 2);

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[5] http://www.oecd.org/env/ehs/oecddefinitionofpolymer.htm

Area	Criteria
	Carcinogenicity (Carc. 1A, Carc. 1B and Carc. 2); Reproductive toxicity (Repr. 1A, Repr. 1B, Repr. 2, Lact.); Aspiration hazard (Asp. Tox. 1); Respiratory/skin sensitisation (Resp. Sens. 1 and Skin Sens. 1); Specific target organ toxicity – single exposure (STOT SE 1 to SE 3); Specific target organ toxicity – repeated exposure (STOT RE 1 and STOT RE 2); Hazardous to the aquatic environment (Aquatic Acute 1, Aquatic Chronic 1 to 4); Hazardous for the ozone layer (Ozone). Furthermore, the monomers or substances contained should not be identified as PBT or vPvB. If no monomers or other substances [Note 4] in the polymer are classified under the CLP or registered under REACH, then the H 2 criterion does not apply.
Eligibility criteria	
Elemental limitations (EL)	EL 1 – the candidate polymer must not contain less than two of the following elements: C, H, N, O, Si and S.
	EL 2 – the candidate polymer must not contain elements, other than the following, covalently bound to carbon: F, Cl, Br and I. It must not contain perfluoroalkyl moieties consisting of a -CF3 or longer chain length.
	EL 3 – the candidate polymer must not contain counter-ions other than the following: Cl-, Br-, I-, Na+, Mg2+, Al3+, K+ and Ca2+.
	EL 4 – the candidate polymer must not contain more than 0.2% w/w of the following elements: Li, B, P, Ti, Mn, Fe, Ni, Cu, Zn, Sn and Zr. Any other element is not allowed.
Cationicity (C)	C 1 – the candidate polymer must not be a cationic polymer. Exceptions are: Solid polymers, not dispersible or soluble in water, not dispersible in air (i.e. not sprayed or processed into powders) and only intended to be used in the solid phase; and Polymers with a low cationic density, i.e. a polymer whose cationic group has a combined equivalent weight greater than 5,000 Da.
	C 2 – the candidate polymer must not be expected to become a cationic polymer, i.e. it must not contain groups reasonably anticipated to become cationic (e.g. amines and isocyanates) and/or be cationic in a natural aquatic environment (4 < pH <9). Exceptions are: Solid polymers, not dispersible or soluble in water, not dispersible in air (i.e. not sprayed or processed into powders) and only intended to be used in the solid phase; and Polymers with a low cationic density, i.e. a polymer whose cationic group as a combined equivalent weight greater than 5,000 Da.
Degradability (D)	D 1 – the candidate polymer must not be designed to substantially degrade, decompose or depolymerise, i.e. it must not be designed to convert into small, simpler substances through oxidation, hydrolysis, attack by solvents, heat, light or microbial action, or through other processes.
	D 2 – the candidate polymer must not be reasonably anticipated to substantially degrade, decompose or depolymerise after manufacture or use, even though it is not intended to do so.
Water absorption (WA)	WA 1 - The candidate polymer must not be a water-absorbing polymer (i.e. a polymer capable of absorbing its own weight in water) with molecular weight (MW) ≥ 10,000 Da.
Criteria on average molecular weight and oligomer content	
Molecular weight and oligomer content (MW/OC)	MW/OC 1 – polymers with 1,000 < MW<10,000 Da must contain <10% oligomer content of molecular weight below 500 Da and <25% oligomer content of molecular weight below 1,000 Da. There are also restrictions on the nature and content of reactive functional groups (see RFG 1 below).
	MW/OC 2 – polymers with MW ≥10,000 Da must contain <2% oligomer content of molecular weight below 500 Da and <5% oligomer content of molecular weight below 1,000 Da. There are no restrictions on the nature and content of reactive functional groups.

Area	Criteria
Criteria on reactive functional groups	
Reactive functional groups (RFG)	RFG 1 – for a polymer with 1,000 < MW < 10,000 complying with criterion MW/OC 1, the following restrictions regarding the content of reactive functional groups apply: No restrictions on low-concern functional groups; If the polymer contains only moderate-concern groups, these groups should have a functional group equivalent weight (FGEW) above 1,000 Da each and a combined FGEW over 1,000 Da; and If the polymer contains high-concern and moderate-concern groups (or high-concern groups only), the combined FGEW of these groups should be over 5,000 Da. Furthermore, each high-concern group should have a FGEW over 5,000 Da and each moderate-concern group should have a FGEW over 1,000 Da. The categories of RFGs are defined as follows. For moderate- and high-concern groups, the main toxicity concerns are indicated in brackets. Low-concern groups: carboxylic acid groups; aliphatic hydroxyl groups; "ordinary" unconjugated olefinic groups; butenedioic acid groups; conjugated olefinic groups present in naturally-occurring fats, oils and carboxylic acids; blocked isocyanates; thiols; unconjugated nitrile groups; halogens (except reactive halogen containing groups such as benzylic or allylic halides); Moderate-concern groups: conjugated olefinic groups not contained in naturally occurring fats (genotoxicity), oils and carboxylic acid; alkoxysilanes with alkoxy groups >C2 (lung toxicity, ecotoxicity); and High-concern groups: pendant acrylates and methacrylates (genotoxicity, skin irritation); aziridines (genotoxicity, skin irritation); carbodiimides (genotoxicity, skin irritation); halosilanes (lung toxicity, ecotoxicity); hydrosilanes (lung toxicity, ecotoxicity); hydrazines (genotoxicity, skin irritation, ecotoxicity); alpha or beta lactones (genotoxicity, ecotoxicity); vinyl sulfones or analogous compounds (genotoxicity, ecotoxicity); acid halides (genotoxicity, skin irritation); acid anhydrides (lung toxicity); aldehydes (genotoxicity, ecotoxicity); hemiacetals (genotoxicity, ecotoxicity); methylolamides (genotoxicity, ecotoxicity); methylolamines (genotoxicity, ecotoxicity); methylolureas (genotoxicity, ecotoxicity); methoxy- and ethoxysilanes (lung toxicity, ecotoxicity); allyl ethers (genotoxicity, cytotoxicity); cyanates, iso(thio)cyanate (genotoxicity, skin irritation); epoxides (genotoxicity, skin irritation); imines (genotoxicity); unsubstituted positions ortho or para to phenolic hydroxyl (genotoxicity); any other RFG not in low or moderate concern groups.
Exceptions	
Polyesters	Polyesters – if the candidate polymer is a polyester from an approved list, it is considered a polymer of low concern regardless of the number average molecular weight or oligomer content. [Note that a proposed list of approved polyester reactants was given in Table 7 in COM (2015); the list is not reproduced here. During the consultation it was pointed out that certain important reactants have been omitted from Table 7 in COM (2015) whereas the same reactants are included in similar criteria from schemes in other jurisdictions (e.g. USA, Canada, Australia). The reason for this omission is not clear and is considered further in the development of criteria for PRR.]

Table notes: [1]: In the OECD (2009) study the polymers were considered in terms of 13 classes: polyesters; polyolefins; polyacrylates; polyethers; polyurethanes; polyamides; polyimides; polysaccharides; polyvinyl; siloxanes and silicones; other; mixed; and epoxy resins. [2] The Classification, Labelling and Packaging (CLP) Regulation – Regulation (EC) No 1272/2008. [3] Persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB). [4] In the 2015 report the word substance is used but it is not entirely clear what this refers to. Here, we have assumed that it relates to a constituent of the polymer itself rather than an additive substance such as a plasticiser, colourant etc. that may be subsequently added to a polymer mixture.

A summary of the comparison, along with possible issues/limitations in considering these in relation to identification of polymers requiring registration, is given in Table 3.2.

Table 3.2 Summary of the rationale for the COM (2015) proposed criteria for polymers of low concern

Criterion	Rationale	Comparison with other schemes world-wide	Possible issues/limitations
Definition of a polymer	Taken from the REACH Regulation and is consistent with the OECD definition of a polymer.	Generally consistent with the OECD definition. Two schemes also include a clause related to the number average molecular weight.	None identified.

Criterion	Rationale	Comparison with other schemes world-wide	Possible issues/limitations
Hazard information	Polymers, monomers and other substances present in the polymer labelled as hazardous in the most serious hazard classes are ruled out from being polymers of low concern.	Several of the approaches do not directly take into account the classification of the polymer.	The proposal in COM (2015) does not consider irritancy or corrosivity as part of the relevant hazard classes. The hazard properties of the polymer may be substantially different from that of the monomers and other substances.
Elemental limitations	Based on commonality amongst other schemes.	Similar elemental limitations are used in several other schemes.	The rationale for inclusion in the COM (2015) proposal is not clear other than it is included in other schemes.
Cationicity	Aquatic toxicity and adverse effects on human health via inhalation have been identified.	Similar criteria appear in several schemes.	None identified.
Degradability	Degradable polymers can convert into smaller compounds which are able to cross biological membranes.	Similar criteria appear in several schemes.	No distinction is made between polymers that are readily biodegradable and those that may degrade to more hazardous products. The exclusion of degradable polymers from being considered as a polymer of low concern may encourage the development of non-biodegradable polymers over biodegradable polymers.
Water absorption	Based on concerns over carcinogenicity for high molecular weight water-absorbing polymers.	Similar criteria are included in two other schemes.	Finding is based on a limited number of studies with high molecular weight polyacrylate polymers. The general applicability of the findings is unclear.
Polyesters	Polyesters made from certain specific alcohols and acids are known to be of low toxicity.	A broadly similar approach is used in three schemes, and a further scheme considers polyesters to be polymers of low concerns if they contain certain structural elements.	The available evidence for the criterion is not clear.
Molecular weight and oligomer content	Based on schemes in other countries and, in particular, the OECD (2009) study.	Broadly in line with approaches in other schemes.	The cut-offs for low molecular weight oligomer contents appear to be a pragmatic choice for identification of polymers of low concern based on the available evidence/experience. The criterion does not consider whether the oligomers can actually be released.
Reactive functional groups	Some polymers could pose a hazard to health or the environment based on their reactivity.	A broadly similar approach is used in three schemes. Other schemes also do not allow specific (or in one case all) reactive functional groups to be present.	The available experimental evidence with polymers for the criterion is not clear in the COM (2015) report. However, the theoretical background to the criterion is explained in the COM (2015) report.

3.1.3 Information on hazards of polymers from the literature search and consultation

The COM (2015) study suggested criteria for identification of polymers of low concern i.e. polymers for which hazardous properties would not be expected. However, it does not necessarily follow that all polymers that do not meet the criteria for polymers of low concern possess hazards. In order to understand better the possible hazards associated with polymers a literature search for available information was undertaken. This is supplemented by information provided by industry, regulators and others on known hazards associated with polymers. This information is used later to inform the development of possible criteria for polymers requiring registration in Section 3.2.

In general, there are only very limited publications on the hazardous effects of polymers themselves, with most of this focused on specific types of polymers where effects have been seen in laboratory tests. Specific examples are given below.

OECD (2009) study on correlations between polymer characteristics and potential for health or ecotoxicological concern

The OECD (2009) report has been reviewed in detail in previous studies on identification of polymers requiring registration or of low concern (e.g. COM (2012) and COM (2015)) and so only brief details are presented here. The OECD study used data for 205 polymers collected from Australia, Canada, Japan, Korea and United States and carried out an analysis to identify any correlations between the polymer characteristics and the potential for health or ecotoxicological concern. For the analysis, the polymers were classified into one of two categories – polymers of low concern (PLC) or non-PLC – based on the USEPA criteria. The main findings are summarised in Table 3.3 below.

Table 3.3 Summary of main findings from the OECD (2009) study

Aspect	Findings
Data availability	The data available were of variable quality.
Polymers of low concern	87.8% of polymers that were considered to be PLC showed low concern for health or ecotoxicological effects. For the 12.2% of polymers that were considered to be PLC but which exhibited some potential for health concern, no explanation was apparent from the available data. OECD (2009) postulated that this could have resulted from mechanisms not effectively covered by the data collected (e.g. hazardous residual monomers), mechanisms not addressed by the PLC or may have resulted from analytical artefacts/assumptions in the methods of analysis used in the study.
Molecular weight	The lower the number average molecular weight (MWn) of the polymer the higher the potential for health or ecotoxicological concern. A higher potential for health or ecotoxicological concern was also found to relate to higher contents of low molecular weight oligomeric species.
Polymer class[6]	No clear trends were observed between polymer class and any observed toxicity but it was noted that many polymer classes were each represented by only a limited number of datasets.
Reactive functional groups	The presence of reactive functional groups was more often found in polymers with potential health or ecotoxicological concern than in PLC; however, the available data were not sufficient to analyse confidently any trends with specific functional groups. Similarly, it is not possible to analyse confidently any trends with functional group equivalent weight (FGEW); however there was some indication that the higher concern polymers had lower FGEW than PLC.

Aspect	Findings
Solubility	A high proportion of polymers with water solubilities in the range 10 to 10,000 mg/L showed potential health concerns. Polymers with water solubilities <10 mg/L showed generally low health concern. No trends could be found between water solubility and ecotoxicological concern.
Other	Several health effects were reported but it was not possible to critically evaluate the quality of these data.

USEPA experience of polymers assessment under the Toxic Substances Control Act (TSCA)

A review of the experiences gained in the environmental assessment of polymers under the TSCA in the United States is available (Boethling and Nabholz, 1997). Around 10,000 premanufacture notices (PMN) have been reviewed by the United States Environmental Protection Agency and, based on this, a number of broad findings on polymers that are of no concern and polymers that may be requiring registration for the aquatic environment were reported by Boethling and Nabholz (1997). The main findings of the review are summarised in Table 3.4 below. Similar findings are also reported in Nabholz and Zeeman (1991).

Table 3.4 USEPA experience of environmental assessment of polymers (based on Boethling and Nabholz, 1997)

Aspect	Findings
Physical properties	An understanding of the following physical properties is important for the assessment of aquatic toxicity. • Water solubility; • Water dispersibility; • Molecular weight; • Charge; and • Cationic charge density.
Biodegradability	Almost all synthetic polymers are essentially non-biodegradable. However, some modified natural polymers and synthetic polymers with ester linkages or other labile groups incorporated into the main polymer chain are biodegradable under favourable conditions.
Removal in waste water treatment	Non-ionic, cationic and amphoteric polymers with number average molecular weights (MW_n) >1000 Da are assumed to partition to solid phases and are removed ~90% from the water phase during waste water treatment (based on the average solids removal rate). Non-ionic, cationic and amphoteric polymers with 500 Da < MW_n <1000 Da are typically removed 50-90% from the water phase. Anionic polymers with negligible water solubility and water dispersibility are assumed to behave similarly to non-ionic polymers. Lower removal rates are assumed for anionic polymers with appreciable water solubility or dispersibility, depending on the MW_n. The removal rates are based on data for elimination of poly.(carboxylic acids) determined in the Semi-continuous Activated Sludge (SCAS) test and the OECD Confirmatory Test. • MW_n <5,000 Da – 0-50% removal from the water phase; • 5,000 Da ≤ MW_n ≤20,000 Da – 50% removal from the water phase; • 20,000 Da ≤ MW_n ≤50,000 Da – 75% removal from the water phase; and • MW_n >50,000 – 90% removal from the water phase.

Aspect	Findings
Insoluble polymers	Insoluble polymers are not expected to be toxic unless they form finely divided particles. Toxicity of insoluble particles does not depend on chemical structure and results from occlusion of respiratory organs such as gills. This type of toxicity only occurs at concentrations that are considered to be of low concern e.g. acute toxicity values generally >100 mg/L and chronic toxicity values >10 mg/L.
Water-soluble or dispersible polymers	Water-soluble or dispersible polymers with molecular weights <1000 Da. These may be absorbed through biological membranes and cause systemic effects. In addition, they may also result in similar direct or indirect effects as below. Water-soluble or dispersible polymers with molecular weights >1000 Da are not absorbed through respiratory membranes of aquatic organisms. Therefore, any toxicity is manifested through either direct surface-active effects on the outer membranes of aquatic organisms and/or indirect via complexation of essential nutrients.
Anionic polymers	Poly(aromatic sulfate/carboxylates) with MW$_n$>1000 have LC$_{50}$/EC$_{50}$ generally in the range 1 to 100 mg/L. Some of the toxicity seen may result from the presence of low molecular weight oligomers (or monomers) present in the polymers tested. However, there is strong evidence of direct toxicity of polymers based on carboxylated biphenol sulfone with MW$_n$ >1000 where it was confirmed that low molecular weight oligomers were absent. No data are available for polymers based on substituted phosphoric acid monomers, but these are assumed to be of similar toxicity to the poly(aromatic sulfate/carboxylates). Poly(aliphatic acids). These are homo- or co-polymers based on one or more carboxylic acid, phosphinic acid and/or sulfonic acid. At pH 7, the main effects are related to their indirect toxicity (nutrient complexation) on green algae. • The chelating effect is directly related to the distances between acid groups. Homopolymers of acrylic acid with carboxyl groups on alternate carbons in the polymer backbone are the most toxic to green algae. The available evidence suggests that polymers with more closely or more widely spaced acid groups are less toxic relative to this polyacrylic acid; and • The toxicity can sometimes be mitigated by testing the Ca^{2+} salt or testing in media with a water hardness of 150 mg CaCO$_3$/l or above.
Non-ionic polymers	Non-ionic polymers of negligible water solubility with MW$_n$ >1000 Da, or <25% oligomers with MW$_n$ <1000 Da or <10% oligomers with MW$_n$ <500 Da are generally of low concern for ecotoxicity. Water-soluble or dispersible non-ionic polymers with MW$_n$ >1000 Da, or <25% oligomers with MW$_n$ <1000 Da or <10% oligomers with MW$_n$ <500 Da, where the monomers are reacted via a random order, generally show LC$_{50}$/EC$_{50}$ values >100 mg/L and are considered to be of low concern for ecotoxicity. Non-ionic polymers with MW$_n$ >1000 Da, or <25% oligomers with MW$_n$ <1000 Da or <10% oligomers with MW$_n$ <500 Da that are blocked in order to use the polymer as a dispersant or surfactant could be toxic to aquatic organisms as a result of a surface-active mode of effect. Non-ionic polymers with MW$_n$ <1000 Da, or >25% oligomers with MW$_n$ <1000 Da or >10% oligomers with MW$_n$ <500 Da may require registration based on the bioavailability of the low molecular weight material.
Cationic polymers	These are polymers that contain a net positively charged atom or that can contain groups that can reasonably be anticipated to become cationic in water. Cationic polymers that are solids or only used in the solid phase are of low concern for environmental toxicity. This includes dispersed beads of cationic polymers. Cationic polymers that are water-soluble or water-dispersible (either as micro- or macro dispersions) are of concern for environmental toxicity. The type of polymer backbone can influence the toxicity (and some physical/chemical properties). A distinction is made between carbon-based, silicone-based and natural (e.g. chitin, starch and tannin) polymers.

Aspect	Findings
	Intrinsic toxicity of cationic polymers increases exponentially with increasing charge density until a toxicity asymptote is reached. The acute toxicity effects in aquatic organism is related to physical disruption of respiratory membranes resulting in interference with oxygen exchange. • It is presumed that cationic polymers adsorb strongly to biological membranes (which are anionic in nature); • It is presumed that chronic toxicity of cationic polymers that contain only small amounts of lower molecular weight oligomers (e.g. <25% of oligomers with molecular weights <1000 Da and <10% of oligomers with molecular weights <500 Da) also occurs by adsorption to biological membranes; • For cationic polymers with MW_n <1000 Da, or >25% oligomers with MW_n <1000 Da or >10% oligomers with MW_n <500 Da, systemic toxicity is also possible; • Aquatic toxicity of cationic polymers is most strongly related to the cationic charge density and polymer backbone and not influenced strongly by the position of the cation relative to the polymer backbone, the molecular weight or whether or not the cation is permanent (e.g. quaternary ammonium ions) or pH-dependent (e.g. aliphatic primary, secondary or tertiary amines); • More than 99.9% of the cationic polymers submitted under TSCA have the nitrogen as the cationic group and the cationic charge density considered in Boethling and Nabholz (1997) is based on the percentage amine nitrogen (%a-N). However other measures of cationic charge density (e.g. cation equivalent weight (EQWT)) and number of cations per 1000 molecular weight (#C/K)) are also used. Boethling and Nabholz (1997) give equations to convert between the different measurements; • Structure-activity relationships based on %a-N are given in Boethling and Nabholz (1997) in order to estimate acute toxicity to fish, *Daphnia* and algae for carbon-based, silicon-based and natural-based polymer backbones; • The toxicity of cationic polymers is mitigated by reaction with dissolved organic carbon (DOC) in water, forming neutral insoluble complexes (floc). The presence of suspended solids in water can also reduce the toxicity. In order to take this into account Boethling and Nabholz (1997) discuss the mitigation factors (MF) this are integrated into the risk assessments of polymers carried out under TSCA. • A similar mitigation in toxicity of cationic polymers is seen when mixed with sediment. Toxicity testing with natural sediment using species which ingest sediment has shown that cationic polymers with charge densities ≥4.2 %a-N (or ≥3 cations/1000 molecular weight or a N-equivalent weight of ≤333) are not bioavailable and are of low concern (e.g. 48h no effect concentrations (NOEC) >100 mg/kg dry weight sediment) to sediment organisms. However, Boethling and Nabholz (1997) caution that no cationic polymer with a significant oligomer content (>25% oligomer content of MW_n <1000 Da or >10% oligomer content of MW_n <500 Da) has been tested.
Amphoteric polymers	These are polymers which contain both cationic and anionic moieties in the same polymer. The toxicity of amphoteric polymers to aquatic organisms is determined mainly by the cationic charge density and the cation-to-anion ratio (CAR). • The toxicity tends to increase with increasing cationic charge density. • For a constant cationic charge density, the toxicity tends to increase with increasing CAR. • Boethling and Nabholz (1997) use a four-step approach to estimate the toxicity of amphoteric polymers. 1. The cationic charge density (%a-N) and the CAR is calculated from chemical structure. 2. The toxicity is predicted assuming that it is a polycationic polymer using the charge density and the structure-activity relationships for carbon-based cationic polymers (see above). 3. A toxicity reduction factor (TRF) is calculated using structure activity relationships developed between the TRF and CAR;. 4. The predicted toxicity values are obtained by multiplying the toxicity predicted (for the assumption that the polymer is polycationic) by the TRF.

Aspect	Findings
	• DOC or suspended solids can mitigate the toxicity of amphoteric polymers in the same way as for cationic polymers.

According to Nabholz and Zeeman (1991), polymers with molecular weights <1000 Da are assessed using similar approaches as for other non-polymeric substances. For example, neutral low molecular weight polymers are generally assessed based on the types of functional group, log K_{ow}, melting point, water solubility and predicted toxicity to aquatic organisms (e.g. using similar quantitative structure activity (QSAR) relationships as for non-polymeric substances). Low molecular weight anionic polymers are generally assessed using a nearest analogue (read-across) method. Low molecular weight cationic polymers are assessed using either specific QSARs for cationic polymers or QSARs for quaternary ammonium surfactants[7]. Low molecular weight amphoteric polymers are treated in similar ways to cationic polymers (where the number of cations is equal to or greater than anions) or to anionic polymers (where the number of anions is greater than cations).

Lithner et al. (2011) study on environmental and health hazard ranking of plastic polymers

A study by Lithner et al. (2011) carried out an environmental and health hazard ranking of 55 thermoplastic and thermosetting polymers. However, this was carried out based on the classification and labelling of the monomers used to manufacture the polymers (and in some cases additives such as plasticisers or blowing agents) rather than the hazards of the polymers themselves, and so is of limited utility in identifying PRR in relation to REACH registration. The Lithner et al. (2011) study assumed that plastic polymers themselves are biochemically inert as a result of the large molecular size and so were not regarded as hazardous for human health or the environment.

HERA (2009) risk assessment of alcohol ethoxylates (AE)

Alcohol ethoxylates comprise a group of substances which are manufactured by the ethoxylation of a long-chain alcohol. Alcohol ethoxylates with <3 ethylene oxide groups per molecular do not meet the REACH definition of a polymer and so are registered under REACH. However, alcohol ethoxylates with three or more ethoxylate groups may meet the REACH definition of a polymer (dependent upon the molecular weight and composition) and so are not themselves registered currently. A detailed risk assessment of alcohol ethoxylates in cleaning products has been carried out (HERA, 2009). HERA (2009) indicates that more than 80% of the alcohol ethoxylates used in cleaning products have hydrocarbon chain lengths between C_{12} and C_{18} and between 0 to 18 ethylene oxide groups, although more typically they have alkyl chain lengths between C_8 and C_{18} and between 3 and 12 ethylene oxide units. The EU market for alcohol ethoxylates in cleaning products was around 275,000-290,000 tonnes/year in the early 2000s.

The HERA (2009) assessment summarised scientific studies that have demonstrated measurable toxicity to aquatic organisms and mammals for some alcohol ethoxylates that would meet the REACH definition of a polymer. The main conclusions of the HERA risk assessment are summarised in Table 3.5 below.

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[7] For example, the manual to the ECOSAR v1.11 ecotoxicity estimation program gives QSARs for cationic polymers (based on %a-N; similar to reported in Boethling and Nabholz (1997) and cationic (quaternary ammonium) surfactants.

Table 3.5 Main conclusions of the HERA (2009) risk assessment for alcohol ethoxylates[Note 1]

Aspect	Findings
Human health	No evidence[8] that alcohol ethoxylates are genotoxic, mutagenic or carcinogenic. No adverse reproductive or developmental effects observed[8]. Majority of available toxicity studies give NOAELs in excess of 100 mg/kg bw/day. The lowest NOAEL was 50 mg/kg bw/day (with a C_{14-15} alkyl chain and 7 ethoxylate groups and a C_{12-14} alkyl chain with 6.5 ethoxylate groups). Alcohol ethoxylates are not contact skin sensitisers but neat alcohol ethoxylates are irritating to eyes and skin. Irritation potential of aqueous solutions is concentration dependent. Skin irritation appears to be related to the degree of ethoxylation with the irritation potential decreasing with increasing ethoxylate content (up to 20 ethoxylate units). No trend in irritation potential with alkyl chain length was found.
Environment	The assessment considered 230 different homologues with hydrocarbon chain lengths between C8 and C18 and with between 0 and 22 ethylene oxide groups. Acute ecotoxicity has been seen in laboratory studies across the range of structures, generally in the 0.1 mg/L to low mg/L range. Chronic aquatic toxicity NOEC data are also available, generally ranging from <0.1 mg/L to low mg/L range. Increasing alkyl chain length tends to increase the toxicity to aquatic organisms whereas increasing number of ethoxylate groups tends to decrease the toxicity to aquatic organisms.

[1] It is important to note that the HERA (2009) study covers substances that do not meet the REACH definition of a polymer along with those that meet the REACH definition of a polymer. The main conclusions reported in Table 3.5 relate, as far as possible, to those substances that may meet the REACH definition of a polymer.

The molecular weights of specific structures within the C_8 and C_{18} range with between 3 and 18 ethoxylate range between 262 and 1062 g/mole and the ethoxylate content (as a % of the total molecular weight) range between 33% and 86% and so at least some of the structures would meet the REACH definition of a polymer.

HERA (2003 and 2004) risk assessment of alcohol ethoxysulfates (AES)

Alcohol ethoxysulfates (also known as alkyl ether sulfates) are anionic surfactants with a wide range of applications including household, institutional and industrial cleaning, personal care products, additives in plastics and paint production and industrial processing (HERA, 2003 and 2004). The general structure of alcohol ethoxysulfates is $C_nH_{2n+1}O(C_2H_4O)_mSO_3X$, where typically n=10-18, m=0-8 and x = sodium, ammonium or triethanolamine. Similar to alcohol ethoxylates, some members of this group where m is 3 or above may meet the REACH definition of a polymer.

A detailed risk assessment of the use of alcohol ethoxysulfates in household cleaning products has been carried out by HERA (2003 and 2004). The European (EU27 plus Norway and Switzerland) production was estimated to be 320,000 tonnes/year in 2000 and about 276,000 tonnes/year of this was thought to be used in Europe. Of this, around 108,000 tonnes/year was thought to be used in household cleaning products. The main conclusions of the HERA risk assessments are summarised in Table 3.6 below.

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[8] Based on >13 bacterial tests, 10 *in vitro* non-bacterial genotoxicity tests, 5 *in vivo* genotoxicity studies, three 2-year oral and one 18-month dermal carcinogenicity studies, three 2-generation reproductive toxicity studies and a range of sub-chronic oral feeding studies which investigated the effects on the organs of the reproductive system, and 6 developmental toxicity/teratogenicity studies.

Table 3.6 Main conclusions of the HERA (2003 and 2004) risk assessments for alcohol ethoxysulfates Note 1

Aspect	Findings
Human health	No evidence[9] that alcohol ethoxysulfates are genotoxic, mutagenic or carcinogenic was found. No adverse reproductive or developmental effects were observed. In chronic and subchronic toxicity studies, no effects were seen at levels up to 75 mg/kg bw/day and no adverse effects of AES were observed up to the highest tested dose levels of 250 mg/kg bw/day. Alcohol ethoxysulfates are not skin sensitisers but neat alcohol ethoxysulfates are irritating to eyes and skin. Irritation potential of aqueous solutions is concentration-dependent. Solutions containing AES at concentrations above 20-30% may be moderately to severely irritating to eyes and slightly to moderately irritating to skin.
Environment	Acute ecotoxicity data was not considered in the HERA (2004) assessment as a large database of chronic ecotoxicity data are available. Chronic aquatic toxicity data are generally ranging from <0.1 mg/L to low mg/L range. Increasing alkyl chain length tends to increase the toxicity to aquatic organisms up to around C_{15} after which the toxicity tends to decrease with increasing alkyl chain length. Increasing the number of ethoxylate groups tends to decrease the toxicity to aquatic organisms.

[1] It is important to note that the HERA (2002 and 2004) assessment covers substances that do not meet the REACH definition of a polymer along with those that may meet the REACH definition of a polymer. The main conclusions reported in Table 3.6 relate, as far as possible, to those substances that may meet the REACH definition of a polymer.

HERA (2014a and 2014b) risk assessment of water-soluble linear polycarboxylates and information on other polyacrylates

A detailed risk assessment of the use of water-soluble linear polycarboxylates in household cleaning products has been carried out by HERA (2014a and 2014b). There are two main types of polycarboxylates using in cleaning products in the EU. These are homopolymers of acrylic acid (total consumption in household cleaning products in Europe (EU27 plus Norway and Switzerland) 21,000 tonnes/year in 2011; HERA, 2014a) and copolymers of acrylic and maleic acid (total consumption in household cleaning products in Europe; 33,000 tonnes/year in 2011; HERA, 2014b).

The mean molecular weight of homopolymers of acrylic acid (P-AA) used in domestic cleaning products ranges from around 1000 to 78,000 Da, and most hazard information has been obtained with the most commonly used commercial P-AA with a molecular weight of 4,500 Da. The polymers are generally used as their neutralised sodium salts (pH 6-8) (HERA, 2014a).

For the copolymers of acrylic acid and maleic acid (P-AA/MA), the mean molecular weight used in domestic cleaning products ranges from around 12,000 to 100,000 Da and most hazard information has been obtained with the most commonly used copolymers with a molecular weight of 70,000 Da. Again, the polymers are generally used as their neutralised sodium salts (HERA, 2014b).

The main conclusions of the HERA risk assessment are summarised in Table 3.7. Very similar conclusions were obtained for both P-AA and P-AA/MA

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[9] Based on approximately 4 *in vitro* bacterial studies, 5 *in vitro* non-bacterial genotoxicity studies, 3 *in vivo* non-bacterial genotoxicity studies, two 2-year oral carcinogenicity studies and two dermal carcinogenicity studies, three 2-generation reproductive toxicity studies and five sub-chronic or chronic toxicity studies were effects on the sex organs were investigated, and 10 oral developmental toxicity/teratogenicity studies

Table 3.7 Main conclusions of HERA (2014a, 2014b) risk assessments for water-soluble linear polycarboxylates

Aspect	Findings
Human health	No evidence was found that the P-AA or P-AA/MA are genotoxic and they were not expected to be carcinogenic[Note 1]. No adverse developmental effects were observed, and they were not expected to be reprotoxic[Note 1] Very low toxicity after oral or dermal applications (LD_{50} >2,000 mg/kg bw/day). Mild, reversible pulmonary irritation was observed after repeated inhalation of both P-AA and P-AA/MA but this effect was not considered as substance-related owing to the physical properties of the respirable dust used in this type of study. P-AA and P-AA/MA are not skin sensitisers and were not expected to be irritating to skin or eyes.
Environment	Acute and chronic aquatic toxicity data are available for fish, *Daphnia* and algae. The water solubility of P-AA and P-AA/MA is dependent upon the water hardness and the presence of ions such as calcium and magnesium must be taken into account in interpretation of the available toxicity data. The most sensitive species tested was *Daphna magna* and long-term NOECs in the range 12 to 450 mg/L were determined for P-AA with a mean molecular weight of 4,500 Da and in the range 3.75 to 350 mg/L for P-AA/MA with a mean molecular weight of 70,000 Da. It was postulated that the effects seen may have been a secondary effect resulting from the presence of insoluble precipitates. P-AA and P-AA/MA showed little or no toxicity to sediment or soil organisms.

[1] For P-AA, based on approximately 11 in vitro bacterial studies, 2 in vitro non-bacterial genotoxicity studies, 1 in vivo non-bacterial genotoxicity study and 2 developmental toxicity studies. For P-AA/MA, based on 7 in vitro bacterial studies, 2 in vitro non-bacterial genotoxicity studies, 1 in vivo non-bacterial genotoxicity study and 1 developmental toxicity study.

A review and assessment of the health impacts of a number of polymers based on acrylic acid or methacrylic acid or one of their salts or esters that are used in cosmetics is also available (Cosmetic Ingredient Review Expert Panel, 2002). These are considered similar in that they are produced in chemical reactions that leave very little residual monomers. The polymers exhibit little toxicity and the principal concern from their use in cosmetics is from the presence of toxic residual monomers. There is some evidence for irritation (but not sensitisation) from acrylate copolymers but these acrylate copolymers are considered safe for use in cosmetic formulations when formulated to avoid irritation.

A similar review is available on 23 crosslinked alkyl acrylate polymers used in cosmetics (Cosmetic Ingredient Review Expert Panel, 2011). The polymers act as absorbents, film formers, emulsion stabilisers, viscosity modifiers, suspension agents, binders and/or skin conditioning agents. The conclusion of the assessment was that crosslinked alkyl acrylates are safe for use in cosmetics at current use concentrations provided that they are not polymerised in benzene. For the latter, a risk assessment of the amount of residual benzene present would be needed. Little toxicity data were available and the acute dermal and oral toxicity data that are available indicate a low level of toxicity. The Panel noted that these crosslinked alkyl acrylates are macromolecules that are not expected to pass through the stratum corneum of the skin, so significant dermal absorption is not expected. Therefore, topically applied cosmetics are not expected to result in systemic or reproductive and developmental toxicity or to have genotoxic or carcinogenic effects upon use.

Studies on cationic polymers

The toxicity of a series of cationic polymers to rainbow trout (*Oncorhychus mykiss*) has been determined (Goodrich et al., 1991). The polymers tested fell within two broad groups: epichlorohydrin/dimethylamine polyamines (three polymers with molecular weights of 10,000, 50,000 or 200,000-250,000 Da) and quaternary amine copolymers (two polymers based on acrylamide/2-(N,N,N)-trimethyl ammonium ethylacrylate chloride with a 10% or 39% charge density). The polymers are stated to be water-soluble. Acute static tests gave LC_{50} values in the range 0.27-1.7 mg/L; the toxicity was 1.7-13.9 times greater under short-term flow-through conditions. Long-term (28-day) flow-through tests showed low acute to chronic LC_{50} ratios. A general increase in toxicity with a decrease of molecular weight was evident in the flow-through tests, and in the long-term studies, the cationic polyamines were more toxic than the acrylamide-based polymers tested.

A CEFIC Long-Range Research Initiative (LRI) project is currently underway to further understand the role of sorption of cationic polymers on their bioavailability and hence toxicity to aquatic organisms (CEFIC LRI, 2017). The presence of negatively charged particulate or dissolved matter (e.g. humic acids) can reduce the apparent toxicity of cationic polymers by one or two orders of magnitude.

A potential for phytotoxicity of cationic polymers has also been demonstrated by Kuboi and Fujii (1983). A total of 44 synthetic polymeric flocculants were screened for toxicity using a turnip root assay. The polymers tested included 30 cationic polymers, 7 non-ionic polymers and 7 anionic polymers. Only the cationic polymers demonstrated toxicity (inhibition of root elongation) in the assay. For the cationic polymers no correlation was evident between the molecular weight and root elongation rate and it was suggested that the mechanism of phytotoxicity was by adsorption of the cationic polymers to the negatively charged root surface.

USEPA (2013) provides general guidelines for assessment of polymers that have an average number molecular weight (MW_n) of greater than 1000 following the methods used by EPA's New Chemicals Program. For cationic polymers, USEPA (2013) reports methods for estimating the aquatic toxicity of cationic polymers based on the %a-N (percentage amine nitrogen) (USEPA, 2012 and Boethling and Nabholz, 1997). The ecotoxicity of both carbon-based and silicon-based polymers correlates with the %a-N up to a %a-N of typically 3.5% or 4.5%) after which the ecotoxicity is essentially independent of the %a-N. Dissolved organic matter has been shown to reduce the toxicity of cationic polymers. Further details are given in Annex F.

De Rosemond and Liber (2004) investigated the toxic components of effluent from a diamond mine. The processing plant’s effluent contains kimberlite ore particles (≤0.5 mm), wastewater, and two wastewater treatment polymers, a cationic polydiallydimethylammoniumchloride (DADMAC) polymer and an anionic sodium acrylate polyacrylamide (PAM) polymer. Toxicity testing with C. *dubia* determined that the cationic DADMAC polymer had a 48-h median lethal concentration (LC_{50}) of 0.32 mg/L and 7-d median effective concentration (EC_{50}) of 0.014 mg/L. The anionic PAM polymer had a 48-h LC_{50} of 218 mg/L. The cationic DADMAC polymer was hypothesised as the toxic component of the mine effluent in a weight of evidence approach.

The use of cationic polymers as flocculants and coagulant aids to control suspended solid levels in the water and wastewater treatment industry is widespread in most developed countries (Rowland et al., 2000). The most frequently used clarification polymers, polyacrylamides, are often proprietary, and little information exists on the ecological impacts of these products.

Further confidential information on the hazards associated with certain cationic polymers was provided by Industry at a late stage in the current project. Unfortunately, there was insufficient time to take these data fully into account in this review but the data showed that such cationic polymers may be hazardous to the aquatic environment.

NICNAS (2018) environmental assessment of nonylphenol ethoxylates and associated esters

A Tier II environmental assessment of nonylphenol ethoxylates and their sulfate and phosphate esters has been undertaken by the Australian Government under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS, 2018).

Commercially available nonylphenol ethoxylates are mixtures of structural isomers and homologues with ethoxylate chains consisting of between 1 and 100 ethoxy ether sub-units, with the average nonylphenol ethoxylate chain consisting of 12-13 ethoxy ether sub-units. The ethoxylate chain length shows a normal distribution around the average number of ethoxy ether units in the chain. Similar to alcohol ethoxylates, and alcohol ethoxysulfates, some members of this group where m is 3 or above are likely to meet the REACH definition of a polymer. The ethoxylate chain in anionic derivatives (e.g. sulfate and phosphate esters of nonylphenol ethoxylates) typically contains between 1 and 4 ethoxy ether sub-units.

The assessment considered 25 substances which were all mixtures of discrete substances and/or low to moderate molecular weight polymers with ethoxy ether chains. Only limited data were available on the properties of nonylphenol ethoxylates but nonyl phenol ethoxylates with less than 10 ethoxy ether units are generally liquids and those with greater than 12 ethoxy ether units are generally solids. The water solubility ranges between 49.6 mg/L (10 ethoxy ether groups) to 154 mg/L (20 ethoxy ether groups).

The nonylphenol ethoxylates all undergo partial degradation in sewage treatment plants to form more stable substances such as nonylphenols, which are known to be environmentally hazardous.

The toxicity of nonylphenol ethoxylate surfactants to aquatic organisms increases with a decrease of ethoxylate chain length. Nonylphenol ethoxylate degradants are more toxic than the parent substances and possess estrogenic activity. This is therefore an example of a degradable polymer where the concern may relate more to the degradation products than the polymer itself.

It should be noted that a number of phenol ethoxylates, also in their polymeric form, are already subject to authorisation or restrictions under REACH (for example 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated and 4-nonylphenol, branched and linear, ethoxylated).

Information on amphoteric polymers

USEPA (2013) reports that ecotoxicity of amphoteric polymers is dependent upon the cation-to-anion ratio and the overall cationic charge density. The toxicity to aquatic organisms tends to increase with cationic charge density and, at a constant charge density, increases with cationic charge density. USEPA (2013) gives methods for estimation of the toxicity to aquatic organisms using the %A-N as for cationic polymers as a starting point and then application of various corrections. Dissolved organic matter has been shown to reduce the toxicity of amphoteric polymers.

CESIO (2019) information on surfactants in the EU

During the consultation, CESIO[10] (2019) made available further information on the polymeric surfactants used within the EU. CESIO is an industry association which represents companies manufacturing and marketing surfactants or their organic intermediates.

Recommendations for the harmonised self-classification and labelling of surfactants have been published (CESIO, 2017). These are based on the hazard information available to CESIO Member companies and recommended classifications for the main surfactants manufactured or supplied in the EU are given based on weight of evidence and expert judgement. The recommended classifications are reviewed every two years.

The CESIO (2017) report considers the surfactants under the following families: alcohol ethoxylates; alkyl ether sulfates, alkyl sulfates, other anionic surfactants and other surfactants. Within each family, the surfactants are further sub-grouped based on chemistry (for example chemical name, carbon chain length, degree of ethoxylation or propoxylation etc. as relevant). It is important to note that the report makes no distinction between non-polymeric surfactants and polymeric surfactants within these broad groups and subgroups.

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[10] Comité Européen des Agents de Surface et de leurs Intermédiaires Organiques - European Committee of organic surfactants and their organic intermediates.

A broad overview of the recommended classifications for the surfactant families that may contain surfactants that meet the REACH definition of a polymer, is given in Annex D.

The information from CESIO indicates that most of the health hazards associated with polymeric surfactants relate to irritation or corrosive properties. However acute toxicity is associated with some products, particularly where 10-20 ethoxylate groups are present (examples for lower and higher numbers of ethylene oxide groups also exist). However, it is also important to note that no classification advice/recommendation is given in the CESIO (2017) report for many of the surfactants, particularly those with high numbers of ethoxylate groups.

For the environment, hazards related to acute or chronic toxicity are evident. From the CESIO (2017) data it is apparent that hazards to the aquatic environment are generally absent in surfactants with >50 ethoxylate groups but below this number the hazard is dependent upon the surfactant family, the alkyl (or hydrophobic group) chain length and the number of ethoxylate groups present.

The molecular weight of the ethoxylate repeat unit ($-C_2H_4O-$) is 44 Da and so polymers with at least 50 ethoxylate groups would have molecular weights of at least $44 \times 50 = 2{,}200$ Da, excluding the molecular weight of the hydrophobic group. This suggests that the most hazardous surfactants would have molecular weights below 2,300-2,500 Da depending upon the hydrophobic group.

Information on high molecular weight polymers

USEPA (2013) outlines the main health effects considered by the USEPA in their assessment of polymers. For high molecular weight polymers (number average molecular weight >10,000 Da, USEPA (2013) indicates that these polymers are generally only requiring registration in relation to lung effects. This is suggested to be a result of overloading of the clearance mechanisms of the lung following inhalation of polymer particles.

A distinction is made between water-soluble polymers, insoluble and non-water absorbing (non-swellable) polymers and water absorbing (swellable) polymers (see below).

According to USEPA (2013) high molecular weight water-soluble polymers are not expected to exhibit lung toxicity as they are rapidly cleared from the respiratory tract.

For high molecular weight insoluble and non-water absorbing polymers, USEPA (2013) indicates that studies reported under TSCA indicate irreversible lung damage from inhalation of respirable polymers with molecular weights of 70,000 Da or greater, but there is a lack of data for polymers with molecular weights between 10,000 and 70,000 Da. In addition, there is a potential concern for physical hazards to lungs from high molecular weight polymer particulates with a significant percentage of the particles <10 microns in size based on their potential for deposition in the deep lung.

A review showing that fluoropolymers meet the criteria for a polymer of low concern has been published by Henry et al. (2018). The 4 fluoropolymers studied, polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP), ethylene tetrafluoroethylene (ETFE), and tetrafluoroethylene copolymers with perfluoroalkyl vinyl ethers (e.g., perfluoroalkoxy polymer, PFA), accounted for approximately 70% to 75% of the world fluoropolymer consumption in 2015. The representative fluoropolymer used in the study was, PTFE, which made up 58% (by weight) of 2015 worldwide fluoropolymer consumption. Fluoropolymers are generally very high molecular weight (>100 000 Da); have high thermal, chemical, photochemical, oxidative, hydrolytic, and biological stability; have low flammability, neutral electrical charge, and resistance to degradation; have negligible residual monomers and low molecular weight oligomer content; have limited low molecular weight leachables; and have no reactive functional groups of concern.

Information on low molecular weight oligomers

A compilation of published toxicological data for cyclic oligomers of polyamide-6,6 was provided during the consultation (PlasticsEurope, 2019a). Cyclic oligomers can be formed during the polymerisation process (polycondensation of hexamethylene diamine and adipic acid) and use of polyamide-6,6, including processing at elevated temperature. In food contact applications, migration of these oligomers can occur into food. The major oligomers have been identified as the cyclic monomer (MW 226 g/mol), dimer (MW 453 g/mol) and trimer (679 g/mol). The cyclic monomer was the main oligomer found in aqueous extracts of polyamide-6,6. The cyclic monomer did not result in adverse effects in rats following 28-day and 90-day repeated dose oral toxicity studies and this, taken together with data for other cyclic amides, showed that the oligomers have a very low potential for systemic toxicity.

A risk assessment for migration of styrene oligomers from polystyrene food containers into food has been published (Gelbke et al., 2019). The oligomers present are formed either as by-products during production of polystyrene or as a result of subsequent irradiation or thermal treatment of polystyrene during downstream applications. The oligomers identified were mainly dimers and trimers (MW ~196 to 312 g/mol). The toxicity of these dimers and trimers has been investigated (as the sum of dimers and trimers). These oligomers are not genotoxic *in vitro* and there is good evidence that they are not endocrine disruptors. No adverse effects were seen at the highest dose level tested (1 mg/kg bw/day) in an oral rat study during pregnancy and lactation.

Gelbke carried out a risk assessment for the styrene dimers and trimers by assessing likely human exposure through the diet based on the concentrations found in studies with food simulations and food and also a modelling approach using the FACET[11] model. This demonstrated that the dimers and trimers present in polystyrene food packaging presented a low risk for consumers.

Information on reactive functional groups

A detailed analysis of the biological reactivity of functional groups was carried out as part of the COM (2015) study and reported in Annex 4 of that report. This was used to justify the reactivity classes for reactive functional groups used in the criteria proposed in COM (2015) for polymers of low concern.

Information on water absorbing polymers

Water-absorbing polymers with number-average molecular weight of 10,000 Da or more and which can absorb their own weight in water (superabsorbent polymers) are of note. USEPA (2013) indicates that there may be concerns for fibrosis and cancer and such polymers are excluded from consideration as polymers of low concern in the United States.

These concerns are based on studies submitted under TSCA which indicate that high molecular weight polyacrylate polymers cause lung neoplasms in animal studies. The background for this is outlined in Federal Register (1995) and was based on the results of a study with a water-absorbing polyacrylate polymer with a molecular weight >1,000,000 Da which was found to cause cancer in a 2-year chronic inhalation study. The water-absorbing capacity of the tested polymer was 100 times its own weight. The criteria for exclusion as polymers of low concern were set at a factor of 100 times lower than the molecular weight and water=absorbing capacity of the tested polymer as the United States Environmental Protection Agency indicated that they were not yet able to establish the exact molecular weight limit and water-absorbing capacity below which such carcinogenic effects could be ruled out.

However, the USEPA has also reviewed data on modified starches and, based on the information submitted, the USEPA was unable to support the concerns for the water retentive capacity of these substances with the potential to lead to lung cancer[12]. The USEPA therefore assesses on a case-by-case basis whether water-absorbing polymers pose a risk and whether further testing is warranted.

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[11] FACET is the Flavourings, Additives and food Contact materials Exposure Tool (Oldring et al, 2017). This is a probabilistic modelling tool developed by a collaborative team of regulators, industry and modelling experts.

[12] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new (accessed 25/02/2019).

The hazards from inhalation of water-absorbing neutralised, cross-linked acrylic acid polymers are reviewed in MAK (2001). MAK (2001) states that the effects on lung seen in long-term inhalation studies using micronised cross-linked polyacrylates are limited to the deep lung (terminal bronchioles and alveolar region) and the tracheobronchial lymph nodes. No substance-related adverse effects were found in any other organs or tissues and it was concluded that the lung tumours of epithelial origin developed as a result of inflammatory changes (neoplasms were found only in animals exposed to concentrations which caused chronic pulmonary inflammation with epithelial hyperplasia). No genotoxic effects were seen in studies with cross-linked polyacrylates and micronised cross-linked polyacrylates.

The review notes that for inhalation studies, micronised particles (diameter <2 µm) of cross-linked polymer have generally been used in order to ensure sufficient respirable dust was present. However, MAK (2001) states that commercially available cross-linked polyacrylates are generally available as granulated solids with average particle size of 300-700 µm and contain practically no respirable dust. Indeed, MAK (2001) notes that the proportion of particles <100 µm is limited to <1% on order to maintain the properties of the products.

MAK (2001) also reported that epidemiological studies in the industries producing and processing cross-linked polyacrylates found no evidence for adverse effects on health, including lung changes and lung function.

Holm et al. (2011) reported the results of an epidemiological study investigating respiratory health effects associated with exposure to superabsorbent polymer and paper dust. The study found that there were no significant effects associated with exposure to superabsorbent polymer.

According to Zohuriaan-Mehr and Kabiri (2008) superabsorbent polymers present a low hazard to the environment.

Information on polyesters

Information was obtained during the consultation on polyethylene terephthalate (PET), a polyester. This indicated that <0.05% of PET products have MWn <1000 Da, 0.05-0.15% have MWn between 1000 and 10,000 Da and >99.85% have MWn >10,000 Da. PET is produced at a high level of purity and contains only very small amounts (total less than 100 ppm) of between 2-5 non-intentionally added substances that are bonded into the polymer matrix. PET is a very stable polymer that is not water or lipid soluble and none of the polymers are considered hazardous[13]. It was also noted that the COM (2015) report omitted the three most important and globally used monomers used in PET manufacture: terephthalic acid (benzene 1,4-dicarboxylic acid; CAS 100-21-0), monoethylene glycol (ethane-1,2-diol; CAS 107-21-1) and dimethyl terephthalate (dimethyl 1,4-benzenedicarboxylate; CAS 120-61-6). These monomers are included as exemptions in other global schemes (e.g. in the United States, Canada and Australia) and there is no obvious reason why they were omitted from the COM (2015) recommendations.

Information on amino resins (ERM, 2018)

The Formacare and Solvent Resin Manufacturers (SRM) sector groups of CEFIC have made available confidential information on the hazards associated with polymers in amino resins (ERM, 2018). Amino resins are typically marketed as mixtures containing resin polymers, unreacted monomer and other reactants, additives and solvents. The resin polymers are typically reaction products and amines or amides (e.g. urea, melamine, benzoguanamine) with aldehyde (e.g. formaldehyde) monomers which then subsequently react with other reactants such as alcohols (e.g. methanol, n-butanol, iso-butanol).

The amino resins contain reactive functional groups such as methylol groups (>N-CH_2-OH) or alkoxymethyl groups (>N-CH_2-OR), which react further with nucleophilic groups.

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[13] The number of polymers considered and actual data available is unclear from the consultation response but the conclusions appear to be based on structural considerations.

The objective of the ERM (2018) study was to evaluate the contribution of the pure polymer to the overall classification applied to the amino resin products considered. In order to facilitate this a tool was developed to derive the likely contribution of the polymer to the overall classification of the product. The method used the known hazards of the amino resin products as a starting point and subtracted out the known effects on the non-polymeric components of the product (e.g. free monomers, reactants, impurities, additives and/or solvents)[14]. Any effect that could not be explained by the non-polymeric components was then attributed to the polymer components[15].

The grouping approach used in the study was based on composition as this is common practice within the industry. Complete composition data was available for all products considered in the study.

Only endpoints where sufficient data were available were discussed in the study. Thus, there was insufficient information available to assess acute inhalation toxicity, toxicity to reproduction, STOT SE[16], STOT RE[17] and aspiration toxicity. The classification of the amino resin products for skin sensitisation, carcinogenicity and mutagenicity was driven by the presence of formaldehyde and so no conclusions could be reach for the polymeric components for these endpoints.

The study found that hazards are associated mainly with alkylated amino resins polymers. The ERM (2018) report investigated these polymers further and concluded that the hazards were associated mainly with butylated amino resin polymers with effects such as irritation being related to the presence of butoxy groups[18]. A more detailed summary of this study is given in a Confidential Annex[19].

Information from PlasticsEurope (PlasticsEurope, 2019b)

The majority of plastics have number average molecular weights significantly above 10,000 Da and the GPC methods used to characterise molecular weights are not necessarily designed to accurately determine the low molecular weight range. In addition, the presence of additives will complicate the determination of the low molecular weight range. In order to reliably quantify the low molecular weight oligomers, it will be required to develop specific techniques and adaptations (PlasticsEurope, 2019b).

Based on a survey of members, PlasticsEurope (2019b) considers that the vast majority of the polymers produced by PlasticsEurope members would not meet the PRR criteria suggested in the background material for the workshop in May 2019. However the survey indicated that for some polymer sub-sectors, a significant percentage of the volume meets one of the molecular weight criteria and/or the RFG1 criterion (see the proposed criteria in Section 3.2). No further information on the numbers of polymers meeting these criteria is currently available.

The European Council of Vinyl Manufacturers (EVCM), a product group of PlasticsEurope, carried out an analysis based on readily available data that showed that the PVC resins placed on the EU market by their members (representing >70% of the EU production capacity) would not meet any of the suggested criteria for PRR (PlasticsEurope, 2019b).

Information on polymers used in detergents and maintenance products (AISE, 2019)

The International Association for Soaps, Detergents and Maintenance Products (AISE) has provided some information on the polymers used in detergents and maintenance products within the EU (AISE, 2019). The polymers most commonly used in detergent and maintenance products can be grouped within the following six polymer categories.

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[14] The approach was based on the mixture classification rules from the CLP Regulation but the rules were applied in the reverse sense.

[15] Consideration of the statistical robustness of this approach is beyond the scope of the current project.

[16] Specific Target Organ Toxicity – single exposure.

[17] Specific Target Organ Toxicity – repeat exposure.

[18] Irritation/corrosion hazard was thought to be related to both the butoxy-group content and formylation rate of the polymers.

[19] Annex made available to the Commission only but not for publication.

- Polyethers (e.g. polyethylene glycol and ethoxylated lauryl alcohol);
- Polyacrylates (e.g. acrylic styrene copolymer and sodium polyacrylate);
- Siloxanes and silicones (e.g. polydimethylsiloxane);
- Polysaccharides (e.g. cellulose gum, xanthan gum and starch);
- Polyvinyl (e.g. polyvinyl alcohol, polyvinylpyrrolidone); and
- Polyesters (e.g. polyethylene terephthalate).

AISE (2019) states that the properties of these polymers, such as particle size distribution, physicochemical properties (such as water solubility) and biotic and abiotic degradability in relevant environmental compartments varies significantly, dependent on the size of the polymer/copolymer used. No further information was provided on these aspects.

AISE (2019) considers that most high-molecular-weight polymers are inherently non-hazardous.

Information from the Classification and Labelling database

A number of basic searches of the ECHA Classification and Labelling (C&L) Inventory have been carried out[20]. The results are briefly summarised below.

- A search for the term "poly" resulted in 3,078 results[21]:
    - 118 (3.8%) Classified for physical hazards;
    - 28 (0.9%) Classified for aspiration hazard[22];
    - 2,299 (74.7%) Classified for health hazards:
        - 201 (6.5%) Classified as CMR[23].;
        - 397 (12.9%) Classified for specific target organ toxicity[24];
        - 668 (21.7%) Classified as skin or respiratory sensitisers[25];
        - 608 (19.8%) Classified for acute toxicity[26]; and
        - 1,907 (62.0%) Classified for corrosivity or irritancy[27].
    - 898 (29.2%) Classified for environmental hazards:
        - 163 (5.3%) Classified for acute aquatic toxicity[28]; and
        - 842 (27.4%) Classified for chronic aquatic toxicity[29].
    - 77 (2.5%) Substances with harmonised classification and labelling.

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[20] https://echa.europa.eu/information-on-chemicals/cl-inventory-database. Search carried out on the 24th October 2018. It is not possible to search the inventory specifically for polymers and so the search was carried out using the term "poly" and "polymer". Note also there is a mixture of CLP and GHS terminology.

[21] For the breakdown some substances are classified in more than one sub-class.

[22] Substances classified as Asp. Tox. 1.

[23] Carcinogenic, mutagenic and/or toxic to reproduction. Substances classified as Car. 1A, Carc. 1B, Carc. 2, Muta. 1A, Muta. 1B, Muta. 2, Repr. 1A, Repr. 1B and/or Repr. 2.

[24] Substances classified as STOT SE 1, STOT SE 2, STOT SE3, STOT RE 1 or STOT RE 2.

[25] Substances classified as Resp. Sens. 1, Resp. Sens. 1A, Resp. Sens. 1B, Skin Sens. 1, Skin Sens. 1A and/or Skin Sens. 1B.

[26] Substances classified as Acute Tox. 1, Acute Tox. 2, Acute Tox. 3, Acute Tox. 4.

[27] Substances classified as Eye Dam. 1, Eye Irrit. 2, Eye Irrit. 2A, Eye Irrit. 2B, Skin Corr. 1, Skin Corr. 1A, Skin Corr. 1B, Skin and/or Corr. 1C, Skin Irrit. 2.

[28] Substances classified as Aquatic Acute 1.

[29] Substance classified as Aquatic Chronic 1, Aquatic Chronic 2, Aquatic Chronic 3 or Aquatic Chronic 4.

- A search for the term "polymer" resulted in 1,670 results:
    - 66 (4.0%) Classified for physical hazards;
    - 1,147 (68.7%) Classified for health hazards:
        - 134 (8.0%) Classified as CMR;
        - 221 (13.2%) Classified for specific target organ toxicity;
        - 444 (26.6%) Classified as sensitisers;
        - 306 (18.3%) Classified for acute toxicity;
        - 12 (0.7%) Classified for aspiration hazard; and
        - 916 (54.9%) Classified for corrosivity or irritancy.
    - 428 (25.6%) Classified for environmental hazards:
        - 59 (3.5%) Classified for acute aquatic toxicity; and
        - 414 (24.7%) Classified for chronic aquatic toxicity.
    - 16 (0.96%) Substances with harmonised classification and labelling.

In terms of numbers, both searches revealed that around 70% of the entries relate to health hazards and around 30% of the entries relate to environmental hazards. The number classified based on their physical hazard is relatively low (<4%). The most numerous classifications relate to corrosivity or irritancy.

It is important to note the following.

- The entries by companies have not been reviewed by regulators;
- Not all entries retrieved by the search are polymers. For example, the search carried out using "poly" will retrieve polyhalogenated substances, and there are a number of petroleum streams retrieved by both searches.
- There may be polymers within the C&L inventory that do not include "poly" or "polymer" in their name. These will not be retrieved by the search.
- It is not clear from the entries within the C&L inventory whether the classification relates to the polymer itself or other constituents present within the polymer (e.g. unreacted monomer or additives added to mixtures.). This limits the usefulness of the information for identifying possible PRR.

Information from polymers notified under the former Dangerous Substances Directive

The classifications of polymers notified under the former Dangerous Substances Directive (DSD) have also been considered. The complete data sets for all 117 polymers notified under DSD were made available and a summary of the main findings from the analysis of these data sets is given below. The data are considered in relation to the molecular weight ranges of the polymers. Molecular weight data was not available for all polymers.

- Six polymers (5%) were reported to have MWn <1000 Da:
    - Five of these were classified as dangerous to the environment and also were labelled for health effects; and
    - One polymer was not classified.
- Fifteen polymers (12.5%) were reported to have MWn >1000 to <5,000 Da;
    - Three were classified as hazardous (two as dangerous to the environment and one as CMR):

        - Two of these polymers had a high content (>20%) of low molecular weight constituents (<1000 Da). Information on the amount of low molecular weight constituents was not available for the other substance.
        - One of the polymers may have had reactive functional groups (this could not be fully established from the information provided).
    - Twelve polymers were not classified as hazardous:
        - Data on the low molecular weight content was available for two of these substances. Both had <10% MW <1000 Da and <5% MW <500 Da.
        - Ten of these substances were polyesters.
- Four polymers (3.3%) were reported to have MWn >5,000 Da to <10,000 Da:
    - One of these polymers was classified as dangerous to the environment and for skin sensitisation. This had surface-active properties.
    - The remaining three polymers were not classified. No information on the low molecular weight content of these polymers was available.
- Twenty eight polymers (23.3%) were reported to have MWn >10,000 Da.
    - Five of these polymers were classified as hazardous:
        - Of these two were on the basis of physical hazards (flammability) and one was for skin sensitisation and may have been based on a high monomer content.
        - The remaining two polymers were classified as dangerous to the environment. Information on the low molecular weight content was available for one of these substances (<2% <1000 Da); no information was given for the other substance. The structural features that leads to the classification of these two polymers is unclear.
    - Twenty three polymers were not classified as hazardous:
        - Information on the low molecular weight content was available for four of these substances. For these, the content <1000 Da was <7%.
- No molecular weight data were reported for 60 polymers (50%):
    - Twenty six polymers were classified as hazardous based on environmental and/or health concerns. It has not been possible to analyse these in more detail but the following should be noted:
        - In at least two cases the polymer content appears to have been relatively low for example solvent or non-polymeric substances may have been present. In these cases, the classification may be driven by these non-polymeric constituents.
        - Reactive functional groups may have been present in at least one case.
        - Two polymers had surface active properties.
        - Several polymers are, or potentially are, cationic.
    - Thirty four polymers were not classified:
        - One of these had a low content of low molecular weight constituents <1000 Da.
- No classification and labelling entry was available for seven polymers (5.8%).

Overall, the total number of polymers classified or labelled as hazardous under the DSD is 40 or ~34%. The following conclusions can be tentatively drawn from the analysis undertaken (given the limitations of the data available).

- There is a higher incidence of hazardous properties within the following groups:
  - Polymers with low MWn (e.g. <1000 Da) or polymers with substantial amounts of constituents with MW <1000 Da);
  - Polymers with reactive functional groups;
  - Polymers with surface active properties; and
  - Cationic polymers.
- There is a lower incidence of hazardous properties within the following groups:
  - High molecular weight polymers which lack reactive functional groups or have low amounts of constituents with MW <1000 Da; and
  - Polyesters.

Information from safety data sheets and product literature

Safety data sheets (SDS) for polymers have been obtained from a search of the internet. Clearly, collection of SDS for all possible polymers is not feasible within the scope of this project. Therefore, searches were made for a number of known polymer types in order to attempt to obtain a reasonable (semi-random) cross-section of SDS that are available. In most cases the SDS distinguish between classifications based on the polymer constituents[30] themselves (e.g. oligomers, polymeric fraction, unreacted monomers, stabilisers) and classifications based on other component[31] substances that may be present in the polymer (e.g. additives); the latter have been disregarded.

A total of 69 SDS have been analysed. For one of these it was not clear from the SDS whether the substance would meet the definition of a polymer and so was discounted (thus giving 68 polymer SDS). The main findings are summarised below.

- Basic physico-chemical data are not given in all cases. For example, water solubility data (or indications of solubility[32]) were given in 48 cases (70%) but much of this was qualitative in nature;
- Very limited information is given in molecular weight or molecular weight distributions;
- Two polymers (2.9%) were classified for physical hazard:
  - H228[33] was applied to a nitro cellulose polymer; and
  - H290 was applied to a hydrolysed polymaleic anhydride polymer[34].
- 25 polymers (37%) were classified for one or more health effects:
  - There were nine polymers (13%) assigned H302[35]:

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[30] ECHA (2017) defines as "constituent" as any single species present in a substance that can be characterised by its unique chemical identity. For this report a polymer constituent means any constituent which falls within the REACH definition of a polymer. This is consistent with ECHA (2012).

[31] ECHA (2017) uses the term component for substances intentionally added to form a mixture.

[32] For example, terms such as soluble, miscible, insoluble.

[33] H228: Flammable solid.

[34] H290: May be corrosive to metals.

[35] H302: Harmful if swallowed.

  - Six (8.8%) of these related to alcohol ethoxylates of various carbon chain length and number of ethoxylate groups. The other related to a hydrolysed polymaleic anhydride.
- One polymer (1.5%) was assigned H314[36]:
  - This was a polyacrylic acid-maleic acid copolymer.
- Four polymers (5.9%) were assigned H315[37]:
  - These included a bis(maleimide) resin, a hydrolysed polymaleic anhydride and two polymers where the identity was not given.
- Three polymers (4.4%) were assigned H317[38]:
  - These were an ethoxylated/propoxylated amine, a rubber curing agent and an elastomer.
- There were 11 polymers (16%) were assigned H318[39]:
  - All of these related to alcohol ethoxylates of various carbon chain length and number of ethoxylate groups or other polymers with surface-active properties.
- Six polymers (8.8%) were assigned H319[40]:
  - These were a bis(maleimide) resin, the sodium salt of a polyacrylic acid, a hydrolysed polymaleic anhydride, an ethoxylated/propoxylated amine, a substituted amine and a polymer where the identity was not given.
- One polymer (1.5%) was assigned H330[41]:
  - This was a polyalkylene glycol ether.
- Three polymers (4.4%) were assigned H332[42]:
  - These were a hydrolysed polymaleic anhydride.
- One polymer (1.5%) were assigned H335[43]:
  - This was a polyethylene glycol with an average molecular weight of 400 g/mole. However other similar polymers were not classified.
- One polymer (1.5%) was assigned H372[44]:
  - This was a polyalkylene glycol ether.
- Two polymers (2.9%) were assigned H372[45]:
  - These were a substituted amine and a polymer where the identity was not given.

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[36] H314: Causes severe skin burns and eye damage.
[37] H315: Causes skin irritation.
[38] H317: May cause an allergic skin reaction.
[39] H318: Causes serious eye damage.
[40] H319: Causes serious eye irritation.
[41] H330: Fatal if inhaled.
[42] H332: Harmful if inhaled.
[43] H335. May cause respiratory irritation.
[44] H372. Causes damage to organs through prolonged or repeated exposure.
[45] H373. May cause damage to organs through prolonged or repeated exposure.

- Eleven polymers (16%) were classified for one or more environmental effects. The safety data sheet for a further polymer, a poly(dialkyldimethylammonium chloride) was unclear as to whether it was classified for environmental effects or not:
  - Three polymers (4.4%) were assigned H400[46]:
    - These were two alcohol ethoxylates and a substituted amine.
  - One polymer (1.5%) was assigned H410[47]:
    - This was a substituted amine.
  - Two polymers (2.9%) were assigned H411[48]:
    - These were a surface-active polymer and a cationic polymer derived from cellulose.
  - Eight polymers (12%) were classified as H412[49]:
    - Six of these polymers (8.8%) were alcohol ethoxylates or similar and the remaining polymers were a hydrolysed polymaleic anhydride and a urethane acrylate dispersion.
- It was not always possible to establish from the safety data sheet whether the classification resulted from the polymer itself or other substances present in the mixture.

The following broad conclusions can be drawn from the SDS.

- The most common classifications for the sample polymers relate to irritancy. This is in broad agreement with the findings from the analysis of the C&L database above.
- For many polymers the SDS is based on limited data and the lack of a hazard classification is often based on an assumption of "no effect" rather than actual data. It is not possible to establish the veracity of such assumptions as part of this project.
- The SDS give only very limited information on important polymer properties such as molecular weight distribution, water solubility and substance identity.
- Where classifications are given, or toxicity/ecotoxicity data are reported, it is not always clear what was tested and what polymer constituents or component substances the data refer to.

Information on persistence of polymers

Fendinger (2000) summarised the results of a five-year industry-sponsored research programme into the environmental fate and effects of polydimethylsiloxanes (PDMS). The tests demonstrated that no adverse effects to aquatic and terrestrial organisms are anticipated from PDMS or its breakdown products at concentrations many times higher than could possibly occur in the environment. Laboratory and field measurements demonstrate that PDMS does not bioaccumulate.

The use of biodegradable polymers is increasing in agriculture, to replace those materials derived from petroleum, thus reducing environmental concerns (Castellani et al., 2016). In accordance with ISO 14855-1, the study evaluated the biodegradability of three biopolymers based on renewable resources (two poly(ε-caprolactone) (PCL) composites and a compatibilised polylactic acid/polybutyrate (PLA/PBAT) blend. The biodegradation tests were carried out under composting conditions using mature olive-mill waste (OMW) compost and inoculum. Some of the samples reached more than 80% biodegradation in <20 days.

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[46] H400: Very toxic to aquatic life.

[47] H410: Very toxic to aquatic life with long-lasting effects.

[48] H411: Toxic to aquatic life with long-lasting effects.

[49] H412: Harmful to aquatic life with long lasting effects.

Biodegradable polymers like poly(lactic acid) (PLA) are seen as a suitable alternative to commodity plastics (Haider et al, 2019). However, poly(lactic acid) is basically non-degradable in seawater. Similarly, the degradation rate of other biodegradable polymers also crucially depends on the environments they end up in, such as soil or marine water, or when used in biomedical devices. This minireview shows that biodegradation tests carried out in artificial environments lack transferability to real conditions and, therefore, highlights the necessity of environmentally authentic and relevant field-testing conditions. The total global production capacity of biodegradable plastics was 870,000 tonnes in 2017.

Besides PLA, which accounts for 24.0% of the global production capacity for biodegradable polymers, mainly starch blends (43.8%), other biodegradable polyesters including poly(butylene succinate) (PBS) (11.4%) and poly(butylene adipate terephthalate) (PBAT, EcoflexU) (11.6%) and polyhydroxyalkonates (PHAs) (5.6%) and 3.5% others are produced on an industrial scale (Haider et al, 2019).

In general, the process of polymer biodegradation can be divided into four steps: i) biodeterioration, ii) depolymerisation, iii) bioassimilation, and iv) mineralisation (Haider et al, 2019). The first step results in fragmentation of the polymer into smaller particles. Microbial enzymes then in turn catalyse the depolymerisation of the polymer chain into oligomers, dimers, or monomers. These smaller molecules can then be taken up into microbial cells and degraded further.

Ecotoxicological data for biodegradable polymers is scarce (Haider et al., 2019). More studies have been carried out in the field of human toxicology, as biodegradable polymers are often used in medical applications. However, for compostable plastics, certain standards and norms have been set, which also include ecotoxicity requirements. The European standard EN 13432, for example, requires data on the germination and growth of plants. In this context, most of the published studies focus on effects that may arise during the application of certain biodegradable products, such as plastic mulch films used in agriculture. Such products are tested for their effects on soil or compost, mostly in combination with a biodegradation test.

Table 2 of Haider et al. (2019) gives an overview of ecotoxicity studies on biodegradable polymers including starch blends, PLA, PBS, and PBAT (EcoflexU). All of the studies assessed the ecotoxicity in combination with biodegradation experiments. The most commonly used test organisms for terrestrial ecosystems are plant species and microorganisms. During the degradation process, a generally increased microbial activity (accompanied by a drop in pH value and abnormal high oxygen demand) can have a temporary negative impact on soil organisms. However, in most studies, no harmful effects of degradation products of the polymers were detected. However, for PLA, cytotoxic and genotoxic effects of degradation products on the common onion (*Allium cepa*) were found and an inhibition of microbial activity caused by PLA mulch films after 84 days of incubation in the soil was detected.

COM (2018a and 2018b) presents the European strategy for plastics in a circular economy which considers biodegradable plastics. The aims of the strategy are as follows (reproduced from COM (2018a and 2018b).

- *Plastics and products containing plastics are designed to allow for greater durability, reuse and high-quality recycling. By 2030, all plastics packaging placed on the EU market is either reusable or can be recycled in a cost-effective manner. Innovative materials and alternative feedstocks for plastic production are developed and used where evidence clearly shows that they are more sustainable compared to the non-renewable alternatives. This supports efforts on decarbonisation and creating additional opportunities for growth;*
- *The increasing market shares of plastics with biodegradable properties bring new opportunities as well as risks. In the absence of clear labelling or marking for consumers, and without adequate waste collection and treatment, it could aggravate the existing problem of plastics leakage and create problems for mechanical recycling. On the other hand, biodegradable plastics can certainly have a role in some applications and the innovation efforts in this field are welcomed.*
- *Establishing a clear regulatory framework for plastics with biodegradable properties.*

- *In response to the high level of plastic leakage into our environment and its harmful effects, solutions have been sought to design biodegradable and compostable plastics. Targeted applications, such as using compostable plastic bags to collect organic waste separately, have shown positive results; and standards exist or are being developed for specific applications.*
- *However, most currently available plastics labelled as biodegradable generally degrade under specific conditions which may not always be easy to find in the natural environment, and can thus still cause harm to ecosystems. Biodegradation in the marine environment is particularly challenging. In addition, plastics that are labelled 'compostable' are not necessarily suitable for home composting. If compostable and conventional plastics are mixed in the recycling process, it may affect the quality of the resulting recyclates. For consumer applications, the existence of a well-functioning separate collection system for organic waste is essential.*
- *Some alternative materials claiming biodegradability properties, such as 'oxodegradable plastics', have been found to offer no proven environmental advantage over conventional plastics, while their rapid fragmentation into microplastics cause concerns. Therefore, the Commission has started work with the intention to restrict the use of oxo-plastics in the EU.*
- *The Commission is particularly attentive to innovation on materials that fully biodegrade in seawater and freshwater and are harmless for the environment and ecosystems*.

The Commission (EC 2018c) has carried out an impact assessment of oxo-degradable plastics on the environment.

ECHA (2019b) have proposed a restriction on the use of intentionally added microplastics. The proposed restriction includes a derogation (3b) for "polymers that are (biodegradable), as set out in the criteria in Annex X". As well as standard OECD test systems for biodegradation, ECHA (2019b) also gives the following ISO tests that can be used to determine biodegradability of microplastics.

- Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium (EN ISO 14852:2018 or EN ISO 14851:2004);
- Plastics – Determination of aerobic biodegradation of non-floating plastic materials in seawater/sediment interface (EN ISO 19679:2016 or EN ISO 18830:2006); and
- Ultimate aerobic biodegradability of plastic materials in soil (EN ISO 17556:2012).

AISE and IFRA Europe (2019) have outlined a number of considerations and suggestions in relation to determining the biodegradability of microplastics[50].

- The test duration of standard ready- and inherent biodegradability tests may need to be extended owing to the physico-chemical properties of microplastics and polymer biodegradation kinetics.
- Modifications in simulation tests may be needed as radiolabelling and cold analytical techniques to monitor parent compound and metabolite concentrations during the tests are limited for microplastics.
- Microplastic biodegradation is an area of emerging science and significant research in this area is currently occurring.

Other information

Lithner et al. (2011) indicated that there are three main processes for manufacturing polymers: bulk polymerisation, solution polymerisation and dispersion polymerisation. They suggested that, as the bulk

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[50] Although the AISE and IFRA Europe (2019) paper considers solid microplastics the considerations may be applicable to other polymers.

process is carried out without solvent, it gives the purest polymers as only monomers, small amounts of catalysts or initiators and possibly chain transfer agents are generally used in the process.

In terms of any future requirements to register polymers in REACH, it is important to consider the following.

- The number of polymers on the market within the EU is large:
  - It is estimated that between 400,000 and >1 million polymers are in commerce. Thermoplastics are the dominant types in terms of volume but thermosetting and other reactive polymers are dominant in terms of numbers (Ashford, 2018).
  - Polymer consumption in Europe was estimated to be around 36.5 million tonnes in 2014 and was predicted to reach 39 million tonnes in 2019[51].
  - More recent figures from PlasticsEurope (2018a) puts the total amounts of plastic produced in the EU-28 (plus Norway and Switzerland) as 64.4 million tonnes in 2017 and the total plastic converter demand at 51.2 million tonnes.
  - According to COM (2007) the main polymer products (in tonnage terms) manufactured in the EU include the following:
    - Polyolefins;
    - Polystyrene;
    - Polyvinyl chloride;
    - Unsaturated polyesters;
    - Emulsion polymerised styrene butadiene rubbers (ESBR);
    - Solution polymerised rubbers containing butadiene;
    - Polyamides;
    - Polyethylene terephthalate fibres; and
    - Viscose fibres.

    Polyolefins (polyethylene), polystyrene, polyvinyl chloride, polyethylene terephthalate, ESBR, polyamides and unsaturated polyester resins make up approximately 80% of the total European consumption of polymers. These high-volume polymers are typically produced in both batch and continuous processes in installations with a capacity typically ranging from 10,000 tonnes/year up to 300,000 tonnes/year.
  - Within each polymer group a wide range of individual product grades may exist (COM, 2017a).

COM (2007) considers that the polymer market can be broadly grouped as follows.

- Polymers based on petroleum-derived substances:
  - Structural materials:
    - Commodity polymers. This includes for example polyethylene, polypropylene, polystyrene, polyvinyl chloride, emulsion styrene butadiene rubber (ESBR) etc. These polymers are relatively low cost and are used in large amounts for structural materials such as tubes, films, profiles, containers, bottles, sheets, tyres, etc.

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[51] https://www.statista.com/statistics/538742/polymer-consumption-in-europe/ (accessed 8th January 2019).

        - Engineering polymers and speciality rubbers. This includes for example acrylonitrile butadiene styrene (ABS), polyamides, polyesters, polyacetals, polymethyl methacrylates, ethylene propylene diene monomer (EPDM), nitrile butadiene rubber (NBR), etc. These polymers are of intermediate cost and are used for special requirements, often for small parts such as clips, valves, special machine parts, etc.).
        - High performance products. This includes for example polyimide, polytetrafluoroethylene, polysulfone, polyetherketone, fluorinated and silicone rubbers, etc. These polymers tend to be higher priced and produced in lower volumes than the above and are used in applications where extreme requirements need to be met (e.g. high temperature, weather or solvent resistance, special wear of optical properties, medical applications where high purity is required, etc.).
        - Thermosetting polymers. This includes polyesters, epoxies, phenolics and alkyd resins. These are often used as coating resins and binders for fibrous reinforcements.
    - Functional materials. These are a relatively small part of the overall polymers market:
        - Commodity applications. This includes applications such as dispersant, detergents, flocculants, thickeners, superabsorbers and adhesives. Examples of polymers used include polyvinyl acetate, polyacrylic acid and derivatives and polyvinyl alcohol.
        - Special technical applications. This includes specialist applications such as membranes, optical fibres, products with electrical conductivity and light-emitting products. These are often relatively high-priced materials where the functionality rather than the mechanical properties is more important.
- Polymers based on renewable resources:
    - Historical examples include fibres from cellulose (cotton) or derivatives (e.g. cellulose acetate), fibres from polypeptides (wool), plastics from cellulose acetate and rubber from tree resin. Not all of these products remain competitive for economic reasons.
    - Newer wood-based plastic products tend to be limited to applications such as laminates for flooring, boats and musical instruments.
- Biodegradable polymers:
    - The market for biodegradable products is generally limited to niche applications. Examples include mulch film in agriculture, garbage bags for composting, paper coating, hygiene films including funeral applications and sanitary towels.
    - COM (2007) estimated that the market size for biodegradable polymers was around 50-200 kt/year in Western Europe (EU-15) with an actual consumption of around 8 kt/year at that time.

3.1.4 Key takeaways from scoping interviews

Meetings have taken place with the project Advisory Group and separately with representatives of the Australian Government National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and People for the Ethical Treatment of Animals (PETA). A number of useful documents have been provided and some of the key information is summarised below.

A number of documents have been provided by Government Canada. These are summarised very briefly in Table 3.8 below.

Table 3.8 Brief summary of documents provided by Government Canada

Document	Brief summary
Guidelines for the notification and testing of new substances: Chemicals and Polymers. Government of Canada (2005)	The document outlines the information requirements required for notification of polymers under the New Substances Notification Regulations (Chemicals and Polymers) of the Canadian Environmental Protection Act, 1999. Polymers with a high number average molecular weight that have a limited percentage of low molecular weight components (<1000 daltons), are chemically stable and do not contain certain reactive or cationic moieties or are polyesters manufactured solely from reactants listed within the Regulations are considered as reduced regulatory requirement (RRR) polymers.
Government of Canada Polymers website[Note 1] **and personal communication from Government of Canada**	Briefly summaries the Government of Canada Chemicals Management Plan for existing substances and how this has been applied to certain polymers under the Canadian Environmental Protection Act (CEPA), 1999. The polymers considered were listed on the Domestic Substances List Inventory and identified as candidates for further action following a categorisation exercise in 2006. A total of 603 polymers were identified as candidates for the polymer rapid screening approach and 275 of these were completed in the first phase (Environment Canada and Health Canada, 2014). The second phase considered the remaining 328 polymers along with a further 8 polymers identified in 2015 (giving a total of 336 polymers). The polymer rapid screening against the criteria set out under section 24 of CEPA [Note 2].resulted in the following: • >550 polymers were found to be of low ecological and human health concern; • 29 polymers were identified as requiring further assessment for ecological considerations; • 19 polymers were identified as requiring further assessment for human health considerations; and • 3 polymers were identified as requiring further assessment for both ecological and human health considerations.
Draft screening assessment reports	Draft screening assessment reports have been provided (or are planned to be published) for the following polymers. • Poly(bios) Group [five polymers] - published November 2018; https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/screening-assessment-polybios-group.html. The five substances considered were: tannins; humic acids; starch, oxidised; starch. 2-hydroxy-3-(trimethylammonio)propyl ether, chloride (SEGAC); and guar gum, s-hydroxy-3-(trimethylammonio)propyl ether, chloride (GEGAC). These were selected as requiring more detailed assessment for potential human health (tannins, humic and oxidised starch) or ecological effects (SEGAC and GEGAC) based on structural alerts and/or uses associated with significant consumer exposure. The toxicological information available indicated that tannins, humic acid and oxidised starch have a low hazard profile for human health. SEGAC and GEGAC both have cationic functionality but, on the basis of the use pattern, exposure pattern and hazard profile, SEGAC and GEGAC were not expected to pose a risk to the environment. • Epoxy Resins Group [four polymers] – published March 2018; https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/screening-assessment-epoxy-resins-group.html. The assessment covers three diglycidyl ethers of bisphenol A (DGEBA) epoxy resins a novolac epoxy resin. The resins contain epoxy reactive functional groups which are associated with potential adverse human health effects, have moderate chronic toxicity (primary associated with lower molecular weight resins MW<1000 Da) and are dermal sensitisers. It was concluded that dietary exposure was negligibly low and that they were not entering the environment in a quantity or concentration that may constitute a danger in Canada to human health or the environment; • Poly(amines) Group [nine polymers] – published November 2018: https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/draft-screening-assessment-polyamines-group.html. The poly(amines) considered had MWn >10 000 Da and all contain cationic amine functional groups and are used mainly as coagulants and flocculants for water and waste water treatment, pulp and paper production and oil field applications. The cationic amine functional groups are in general associated with adverse effects to fish, invertebrates and algae however the assessment found that the nine poly(amines) considered were expected to show moderate to low toxicity to aquatic organisms and low toxicity to sediment dwelling species in the natural environment as they form

Document	Brief summary
	colloidal solids which are not expected to be bioavailable. Therefore, it was concluded that they are not entering the environment in a quantity or concentration that may constitute a danger in Canada to human health or the environment. • Phenol-Formaldehyde Resins Group [eight polymers] – publication planned for 2019-2020. • Poly(alkoxylates/ether) Group [twenty-one polymers] – publication planned for 2019-2020. • Other Polymers Group [five polymers] – publication planned for 2019-2020.

[1] https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan/initiatives/polymer-rapid-screening-approach.html (accessed 2nd January 2018). [2] Section 64 of CEPA 1999 considers substances to be harmful if they a) have or may have immediate or long-term harmful effect on the environment or its biological diversity; b) constitute or may constitute a danger to the environment on which life depends; or c) constitute or may constitute a danger to human life or health in Canada. https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/general-information/fact-sheets/assessment-existing-substances.html (accessed 17th March 2020).

Health Canada has also provided some initial feedback on their experience from the notification of polymers. This is summarised in **Table 3.9**. A search of the Canadian Domestic Substances List (DSL)[52] for "poly" gave 22,513 entries[53].

Table 3.9 Brief summary of experience of Health Canada in the notification of polymers

Area	Brief summary of experience
Numbers and types of notification	Around 200-250 polymer notifications are received per year. The majority of polymers meet the criteria for reduced reporting requirements (polymers of low concern). Polymers with number average molecular weight >>10,000 Da are often true plastics or very highly cross-linked solids. Many notifications are for polyacrylate copolymers and polyolefin copolymers.
Molecular weight information	Typically receive molecular weight data (most often gel permeation chromatography data) on the isolated polymer. Any additives or impurities which might complicate the GPC interpretation are identified in the reporting form. In some cases, solvents are included as the polymer is difficult to isolate. It is being considered whether all polymers with number average molecular weight <1000 Da should require the testing prescribed for non-polymeric substances.
Safety data sheets	The (eco)toxicity data reported in safety data sheets is often inadequate to assess the hazards of the polymer itself. For example if the product contains mostly solvent or reactive diluent then the data reported often refers to those components and these can be hazardous whereas the polymer component may not be.
Other issues	One of the biggest issues is determining whether a substance meets the polymer definition. In principle a polymer as described by the definition can conceptually consist of three chemical species in a sample, and the regulators have received an example where essentially four discrete substances (as determined by HPLC) in a sample met the polymer definition. The polymer status of UVCB chemicals can also be difficult to ascertain.

The Government of Canada (2018) reported the results of the polymer rapid screening assessments for existing polymers in Canada. 603 polymers were initially identified as candidates for polymer rapid screening

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[52] https://pollution-waste.canada.ca/substances-search/Substance?lang=en

[53] Not all entries retrieved by the search will be polymers. For example, the search carried out using "poly" will retrieve polyhalogenated substances.

(275 polymers were assessed in phase 1 and 336 polymers in phase 2[54]). These polymers met the categorisation criteria under subsection 73(1) of CEPA[55], or were considered a priority based on other human health or ecological concerns. The second phase of the polymer rapid screening used conservative assumptions to identify which of these polymers warrant further evaluation and which are expected to be of low concern for human health or the environment.

The second phase of the polymer rapid screening for ecological concerns was based on four main steps. The first step was to identify the polymers which are not likely to be of ecological concern based on low import or manufacture volumes (<1000 kg/year). The second and third steps involved identifying polymers that are likely to have water extractability >2% by weight and to determine whether these polymers contain reactive functional groups (the step on reactive functional groups is not applied to polymeric surfactants). The final step was to apply two exposure scenarios that are protective of the environment and comparing exposure to a conservative acute ecotoxicity value for each polymer. The exposure scenarios effectively assume 5% release to water for a point source release (such as manufacture and blending) and 100% release from multiple point sources for down-the-drain use. If the predicted exposure is greater than the predicted effects threshold then the polymer is identified as requiring further assessment.

The human health component used a risk matrix to assign a low, moderate or high level of potential concern based on the hazard and exposure profiles of the polymers. This was carried out by firstly considering the maximum direct and indirect exposure potential, and corresponding exposure band, based on use pattern, import, manufacture or use volume and water extractability. Secondly, the hazard potential, and corresponding hazard band, was determined based on the presence of reactive functional groups and available toxicological data. Polymers with a moderate-to-high exposure potential and high hazard potential were identified as requiring further assessment.

Two polymers were found to be nonylphenol ethoxylates and are already subject to further risk assessment/risk management activities. A further 51 substances were identified as requiring further assessment solely due to ecological considerations and 19 polymers were identified as requiring further assessment solely due to human health considerations. A further 3 polymers were found to require further assessment based on both ecological and human health concerns. Overall it was concluded that 73 polymers (12% of the 603 polymers undergoing rapid screening) required further assessment. It was concluded that the remaining 283 polymers do not meet any of the criteria for defining a toxic chemical under section 64 of CEPA.

During the study workshop, further information on the experience in Canada with registration of new substances and polymers was presented. Around 20,000 notifications have been assessed, around half of which (10,000) are polymers. Of the 10,000 polymers around half (5,000) were concluded to be of low concern and referred to as RRR (reduced regulatory requirement[56]) substances, as no action will be taken on them. Of the 10,000 polymers, only 4,000 are unique. Four polymers were initially considered as RRR but have subsequently been considered to have potential to degrade to long-chain fluorinated compounds and so are no longer considered to be of low concern. The main concern in relation to health effects seems to lie with polymers with a molecular weight of <1000 Da.

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[54] The rapid screening approach, https://www.canada.ca/en/health-canada/services/chemical-substances/chemicals-management-plan/initiatives/rapid-screening-approach-chemicals-management-plan.html. The latter figure includes an additional 8 polymers that subsequently added and included in phase 2.

[55] This requires the Ministers of Health and of the Environment to categorize the substances on the Domestic Supply list to identify those that pose the greatest potential for exposure of the general population in Canada as well as those persistent or bioaccumulative substances considered to be inherently toxic. https://www.canada.ca/en/health-canada/services/environmental-workplace-health/environmental-contaminants/existing-substances/categorization-substances-domestic-substances-list.html (accessed 17 March 2020).

[56] Considerations for RRR polymers include > 10,000 MW, as well as reactive functional groups.

The US Toxic Substances Control Act (TSCA) Inventory[57] contains the following numbers of exempted polymers[58].

- Nine polyester polymers that are made only from reactants included in the specified list of low concern reactants;
- One polymer with (a) a MWn >= 1000 Da < 10,000 Da and (b) an oligomer content <10% below 500 Da and <25% below 1000 Da;
- No polymers with (a) a MWn >= 10,000 Da and (b) an oligomer content < 2% below 500 Da and < 5% below 1000 Da; and
- Three hundred and fifty-four polymers with a MWn >1000 Da.

Searching the inventory for "poly" gave too many hits to be reported. USEPA (2018) reports that in 2006 the TSCA Inventory contained approximately 82,900 chemical substances of which 29,500 were polymers.

During the consultation, one respondent indicated that approximately 10% of their polymers would not meet the polymers of low concern criteria in the USA.

Within Australia, proposals are currently being developed for how polymers will be dealt within under the new industrial chemicals scheme (AICIS – the Australian Industrial Chemicals Introduction Scheme). Drafts of the proposals were subject to public consultation during 2018 and the Australian authorities are currently in the process of refining the proposals. Therefore, the information presented below is subject to change.

The basic approach is that under the new scheme, is that all industrial chemical introductions, including introductions of polymers, that are not listed in the Australian Inventory, must be categorised in one of the following main categories.

- Exempted (very low risk) introductions;
- Reported (low risk) introductions; and
- Assessed (medium to high risk) introductions.

Thus, pre-market assessments of chemicals or polymers will only be conducted in chemicals or polymers that present a medium to high risk. Both the hazard and exposure are considered in making this decision.

The categorisation is carried out in a number of steps.

- Polymers that will be automatically assessed owing to their human health and environmental concerns are firstly identified. These include:
    - Certain polymers at the nanoscale;
    - Certain fluorinated organic polymers (those containing a sequence of ≥4 but <20 fully fluorinated carbon atoms); and
    - Persistent polyhalogenated organic polymers introduced at >100 kg/year.
- The next step is to identify polymers that will be automatically exempted owing to their expected very low indicative risk for human health and the environment. These include:
    - Polymers of low concern, other than high molecular weight polymers that have lung overloading potential;

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[57] https://www.epa.gov/tsca-inventory/how-access-tsca-inventory#download

[58] Search carried out on 17 July 2019.

- A polymer that is comparable to a listed polymer because it contains all the same reactants as the listed polymer and any additional reactants it contains are present at ≤2% by weight; and
- A low concern biopolymer. This is a biopolymer that only fails the criteria for a polymer of low concern because it is not stable.

For the remaining polymers the indicative human health risk, the indicative environmental risk and the overall indicative risk need to be determined using a multi-step process whereby both the hazards and exposure potential are assigned to bands. Full details of the proposal are given in the Industrial Chemicals (General) Rules 2018 Exposure Draft (Australian Government, 2018a) and the associated draft Categorisation Guideline (Australian Government, 2018b), and are not reproduced here. A brief summary of the hazards and exposure that can lead to categorisation in the medium and high-risk categories proposed in the draft AICS is given in Table 3.10 below.

Table 3.10 Summary of hazards and exposure leading to medium and high-risk categories proposed in draft AICS

Risk	Criteria
Indicative human health risk – Hazard band C	The following hazards (Hazard band C) result in a medium to high human health risk irrespective of the exposure band. • Carcinogenicity; • Mutagenicity; • Genotoxicity; • Reproductive toxicity; • Developmental toxicity; and • Adverse effects mediated by an endocrine mode of action.
Indicative human health risk – Hazard band B	The following hazards (Hazard band B) result in a medium to high health risk for polymers in Exposure band 3. • Acute toxicity (fatal or toxic)[Note 1]; • Specific target organ toxicity after single exposure; • Specific target organ toxicity after repeated exposure[Note 2]; • Skin corrosion [Note 3]; • Eye damage[Note 3]; • Skin sensitisation[Note 4]; • Respiratory sensitization; • Respiratory corrosion; and • Also included in Hazard band B are high molecular weight polymer that is water absorbing[Note 5], high molecular weight polymer that is reactive[Note 6] and high molecular weight polymer that contains certain chemical elements[Note 7]. Exposure band 3 applies in the following two cases as follows. • The introduction is for an end use other than in cosmetics, tattoo ink or personal vaporisers: ○ the total volume introduced is >1000 kg; and ○ the concentration at introduction and at the end use is >1% unless: a) the introduction is solely for the use in research and development; and b) the chemical is not made available to the general public on its own, in combination with one or more other industrial chemicals or as part of an article, including where the industrial chemical undergoes a physical or chemical change to produce the article; and c) control measures are used to eliminate or minimise the risks from the introduction or use of the industrial chemical to persons involved in the research and development for which the industrial chemical is introduced; and d) the use of the industrial chemical is subject to the control of the person who introduces the industrial chemical. • The introduction is for an end use in cosmetics, tattoo inks or personal vaporisers:

Risk	Criteria
	o the total volume introduced is >100 kg and o the concentration at introduction at the end use is >1%.
Indicative environment risk – Hazard band D	The following hazards (Hazard band D) result in a medium to high environment risk irrespective of the exposure band. • Persistent, bioaccumulative and toxic; • Ozone-depleting chemicals; • Synthetic greenhouse gas; • Contains arsenic, cadmium, lead or mercury; and • Adverse effects mediated by an endocrine mode of action.
Indicative environment risk – Hazard band C	For the indicative environment risk, the following hazards (Hazard band C) result in a medium to high environment risk for polymers in Exposure band 4 or 3. • Very toxic to any aquatic life; and • Persistent and bioaccumulative. Exposure band 4 applies in either of the following two cases as follows. • The environment categorisation volume is > 10,000 kg; • The introduction involves release into the environment of any of the following: o intentional release during use to land, biota, natural waterways or municipal water supplies; o intentional release to air during use (other than solely domestic or personal use; o if the industrial chemical is introduced for an end use in fire-fighting - release (intentional or otherwise) into the environment; o if the industrial chemical is introduced for an end use in offshore drilling – release (intentional or otherwise) into the ocean. Exposure band 3 applies as follows. • The introduction does not involve releases into the environment of a kind mentioned above; and • the environmental categorisation volume is >1000 kg but ≤10,000 kg.
Indicative environment risk – Hazard band B	The following hazards (Hazard band B) result in a medium to high environment risk for polymers in Exposure band 4. • Toxic to any aquatic life; and • Exposure band 4 is as above.

[1] It can be assumed that the acute toxicity (fatal or toxic) definition does not apply to high molecular weight polymers that has <5% by mass of molecules with molecular weight <1000 g/mole or <2% by mass of molecules with molecular weight <500 g/mole.

[2] It can be assumed that the specific target organ toxicity after repeated exposure definition does not apply to high molecular weight polymers unless they are known to be corrosive or severely irritating.

[3] It can be assumed that the skin corrosion and eye damage definitions do not apply to high molecular weight polymers, other than polymers that contain any of the following reactive groups with a combined functional group equivalent weight of <1000 g/mol: anhydride, epoxide, sulfonic acid, amine.

[4] It can be assumed that the skin sensitisation definition does not apply if the chemical is a high molecular weight polymer that contains: a) only low concern functional groups; or b) the only high concern functional groups are unsubstituted positions ortho and para to phenolic hydroxyl groups, partially-hydrolysed acrylamides, or has a combined functional group equivalent weight of ≥1000 g/mol.

[5] A high molecular weight polymer that is water absorbing has a number average molecular weight ≥10,000 g/mole, and is capable of absorbing its own weight or more in water, and is in particulate form, and contains particles with a particle size <10 micrometres.

[6] A high molecular weight polymer that is reactive has a number average molecular weight ≥1000 g/mole and <10,000 g/mole, and has moderate and/or high concern reactive functional groups, and has ≥5% by mass of molecules with molecular weight <1000 g/mole or ≥2% by mass of molecules with molecular weight <500 g/mole, and has combined functional group equivalent weight <1000 g/mole (moderate concern reactive functional groups only) or combined functional groups equivalent weight <5,000 g/mole (high concern and moderate concern functional groups).

[7] A high molecular weight polymer that contains certain chemical elements means a polymer that has a number average molecular weight ≥1000 g/mole and <10,000 g/mole and where any of the following apply: does not contain as an integral part of its composition (other than as an impurity) and of the chemical elements set out in Schedule 1, Clause 6 of the rules; or contains as an integral part of its composition (other than as an impurity) chemical elements other than those set out in Schedule 1, Clause 7 of the rules; or contains as an integral part of its composition (other than as an impurity), 0.2% or more by weight of any combination of the chemical elements set out in Schedule 1, paragraph 7(s) of the rules.

A number of reports and sources of information have also been provided by the European Environmental Bureau (EEB). These are summarised below.

- Considerations and criteria for sustainable plastics from a chemicals perspective. Background Paper 1. OECD Global Forum on Environment: Plastics in a Circular Economy:
  - Discusses the principles for sustainable plastic design and outlines a broad approach to hazard assessment referencing the globally harmonised system for classification and labelling (GHS), Cradle to Cradle (C2C) Certification[59], the USEPA Safer Choice Polymer Screen linked to the Sustainable Futures Summary Assessment (USEPA, 2013; already reviewed) and the GreenScreen for Safer Chemicals v.1.4[60], and also considers the consideration of polymers of low concern in the United States and Canada (already reviewed).
- Guidelines for sustainable bioplastics. Version 1.0. May 2009. Sustainable Biomaterials Collaborative:
  - Provides a roadmap for improvement of the sustainability of bioplastics. In terms of hazards to the environment and health the main focus appears to be on the substances used to make (or added to) polymers rather than the polymers themselves.
- Dossier – Non-intentionally added substances (NIAS). Food Packaging Forum. Second edition, June 2018:
  - Outlines in general terms the approach to identification and assessment of non-intentionally added substances (NIAS) in food contact materials. NIAS can potentially migrate into food and can include side products, breakdown products and contaminants; and
  - Also covers some of the analytical approaches used for quantification of NIAS in food contact materials.
- Chemicals associated with plastic packaging (Groh et al., 2019): Inventory and hazards[61]:
  - Presents a database of chemicals associated with plastic packaging, which includes chemicals used during manufacturing and/or present in the final plastic packaging. This identified 906 chemicals likely associated with plastic packaging. A ranking was developed based on the classification and labelling and of the 906 substances, 63 ranked highest for human health hazards and 68 ranked highest for environmental hazards. In addition, 7 of the substances were identified PBT or vPvB and 15 were identified as endocrine-disrupting chemicals. The identified hazardous chemicals are used in plastics as monomers, intermediates, solvents, surfactants, plasticisers, stabilisers, biocides, flame retardants, accelerators and colourants among other functions. Therefore, the main hazards considered were related to the monomers or additives present rather than the polymers themselves.
- The plastics scorecard. https://www.bizngo.org/sustainable-materials/plastics-scorecard.:

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[59] This is the Cradle to Cradle Certified Product Standard. For the hazard components, the focus is mainly on substances that may be present in polymers rather than the polymers themselves. https://www.c2ccertified.org/images/uploads/C2CCertified_Product_Standard_V3_121112.pdf (accessed 8th January 2019).

[60] This is a tool for identifying hazardous chemicals and safer alternatives to support product design and development, materials procurement and as part of alternatives assessment to meet regulatory requirements. https://www.greenscreenchemicals.org/ (accessed 8th January 2019).

[61] https://peerj.com/preprints/27036/ (accessed 8th January 2019).

    - This is a method for evaluation of the chemical footprint of plastics developed by BizNGO. The footprint is based on the number and mass of chemicals of high concern[62] used in the manufacturing and supply chains and contained in the final product. As such, it focusses mostly on the starting materials and additives used in the manufacture of polymers rather than the hazards of the polymer itself.
- Food Packaging Forum website (https://www.foodpackagingforum.org/).:
    - This website provides information on food packaging and health, including information on latest news related to food packaging issues and migration models.
- Clean Production Action website (https://www.cleanproduction.org/):
    - Provides information on tools and strategies for green chemicals, sustainable materials and environmentally preferable products. The website links to three main projects:
        - BizNGO. The plastics scorecard above was developed by this organisation.
        - Chemical Footprint Project. This provides an internal assessment survey for companies to benchmark their efforts in reducing their chemical footprint.
        - GreenScreen® for Safer Chemicals. This tool is designed to assess and benchmark chemicals based on hazard.

The view of one consultee obtained during the consultation was that there are a few types of polymers that are associated with acute/local hazards but that systemic and longer-term effects from exposure to polymers are extremely rare owing to negligible transmembrane bioavailability as a result of the large molecular size. Polymers with a high abundance of reactive functional groups can be skin or eye irritants and/or skin sensitisers if those reactive functional groups are bioavailable. Examples of polymers that can be irritants include non-ionic polyether surfactants and amino-functional polymers. Where aerosol use generates respirable particles, inhalation hazards due to local effects can occur with irritant polymers. Some other specific polymer types may also be associated with inhalation hazards from respirable aerosol exposure (e.g. polyalylene glycols, water proofing polymers) but most polymers result in the same types of (physical) effects from inhalation as other “inert” particles (such as wood dust).

3.1.5 Gaps and limitations from data collection

The gaps and limitations of the data collection are summarised below:

- There is some commonality between the various regulatory schemes, including the scheme proposed in COM (2015) for identifying polymers of low concern. However, this does not mean that all polymers that do not meet those criteria are equally hazardous or of high concern;
- Information on the hazardous properties of polymers is generally not readily available;
- More data are readily available for some types of polymers:
    - These tend to be the more -water-soluble polymers such as alcohol ethoxylates, alcohol ethoxysulfates, water-soluble polycarboxylates and cationic polymers.
    - There is experimental evidence of toxicity and/or ecotoxicity for these broad groups of polymers.
- Some polymers are classified for irritancy:

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[62] Within the scheme a chemical of high concern is defined as having any of the following properties: 1) persistent, bioaccumulative and toxic; 2) very persistent and very bioaccumulative; 3) very persistent and toxic; 4) very bioaccumulative and toxic; 5) carcinogenic; 6) mutagenic; 7) reproductive or developmental toxicant; 8) endocrine disruptor; or 9) neurotoxicant.

  - This is not considered in the COM (2015) proposed criteria, but it is a hazardous property, although it could be argued whether it is a hazardous property severe enough to be included as a criterion for PRR.
  - This may, in part, be a result of the pH of the polymer (or polymer solution) but it is not possible to establish this from the available data.
- The safety data sheets reviewed so far are of variable quality and are not always clear as to which polymer constituents or component substances the data refer to.
- Similarly it is not clear from the ECHA C&L Inventory if the classification is based on the polymer itself themselves or other constituent or component substances (e.g. unreacted monomer or additives added to mixtures).
- Basic information on polymer properties such as molecular weights and water solubility is not always available in the safety data sheet.
- The hazard data presented in safety data sheets are often based on an assumption of "no effect" rather than actual data. It is not possible to establish the veracity of such assumptions as part of this project.
- Information on impurities present in polymers is scarce.
- Industry representatives have reported that they have data on many polymers but need time to collate this information. The information provided so far suggests that many polymers are not hazardous[63].

3.1.6 Outcome

The main findings from Task 1.1 are summarised in Table 3.11.

Table 3.11 Main findings from Task 1.1

Aspect	Findings
Definition of a polymer	The definition of a polymer within REACH is consistent with the OECD definition of a polymer and in other polymer notification schemes worldwide.
COM (2015) study and criteria for polymers of low concern	The criteria proposed in the COM (2015) study for identification of a polymer of low concern are generally consistent with polymer notification schemes world-wide, particularly those in the United States, Canada and Australia. The rationale behind some of the criteria for polymers of low concern proposed in COM (2015) is not always clear, and some possible issues and limitations with the approach have been identified. This is the case in particular with the criteria related to the following areas. • Hazard information. The proposal in COM (2015) does not consider irritancy or corrosivity as part of the relevant hazard class and the hazard properties of the polymer may be substantially different from that of the monomers and other substances present. • Elemental limitations. The rational for inclusion in the COM (2015) proposal is not clear. • Degradability. No distinction is made between polymers that are readily biodegradable and those that may degrade to more hazardous products. • Water absorption. This is based on findings from a limited number of studies with high molecular weight polyacrylate polymers. The general applicability of the findings is unclear. • Polyesters. The available evidence for the criterion is not clear.

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[63] The Commission intend to consider further information submitted after the end of this study through CARACAL.

Aspect	Findings
	• Molecular weight and oligomer content. The cut-offs for low molecular weight oligomer contents appear to be a pragmatic choice for identification of polymers of low concern based on the available evidence/experience. • Reactive functional groups. The available experimental evidence for the criterion is not clear. However, the theoretical background to the criterion is based on sound science.
OECD (2009) study	The OECD (2009) study found a number of trends between polymer properties and potential for health or ecotoxicological concern. • The lower the number average molecular weight (MWn) of the polymer the higher the potential for health or ecotoxicological concern. • A higher potential for health or ecotoxicological concern was also found to relate to higher contents of low molecular weight oligomeric species. • No clear trends were observed between polymer class and any observed toxicity but it was noted that many polymer classes were each represented by only a limited number of datasets. • The presence of reactive functional groups was more often found in polymers with potential health or ecotoxicological concern than in polymers of low concern; however the available data was not sufficient to analyse confidently any trends with specific functional groups. Similarly, it is not possible to analyse confidently any trends with functional group equivalent weight (FGEW); however there was some indication that the higher concern polymers had lower FGEW than polymers of low concern. • A high proportion of polymers with water solubilities in the range 10 to 10,000 mg/L showed potential health concerns. Polymers with water solubilities <10 mg/L showed generally low health concern. No trends could be found between water solubility and ecotoxicological concern.
Experience of environmental assessment of polymers in the United States	Insoluble polymers are not expected to be toxic unless they form finely divided particles. The toxicity of insoluble particles does not depend on chemical structure and results from occlusion of respiratory organs such as gills. Water-soluble or dispersible polymers with molecular weights <1000 Da are requiring registration as they may be absorbed through biological membranes and cause systemic effects. Water-soluble or dispersible polymers with molecular weights >1000 Da may show toxicity through either direct surface-active effects on the outer membranes of aquatic organisms and/or indirect via complexation of essential nutrients. Examples include: • Anionic polymers; • Cationic polymers; and • Amphoteric polymers. Non-ionic polymers of negligible water solubility with MW_n >1000 Da, or <25% oligomers with MW_n <1000 Da or <10% oligomers with MW_n <500 Da are generally of low concern for ecotoxicity. Water-soluble or dispersible non-ionic polymers with MW_n >1000 Da, or <25% oligomers with MW_n <1000 Da or <10% oligomers with MW_n <500 Da, where the monomers are reacted via a random order, generally show LC_{50}/EC_{50} values >100 mg/L and are considered to be of low concern for ecotoxicity. Non-ionic polymers with MW_n >1000 Da, or <25% oligomers with MW_n <1000 Da or <10% oligomers with MW_n <500 Da that are blocked in order to use the polymer as a dispersant or surfactant could be toxic to aquatic organisms as a result of a surface-active mode of effect. Non-ionic polymers with MW_n <1000 Da, or >25% oligomers with MW_n <1000 Da or >10% oligomers with MW_n <500 Da may be requiring registration based on the bioavailability of the low molecular weight material.

Aspect	Findings
Available data on hazards of polymers	The data available on hazards of polymers are of variable quality. The literature search identified possible hazards from the following types of polymers. • Alcohol ethoxylates used as surfactants; • Alcohol ethoxysulfates used as surfactants; • Water-soluble linear polycarbonates used as surfactants; • Nonylphenol ethoxylates. The main concern here relates mainly to degradation to more hazardous metabolites; and • Cationic polymers in general. The classification and labelling data available for 117 polymers under the DSD have been analysed. Overall, ~34% of the polymers were classified or labelled as hazardous. There is a higher incidence of hazardous properties within the following polymer types: • Polymers with low MW (e.g. 1000 Da) or polymers with substantial amounts of constituents with MW <1000 Da); • Polymers with reactive functional groups;. • Polymers with surface active properties; and • Cationic polymers. There is a lower incidence of hazardous properties within the following polymer types: • High molecular weight polymers which lack reactive functional groups or have low amounts of constituents with MW <1000 Da; and • Polyesters. Analysis of a cross-section of available safety data sheets for polymers revealed the following. • Basic physico-chemical data are not given in all cases. For example, water solubility data (or indications of solubility) were given in 36 cases (64%) but much of this was qualitative in nature. • Two polymers (3.6%) were classified for physical hazard. These were a nitro cellulose polymer and a hydrolysed polymaleic anhydride polymer. • 14 polymers (25%) were classified for one or more health effects. These included several alcohol ethoxylates, a hydrolysed polymaleic anhydride. a polyacrylic acid-maleic acid copolymer, a bis(maleimide) resin, the sodium salt of a polyacrylic acid and a polyethylene glycol. • Six polymers (10.7%) were classified for one or more environmental effects. These included several alcohol ethoxylates and a hydrolysed polymaleic anhydride. The safety data sheet for a further polymer, a poly(dialkyldimethylammonium chloride) was unclear as to whether it was classified for environmental effects or not. • It was not always possible to establish from the safety data sheet whether the classification resulted from the polymer itself or other substances present in the mixture. • The most common classifications for the sample polymers relate to irritancy. This is in broad agreement with the findings from the analysis of the C&L database above. • For many polymers the SDS is based on limited data and the lack of a hazard classification is often based on an assumption of “no effect” rather than actual data. It is not possible to establish the veracity of such assumptions are part of this project. • The SDS give only very limited information on important polymer properties such as molecular weight distribution, water solubility and substance identity. • Where classifications are given, or toxicity/ecotoxicity data are reported, it is not always clear what was tested and what constituents or component substances the data refer to. Information on impurities present in polymers is scarce.

Aspect	**Findings**
Criteria for polymers requiring registration	No specific criteria are currently agreed for identification of polymers requiring registration The analysis carried out in task 1 has identified a number of polymer types that may be requiring registration. These are summarised below and will be used as the starting point for development of criteria for polymers requiring registration in Task 1.2. • Polymers with existing hazard classifications; • Cationic polymers; • Anionic polymers; • Amphoteric polymers; • Nonionic polymers with surface-active properties; • Polymers containing low molecular weight oligomers or impurities; • Polymers with reactive functional groups; • Some types of degradable polymers; and • Polymers capable of absorbing their own weight or more in water.

The review of previous regulatory activity and literature sources provides much useful prior art for the establishment of criteria for polymers requiring registration and a possible regulatory structure for registration. It also shows that coverage of the polymers on the market is not uniform in polymer type or in the completeness of data availability.

3.2 Task 1.2 Development of criteria for polymers requiring registration (PRR)

3.2.1 Introduction to identification of polymers requiring registration

This subsection considers and develops criteria that could be used for the identification of PRR. It uses as a starting point the information in COM (2015) and existing regulatory schemes reviewed in Task 1.1, along with the information found in the literature search and consultation reported in Task 1.1.

The current approaches in most regulatory schemes in relation to polymer notification or registration effectively use criteria to identify polymers of low concern which are then either exempt or have reduced regulatory requirements compared with non-polymeric substances. This approach is relatively conservative in that the criteria for identifying polymers of low concern are based on experimental evidence combined with experience gained through assessment of polymers and other substances that leads to a high confidence that polymers that meet the criteria for a polymer of low concern will then not present an unacceptable hazard or risk to humans or the environment. However, such approaches do not specifically identify which polymers out of the remainder are polymers requiring registration.

The following section discusses possible criteria for identification of PRR and whether, and in what form, these could be used in identifying candidate polymers requiring registration for possible registration under REACH. The criteria are presented in two groups: firstly, those where there is reasonably strong evidence for possible hazards from the polymer; and secondly those were there is less strong evidence for possible hazards.

The starting point for the suggested criteria is the existing (i.e. used in regulatory schemes outside of the EU) criteria for polymers of low concern and the criteria for polymers of low concern proposed in COM (2015) and the review of available information carried out in Task 1.1.

It is important to note that, if a polymer does not meet the criteria for a polymer of low concern, it does not automatically follow that the polymer will have properties that are hazardous to humans or the environment nor that it is a polymer requiring registration in terms of the aims of the current project. However, it can be stated with a reasonably high level of confidence that if a polymer meets these existing or proposed criteria for a polymer of low concern, then it should not be a polymer requiring registration within the current REACH context. These criteria have been supplemented with the information found in the literature search and during the initial consultation.

When developing the criteria, the assumptions given in **Table 3.12** have been taken into account in relation to monomers (or any other substances) used in the manufacturing of the polymer and the various additives that may be present in polymers.

Table 3.12 Assumptions for monomers and other substances present in polymers

Constituent	Assumptions for monomers (or any other substances) used in manufacturing of polymers and the various additives that may be present
Monomers	Monomers or any other substances manufactured in or imported into the EU are already subject to their own registration requirements under REACH. Monomers or any other substances present in polymers manufactured in or imported into the EU, where the monomer(s) or other substance(s) has not been already registered by an actor up the supply chain are subject to their own registration requirements under REACH Article 6(3) when both of the following conditions are met. • The polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s); and • The total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year. In this context, the total quantity is the total quantity of monomer or other substance ending up chemically bound to the polymer. In addition, in cases where the polymer includes unreacted monomer or residues from any other substances within the meaning of Article 6(3), this also needs to be registered. Both the reacted monomer and unreacted monomer (or reacted substance or unreacted substance) should be covered in the same registration dossier for the monomer substance (or the other substances).
Additives	Here it is important to distinguish between additives which are necessary to preserve the stability of the polymer (these are constituents of the polymer) and other additives that may be added to the polymer (these are components of the polymer mixture). Additives necessary to preserve the stability of the polymer: These are considered to be part of the polymer (constituents) and so may not necessarily be registered under REACH. However, in cases where these additives are substances in their own right that are manufactured or imported into the EU they will also be subject to their own registration requirements under REACH. Other additives added to polymers (components), that are manufactured in or imported into the EU, are already subject to their own registration requirements. Other additives may be present in imported polymers. These are already required to be registered if the quantity of additive imported in this way exceeds 1 tonne/year. Other additives may also be present in imported articles. In this case it is possible that the additive may not be registered unless: • the additive itself is already on the market in the EU (and so subject to the normal registration requirements); and • the additive in the article is intended to be released and the quantity imported exceeds 1 tonne/year; or the additive is a SVHC present at >0.1% w/w and the total present in the article is >1 tonne/year; in this case the additive has to be notified.

The current REACH registration requirements already consider the hazards from monomers and other substances used in the manufacture of polymers and additives other than those necessary to preserve the stability of the polymer. The requirements also cover the monomers, other substances and

additives (other than those necessary to preserve the stability of the polymer) in imported polymers. The registration for these should cover the entire lifecycle of the monomer, substances and additives including the presence/use in polymers. Therefore, these substances are all considered to be adequately covered within the existing REACH requirements and no further consideration is given to these in developing the possible criteria for polymers requiring registration. (cf table 2.2 p.16).

For additives used to preserve the stability of the polymer (and which are thus considered as part of the polymer), as noted in Table 3.12 above, it is possible that in some cases these may themselves already be registered as substances in their own right. However, that may not necessarily be the case in all circumstances (where the additive substances do not meet the current registration requirements for a substance). Therefore, this needs to be considered in the development of the criteria for polymers requiring registration.

The current REACH requirements for import of polymer articles are the same as for other (non-polymer) articles. It would therefore be inconsistent to have further registration requirements for polymer articles above those already in place for articles in general, and so this aspect is not considered specifically in the development of the criteria for polymers requiring registration.

When considering the criteria, it is important to bear in mind that they are intended to provide a pragmatic approach for identifying polymers that could possess properties that may present hazards to human health or the environment. The criteria are developed taking into account existing experience and the available evidence on properties or features of polymers that are associated with potential hazards to human health or the environment. The criteria are necessarily generalised and if a polymer meets one or more of these criteria, it does not necessarily follow that the polymer will possess hazardous properties (or indeed uncontrolled risks), but rather that the polymer could be considered as a candidate for subsequent registration whereby information on the actual hazards presented by the polymer are provided, documented and, if necessary, are assessed in more detail should hazards be identified. It should be noted that in REACH all non-polymeric substances on the market are registered regardless of hazard.

3.2.2 Possible issues arising from the definition of a polymer

The first stage in deciding if a polymer is a PRR is to decide whether the polymer meets the REACH definition of a polymer as given in Article 3(5) of the REACH Regulation and explained further in ECHA (2012).

It is important to note the following point related to polymers produced as solutions: The REACH definition of a substance (Article 3(1) of the REACH Regulation) excludes any solvent which may be separated without affecting the stability of the substance or changing its composition. The corollary to this is if a polymer is produced in solution and the solvent cannot be removed without affecting the stability of the polymer (substance) or changing its composition then the solvent should be considered to be part of the polymer (substance). If this is the case, then it would also be necessary to consider the solvent as part of the polymer when determining if it meets the REACH definition of a polymer (Article 3.5). In particular if the solvent content is high (e.g. 50 percent or more of the weight of the polymer solution) then the REACH definition of a polymer may not be met[64].

Health Canada/Government Canada have indicated that determining whether a substance meets the definition of a polymer is not always straight forward. However, under REACH this may be less problematic as substances that do not meet the definition of a polymer should have already been registered.

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[64] The REACH Article 3(5) definition states that a polymer comprises the following: a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; b) less than a simple weight majority of molecules of the same molecular weight.

3.2.3 What would make a polymer a Polymer requiring registration (PRR)?

To develop criteria for the identification of a polymer requiring registration it is firstly necessary to define what properties, in terms of hazard, would make the polymer a concern for human health or the environment. This leads to some fundamental questions, for example would a polymer be requiring registration if it showed adverse effects (hazards) in a given toxicological or ecotoxicological test at only very high concentrations, or would it require the adverse effects to lead to a hazard classification of some kind (for example the thresholds for hazard classification under the CLP Regulation[65] or some other thresholds)?

It is important to note that polymers are required to be classified under the CLP Regulation based on the available information. Therefore, polymers that already attract a hazard classification under the CLP Regulation could, on one level, be a polymer requiring registration. However, there are other factors that need to be considered.

Polymers that are not currently classified as hazardous may have been assessed as such based on a lack of information. It may be that they still have properties that would be requiring registration that have not yet been investigated. This may also be the case for many non-polymeric substances. Others may have been classified on the basis of the properties of the non-polymeric constituents.

A pragmatic approach is therefore needed in deciding when a polymer would be requiring registration or not. Once an understanding of what a polymer requiring registration may be in terms of its hazard profile it is then possible to define criteria that can be used to screen for polymers that may meet that profile. As a starting point, if it is assumed that many polymers are of low concern based on their high molecular weight/lack of bioavailability, the following hazard profile can be considered. Existing classification would be a key indicator.

A polymer requiring registration would pose one or more of the following hazards to human health and/or the environment:

- Acute ecotoxicity L(E)C50 ≤100 mg/L. This is based on the upper limit from the CLP criteria (ECHA, 2017a) for acute toxicity in relation to hazard classification for the environment. It also corresponds to concentration used in the limit test in the OECD guidelines for acute toxicity testing for fish (OECD, 1992), Daphnia sp. (OECD, 2004) and algae (OECD, 2011). Below this concentration it could be assumed that the polymer would be a polymer requiring registration in terms of hazards for the environment.
- For hazards to human health, it is difficult to set an effect level or concentration below which a given hazard would be considered to be requiring registration as this depends on the nature of the hazard. The concentration limits used for classification and labelling in the CLP Regulation could be used as a guide here.
- Possibility of formation of degradation products that are equally or more bioavailable and/or toxic than the polymer itself during use;.
- The presence of specific features in the polymer that may lead to toxicity to man or the environment.

This suggested hazard profile could be the basis of definition of criteria for polymers requiring registration under REACH. Determining whether these hazards present a risk to humans or the environment would then be part of any subsequent risk assessment undertaken.

In terms of defining criteria for identification of polymers requiring registration it is suggested to exclude, polymers that are known to be, or are suspected to be, of low concern. As discussed in Task 1, criteria for

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[65] 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. Official Journal of the European Union, L353, 31.12.2008, p.1.

identification of polymers of low concern have been defined previously in COM (2015) taking into account criteria that are used in regulatory schemes world-wide. Thus, it is assumed here that if a polymer meets the criteria in COM (2015) for a polymer of low concern it should not be a candidate for a polymer requiring registration unless there are specific additional factors that were not considered previously in COM (2015). Thus, the criteria proposed in COM (2015) have been considered, where relevant, within the criteria proposed in the following section for identification of a polymer requiring registration.

3.2.4 Suggested criteria for a polymer requiring registration with a stronger evidence base

Polymers classified as hazardous under the CLP Regulation

Discussion on hazard classification

As an overarching criterion, it is suggested that polymers with an existing hazardous classification under the CLP Regulation (including self-classification) are considered as a polymer requiring registration. However, it is relevant to consider that not all hazard classifications may be as relevant for the registration of polymers.

In line with the approach recommended in COM (2015), the hazard classes considered to be most relevant are those from the CLP Regulation which are considered most serious for health and the environment. Polymers classified under the EU CLP regulation in any other hazard classes (e.g. those resulting solely from physical hazards[66] or health hazards not covered below[67]) are considered not to meet the criterion for registration. Such hazards from polymers are, however, already covered under the EU CLP regulation. The rationale for this is that classification in one of these hazard classes alone would already provide sufficient information, via the safety data sheet, on safe use and that registration would be unlikely to provide any further information on safe use and, in the case of skin or eye irritants, the effects are potentially reversible. However, such polymers should also be assessed against the other criteria in order to determine if they have other properties that mean that they should be considered as polymers requiring registration.

Conclusion on hazard classification

For polymers for which information on hazard classification under the EU CLP regulation is available, a polymer requiring registration would be classified as any of the following classes:

- Acute toxicity (Acute Tox. 1 to Acute Tox. 4);
- Germ cell mutagenicity (Muta. 1A, Muta. 1B or Muta. 2);
- Carcinogenicity (Carc. 1A, Carc. 1B or Carc. 2);
- Reproductive toxicity (Repr. 1A, Repr. 1B, Repr. 2 or Lact.);
- Aspiration hazard (Asp. Tox. 1);
- Respiratory/skin sensitisation (Resp. Sens. 1, 1A or 1B)
- Skin sensitisation (Skin Sens. 1, 1A or 1B);
- Specific target organ toxicity – single exposure (STOT SE1 to SE3);
- Specific target organ toxicity – repeated exposure (STOT RE 1 and STOT RE 2);

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[66] i.e. Aerosol 1, 2 or 3, Des. Expl. 1, 2, 4 or 4, Expl. 1.1, 1.2, 1.3, 1.4, 1.5 or 1.6, Flam. Gas 1 or 2 (including combinations with Chem. Unst. Gas A or B), Flam. Liq. 1, 2, or 3, Flam. Sol. 1, 2, Met. Corr. 1, Org. Perox. A, B, C, D, E, F or G, Ox. Gas 1, Ox. Liq. 1, 2 or 3, Ox. Sol. 1, 2 or 3, Press. Gas, Pyr. Liq. 1, Pyr. Sol. 1, Self-heat. 1, or 2, Self-react. A, B, C, D, E, F or G, Unst. Expl. or Water-react. 1, 2 or 3.

[67] i.e. Eye Irrit. 2, 2A or 2B, Skin Irrit. 2.

- Eye Dam. 1 or Skin Corr. 1, 1A, 1B or 1C;
- Hazardous to the aquatic environment (Aquatic Acute 1, Aquatic Chronic 1 to 4); and
- Hazardous for the ozone layer (Ozone).

If no information is available on hazard classification of the candidate polymer, then this criterion does not apply.

It should be stressed that the classification here should relate to the polymer itself (i.e. those constituents that fall within the REACH definition of a polymer). Specifically excluded are classifications that result from the presence of monomers or additives other than those necessary to preserve the stability of the polymer[68].

Cationic polymers

Discussion on cationic polymers

Cationic polymers as a broad group are known to lead to measurable toxicity to aquatic organisms in laboratory tests when they are soluble or dispersible in water. USEPA (2012) and Boethling and Nabholz (1997) outline methods that can be used to predict the aquatic toxicity of cationic polymers and these are discussed in Annex F. The experimental data behind these predictive methods is summarised in Boethling and Nabholz (1997), although the exact identities of the polymers tested is not given.

USEPA (2012) and Boethling and Nabholz (1997) consider that there is no molecular weight limit for toxicity to aquatic organisms, and report that some polycationic polymers with molecular weights >1,000,000 Da are toxic to aquatic organisms. The reason for this is that the toxicity is not related to absorption of the polymer within the organism but rather to adsorption on the respiratory membranes of aquatic organisms.

The data from the analysis of the DSD data set carried out in Task 1.1 contained several cationic polymers that were classified as hazardous which also provides support for the hazardous properties to aquatic organisms.

Further confidential information on the hazards associated with certain cationic polymers was provided by Industry at a late stage in the current project. Unfortunately there was insufficient time to take these data fully into account in this review but the data showed that such cationic polymers may hazardous to the aquatic environment, and at concentrations similar to those predicted by Boethling and Nabholz (1997).

It is also relevant to consider the form of the polymer. In terms of hazards to the environment the most concern would be associated with those cationic polymers that are either soluble in water or dispersible in water. Insoluble polymers would not lead to significant exposure to aquatic organisms. However, for insoluble polymers, inhalation exposure to sprays/dust/powders could potentially occur in some applications and this could be requiring registration in relation to human exposure.

The approach outlined in USEPA (2012) and Boethling and Nabholz (1997) also takes into account mitigation factors (MF). These are used to take into account that dissolved organic carbon (DOC), particularly humic acid and other acidic substances, reduces the toxicity of cationic polymers in the aquatic environment. Laboratory studies usually have relatively low levels of DOC compared with the natural environment and so the results from standard aquatic toxicity tests may overestimate the toxicity of the cationic polymers to organisms in the environment. These factors, whilst important, are more relevant to the risk assessment of cationic polymers (i.e. as to whether the polymer presents a risk to the environment from a specific use) than understanding of the intrinsic hazards of the polymers. Furthermore, similar mitigation considerations are not necessarily specific to cationic polymers, for example the toxicity of non-polymeric cationic substances may also be similarly mitigated by the presence of DOC, and this needs to be considered on a case-by-case basis as part of a detailed risk assessment. Therefore, it is proposed that mitigation factors are not taken into

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[68] In line with the REACH definition of a polymer.

account when deciding if a cationic polymer is a polymer requiring registration or not but that such mitigation factors are taken into account in any subsequent risk/safety assessment requirements following registration.

The predictive methods in USEPA (2012) and Boethling and Nabholz (1997) apply to cationic polymers where nitrogen is the basis of the cationic group. Much less information appears to be available on cationic polymers based on phosphonium, sulfonium or other cationic groups. As the mechanism of toxicity of cationic polymers in general is related to adsorption to respiratory surfaces there is no reason to suspect that cationic polymers based on cationic groups other than nitrogen-based would be of a lower concern than those with nitrogen-based cationic groups. Therefore, any requirement to include cationic polymers as polymers requiring registration for registration under REACH should equally apply to all cationic groups.

In terms of human health concerns from cationic polymers, much less publicly available information appears to be available. COM (2015) considered that the human health concerns from cationic polymers are related to inhalation of cationic polymers which can then bind irreversibly to the lung membranes (which are anionic) resulting in acute and chronic lung toxicity.

Conclusion on cationic polymers

The overall conclusion is that cationic polymers should be considered as polymers requiring registration. Such polymers will typically contain one or more of the following groups.: Primary, secondary and tertiary amine groups or quaternary ammonium groups; and

- Phosphonium or sulfonium groups, or other groups that are, or can become, cationic.

Based on the criteria C1 and C2 for cationicity defined in COM (2015), the following criteria are suggested for identification of a polymer requiring registration.

- The polymer is a polymer requiring registration if it is a cationic polymer. Exceptions to this are:
  - Polymers with low cationic density, i.e. a polymer whose cationic group has a combined equivalent weight greater than 5,000 Da.

The exception in relation to the cationic group with a combined equivalent weight greater than 5,000 Da is proposed in COM (2015), and also appears in the regulatory schemes in the United States, Canada and Australia (see Task 1.1). The exact experimental basis behind this is not clear and may be based on experience gained within these regulatory schemes. It would appear necessary to make a distinction between a cationic polymer and a polymer with a limited number of cationic groups and, in the absence of other information, this molecular weight equivalent of 5,000 Da is suggested here. However, during the study workshop it was suggested that the equivalent molecular weight of 5,000 Da is too high for identification of a PRR and a lower value may be more appropriate. There is currently insufficient data available to test this. There is an ongoing CEFIC LRI project[69] which aims to improve the aquatic toxicity testing and risk assessment of cationic polymers and this project may provide further useful insights into this aspect.

COM (2015) also included an exception for solid polymers, not dispersible or soluble in water, not dispersible in air and only intended to be used in the solid phase. The basis for this is risk based assuming that the cationic polymers that would be of highest concern are those that are soluble or dispersible in water, as these can potentially lead to exposure of aquatic organisms following release/use. For human exposure, the highest concern would be extended to cationic polymers where inhalation exposure to sprays, dusts or powders could occur. However, in order to apply such an exemption for PRR would require knowledge of the use pattern and exposure potential. Although exposure potential is an important consideration when carrying out a chemical safety assessment under REACH it is recommended that such an exposure-related exemption is not included in the criteria for a PRR for the following reasons:

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[69] http://cefic-lri.org/projects/eco-46-improved-aquatic-testing-and-assessment-of-cationic-polymers-itap/

- The PRR should be as far as possible hazard based as REACH considers both hazard (classification and labelling) and risks.
- Manufactures and importers of polymers may not necessarily know all the downstream uses of their polymers.
- Uses can change in the future.
- It would be necessary to provide guidance as to what is meant by "soluble in water" and "not dispersible in water". This may be problematic in cases where the polymer has a relatively low solubility in water (e.g. mg/L level or below) as (a) information may not be available on the actual solubility and (b) the polymers may contain many constituents of differing water solubility making measurement and/or interpretation of water solubility data difficult. Similarly, many polymers are dispersible in water using appropriate dispersing agents but are never actually produced or used in this form.
- It would be necessary to provide guidance as to what is meant by "solid polymer" as properties such as melting point may not be appropriate for some polymers (for example glass transition temperature is often used to describe the properties of polymers).

COM (2015) also proposed a similar criterion for polymers that could potentially become cationic in the environment. This was discussed in detail at the workshop and it was suggested that pKa values may be a useful indicator for such substances. However, experience from regulators suggests that for such polymers protonation generally occurs only on a few sites and they rarely become highly protonated. In addition, there is not much evidence for the toxicity of these substances. There was general agreement at the workshop that a criterion based on the potential to become cationic was not needed.

Anionic polymers

Discussion on anionic polymers

COM (2015) does not give specific criteria for anionic polymers in relation to polymers of low concern. USEPA (2012) and Boethling and Nabholz (1997) indicate that there are two classes of anionic polymers that are known to be toxic to aquatic organisms. These are poly(aromatic acids) and poly(aliphatic) acids that are soluble or dispersible in water with average molecular weights >1000 Da. The toxicity seen with these anionic polymers is thought to be the result of complexation of nutrients metals[70] and/or surface activity rather than resulting from absorption through surface membranes of the organisms.

USEPA (2012) indicates that, in most cases, the level of toxicity seen is related to the structure and the distance between anionic groups on the polymer backbone.

- Poly(aromatic acids). Polymer structures that have been associated with hazards to aquatic organisms include carboxylated/sulfonated diphenolsulfones, sulfonated phenols, sulfonated cresols, sulfonated diphenylsulfones and sulfonated diphenyl ethers. The acute L(E)C_{50} values for these types of polymers are generally in the range 1 to 100 mg/L (USEPA, 2012) and is not influenced significantly by water hardness.

  Polymer structures that have been associated with a lower aquatic hazard include those based on sulfonated naphthalene and sulfonated benzene.

  USEPA (2012) indicates that the toxicity can be estimated by use of a nearest analogue (read-across) approach, using test data available for polymers of known composition. Boethling and Nabholz (1997) reports that there are no data for poly(aromatic phosphate) polymers and that

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[70] Toxicity in laboratory studies resulting from complexation alone does not necessarily suggests that such hazardous properties will be expressed in the environment.

these polymers should be considered to be of equivalent toxicity as the poly(aromatic sulfonates/carboxylates) until further information is available.

- Poly(aliphatic acids). These types of polymers are derived from repeating carboxylic acid, sufonic acid and/or phosphinic acid units and can be homopolymers of one acid or can be copolymers containing more than one acid. The polymers generally show a very low level of toxicity to fish and aquatic invertebrates at pH 7, with acute L(E)C_{50} values >100 mg/L. However, in laboratory studies the polymers are generally more toxic to algae than fish and aquatic invertebrates and this toxicity to algae is thought to result from complexation of nutrient metals.

  The toxicity to algae is very dependent upon the polymer structure and is influenced by the distance between repeating acid units and the presence of non-chelating groups. Water hardness is also known to influence their toxicity to algae.

  USEPA (2012) indicates that the toxicity can be estimated using a nearest analogue (read-across) approach, using test data available for polymers of known composition. USEPA (2012) also indicates that mitigation factors can be taken into when estimating the level of toxicity likely to occur in the environment.

The literature search carried out in Task 1.1 identified hazard data for several groups of anionic surfactants including alcohol ethoxysulfates and water-soluble linear polycarboxylates (homopolymers of acrylic acid and copolymers of acrylic and maleic acid). These data again suggest that such anionic polymers used as surfactants may pose hazards to aquatic organisms and the data in Task 1.1 are generally consistent with the information in USEPA (2012).

In terms of hazards to human health, the data identified in Task 1.1 suggest that anionic polymers are generally of low toxicity to mammals, but that solutions containing some anionic polymers may be irritating to skin and/or eyes.

Conclusion on anionic polymers

Given that some anionic polymers are known to lead to hazards to aquatic organisms and in many cases the effect concentration (e.g. L(E)C_{50}) is <100 mg/L, it is relevant to consider criteria for anionic polymers in terms of polymers requiring registration. As far as the authors are aware, no criteria have been defined specifically for anionic polymers as yet but, by comparison with the criteria for cationic polymers, the following criteria are suggested for anionic polymers.

- The polymer is a polymer requiring registration if it is an anionic polymer. The highest priority would be for such polymers that are surface active. Exceptions to this are[71]:
  - Polymers with low anionic density, i.e. a polymer whose anionic group has a combined equivalent weight greater than 5,000 Da.
- The polymer is a polymer requiring registration if it is expected to become an anionic polymer, i.e. if it contains groups reasonably anticipated to become anionic (e.g. acid groups or salts of acid groups) and/or be anionic in a natural aquatic environment (4 < pH <9). The highest priority would be for such polymers that are surface active. Exceptions to this are:
  - Polymers with a low anionic density, i.e. a polymer whose anionic group has a combined equivalent weight greater than 5,000 Da.

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[71] The version of these criteria presented at the workshop included an exemption for solid polymers not dispersible or soluble in water, not dispersible in air and only intended to be used in the solid phase. However, for the reasons discussed under the conclusions on cationic polymers it is recommended that such risk-based clauses are not included in the final criteria for a PRR.

It is also important to note that that the concern for this type of polymer is based mainly on ecotoxicity of two main types of anionic polymers, poly(aromatic acids) and poly(aliphatic) acids that are soluble or dispersible in water. The general applicability of this criterion for other types of water-soluble or dispersible anionic polymers is currently unclear, although it is clear from the analysis carried out in Task 1.1 that hazards exist with anionic (and other polymers) that possess surface active properties.

During the consultation and workshop, it was indicated that there are large classes of acrylic and methacrylic acid-based polymers which have carboxylic acid end groups and so are anionic. These polymers are typically non-hazardous and so the term anionic polymer may be too broad. Participants in the workshop considered that the equivalent weight cut-off of 5,000 Da may be too high. However, there is currently insufficient data available to investigate this aspect further. The available data suggest that anionic polymers with surface active properties are the most hazardous sub-group. Therefore, any initial requirements for polymers requiring registration should focus firstly on the anionic polymers with surface active properties in aqueous solution.

In order to apply this, the surface activity in aqueous solution associated with the most hazardous sub-group would need to be defined. This should be based on the current test guideline for surface tension (A5 of Council Regulation (EC) No 440/2008[72]). This states that substances which show a surface tension lower than 60 mN/m under the conditions of the test method should be regarded as being surface-active materials.

Amphoteric polymers

Discussion on amphoteric polymers

Amphoteric polymers contain both positive and negatively charged groups within the same polymer. USEPA (2012) and Boethling and Nabholz (1997) consider the aquatic toxicity of water-soluble or dispersible amphoteric polymers to be intermediate between that of cationic polymers and that of anionic polymers, and the toxicity is dependent upon the cation-to-anion ratio (CAR)[73] within the same molecule and the overall cationic charge density. The following trends are found:

- The toxicity of amphoteric polymers tends to increase with increasing cationic charge density; and
- At a constant cationic charge density, the toxicity tends to increase with increasing CAR.

USEPA (2012) uses a step-wise approach to estimate the aquatic toxicity of this type of polymers. This is briefly summarised below.

- Step 1. Calculate the base toxicity in the same way as for cationic polymers.
- Step 2. Determine the CAR.
- Step 3. Calculated the toxicity reduction factor (TRF) using the SARs given in USEPA (2012). SARs for estimated TRFs are available for acute toxicity to fish and Daphnids and acute and chronic toxicity to algae. However, according to Boethling and Nabholz (1997) the number of data points used to develop the SARs is limited (either 2 or 3 data points depending on the SAR).
- Step 4: Calculate the final predicted toxicity effect level by multiplying the base toxicity by the TRF.

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[72] Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Official Journal of the European Union, L142/1, 31.5.2008.

[73] The CAR can be estimated from the ratio of sum of the mole ratios of all cationic monomers used to manufacture the polymer to the sum of the mole ratio of anionic monomers.

Mitigation factors may also be taken into account when estimating the level of toxicity likely to occur in the environment.

Few other data appear to be readily available for hazards to the environment or human health from amphoteric polymers.

Conclusion on amphoteric polymers

As the aquatic toxicity of amphoteric polymers is related to both the cationic and anionic groups present, it is suggested that amphoteric polymers should be treated in a similar way as cationic and anionic in terms of identification of polymers requiring registration. Therefore, by analogy with the approach suggested for cationic and anionic polymers, the following criteria are suggested for amphoteric polymers in relation to polymers requiring registration:

- The polymer is a polymer requiring registration if it is an amphoteric polymer. Exceptions to this are[74]:
    - Polymers with low cationic and anionic density, i.e. a polymer whose cationic and anionic groups each have a combined equivalent weight greater than 5,000 Da.

Similar to the case with cationic polymers, the workshop considered that there was no need for a criterion to cover polymers that could potentially become amphoteric. Experience from a regulator suggested that the hazards from amphoteric polymers is often related to low molecular weight polymers only. Similarly, participants in the workshop considered that the equivalent weight cut-off of 5,000 Da may be too high. However, there is currently insufficient data available to investigate these two aspects further.

Nonionic polymers with surface-active properties

Discussion on nonionic polymers with surface-active properties

USEPA (2012) identifies nonionic polymers where the polymer functions as a surfactant or dispersant (e.g. possesses surface-active properties) which may have hazardous properties for aquatic organisms, and that these polymers are usually assessed by the USEPA using a nearest analogue (read-across) approach. However, no further details are given in USEPA (2012).

The literature search carried out in Task 1.1 identified potential hazards to the environment associated with some nonionic polymers with surfactant properties including alcohol ethoxylates and nonylphenol ethoxylates (although for the latter the main hazards were related more to degradation products rather than the polymers themselves). In general, the toxicity to aquatic organisms for these groups of nonionic polymers tended to decrease with increasing number of ethoxylate groups and, for the alcohol ethoxylates, the acute $L(E)C_{50}$ was found to be in the range 0.1 mg/L to the low mg/L range across the group of alcohol ethoxylates used as surfactants in cleaning products. The alcohol ethoxylates appear to be of generally low hazard to human health but some neat alcohol ethoxylates are irritating to eyes and skin.

Few data appear to be readily available for other types of nonionic polymers.

Conclusion on nonionic polymers with surface-active properties

Based on the aquatic toxicity seen with the alcohol ethoxylates it cannot currently be ruled out that hazards to aquatic organisms may also exist for other nonionic polymers that are water-soluble or dispersible. Therefore, it is suggested that the following criteria are considered in relation to identification of polymers

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[74] The version of these criteria presented at the workshop included an exemption for solid polymers not dispersible or soluble in water, not dispersible in air and only intended to be used in the solid phase. However, for the reasons discussed under the conclusions on cationic polymers it is recommended that such risk-based clauses are not included in the final criteria for a PRR.

requiring registration (based on analogy with the approach taken for cationic, anionic and amphoteric polymers). Note, however, in this case it is not considered necessary to include an exception based on the molecular weight equivalent of nonionic groups that have surface active properties as the concern is based on the surface-active properties rather than nonionic group density.

- The polymer is a polymer requiring registration if it is a nonionic polymer with surface-active properties[75].

As before it will also be necessary to provide guidance as to what is meant by surface-active properties. Again, this should be based on the current test guideline for surface tension (A5 of Council Regulation (EC) No 440/2008). This states that substances which show a surface tension lower than 60 mN/m under the conditions of the test method should be regarded as being surface-active materials.

3.2.5 Other potential criteria for a polymer requiring registration with a weaker evidence base

Nonionic polymers

USEPA (2012) considers the aquatic toxicity of nonionic polymers and concludes that these are generally of low concern in terms of hazard to the aquatic environment owing to their generally negligible water solubility. However, USEPA (2012) highlights two exceptions to this.

- Non-ionic polymers where the polymer is used as surfactant or dispersant. These surface-active properties mean that the polymer may cause toxicity to aquatic organisms. These types of nonionic polymers have already been considered further above (see the suggested criteria for nonionic polymers with surface-active properties).
- Non-ionic polymers where there is a significant low molecular weight oligomer content. This is defined in USEPA (2012) as ≥25% oligomers with molecular <1000 Da or ≥10% oligomer content with molecular weight <500 Da). USEPA (2012) indicates that these lower molecular weight oligomers may be bioavailable and the toxicity to aquatic organisms can be estimated using standard SARs (e.g. ECOSAR). USEPA (2012) considers polymers with molecular weights of 1000 Da and above to not be bioavailable and unlikely to show adverse effects on aquatic organisms through absorption. This is considered further in the suggested criteria for low molecular weight oligomers below.

Low molecular weight oligomers

Discussion on low molecular weight oligomers

It is important to note that the potential hazard from low molecular weight oligomers present in polymers is not restricted to nonionic polymers. The same considerations can also be applied to other polymer types and this should be considered as a general issue for polymers.

The available database on hazards associated with the presence of low molecular weight oligomers present in polymers is limited. However, there is a good theoretical background for the inclusion of a criterion based on the presence of low molecular weight oligomers for a polymer requiring registration. This is for the following reasons. When considering this it is important to recognise that there are two aspects that are equally important: a) the bioavailability of the low molecular weight oligomers in terms of their potential to

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[75] The version of these criteria presented at the workshop included an exemption for solid polymers not dispersible or soluble in water, not dispersible in air and only intended to be used in the solid phase. However, for the reasons discussed under the conclusions on cationic polymers it is recommended that such risk-based clauses are not included in the final criteria for a PRR.

be taken up into organisms and b) the mobility of the low molecular weight oligomers within the polymer matrix (physical availability).

- Almost all non-polymeric substances covered already by REACH have molecular weights <1000 Da. Many of these non-polymeric substances possess hazards to human health and/or the environment. Much less is known about the hazards associated with polymers (or constituents within the polymer) with molecular weights <1000 Da, although the analysis carried out in Task 1.1 on the information from the DSD suggests that a substantial number of these may have hazardous properties.
- In general, substances with molecular weights <1000 Da, with some dependence on the structure, are known to be bioavailable (see below).
- In general, the lower molecular weight constituents of the polymers may, depending on the structure, be mobile in the polymer matrix, potentially leading to additional routes of exposure compared to those for the higher weight polymer constituents (for example leaching into water, volatilisation into air).
- The possibility of adverse effects from these lower molecular weight constituents cannot be ruled out.

Therefore, it is necessary to include a criterion based on the presence of low molecular weight oligomers in the criteria for polymers requiring registration. The nature of the oligomers will be a function of the monomer(s) used and the polymer production process. Not all monomers or polymer production processes will lead to the formation of low molecular weight oligomers that are hazardous to the environment or human health but there is currently no easy way in which to predict when that will be the case. Similarly, not all low molecular weight oligomers will be mobile within the polymer matrix and this will be dependent upon the polymer matrix, the conditions of use of the polymer etc. Thus, there is a reasonable case that the criterion does not exclude certain oligomer types at the current stage of knowledge. It is possible that in the future, as experience is gained, a list of acceptable oligomer types could be developed so that polymers that contained the acceptable oligomers would no longer be considered as polymers requiring registration, but the state of knowledge is not sufficiently advanced on this aspect to include such a list in the criteria at present.

EFSA (2016 and 2017) discusses risk assessment of polymers used in food contact applications, including their recommendations over low molecular weight oligomers. The safety assessment of polymeric additives and oligomers should take into consideration the molecular mass. Compounds with a molecular weight above 1000 Da are unlikely to be absorbed by the gastrointestinal tract and so they are not considered to present an oral toxicological hazard, unless they are hydrolysed or induce a local effect on the gastrointestinal tract, such as stomatitis, oesophagitis and/or mucositis. If the latter can be excluded, a cut-off value for the molecular mass at 1000 Da is recommended, as it covers any shape of molecules influencing the likelihood of absorption. Most substances below 600 Da are absorbed and the rate of absorption is determined by factors other than size and shape of the molecule. For poly- and per-fluoro compounds, a cut-off value of 1,500 Da could be appropriate, because the molecular volume of C-F is smaller than that of C-H molecules of the same molecular mass.

Groh et al. (2007) have suggested that a 1000 Da cut-off may be too low for some polymer types. Co-exposure with permeation enhancers may lead to a higher uptake of low molecular weight compounds. For example, co-exposure with the food emulsifier polysorbate 80 was shown to increase the oral absorption of di-(2-ethylhexyl)phthalate (DEHP, CAS 117-81-7) in rat and several surfactants as well as chitosan were shown to be potent enhancers of permeation through the buccal mucosa. This needs to be considered when estimating and modelling the internal exposure to food contact chemicals. Second, permeation enhancers may also facilitate the uptake of high molecular weight compounds. This raises the question of whether the molecular weight cut-off of 1000 Da, generally applied in the toxicological assessment of food contact materials, is scientifically still justified.

In contrast to this, Bos and Meinardi (2000) argued that molecular weight of a compound must be under 500 Da to allow skin absorption as larger molecules cannot pass the corneal layer. As the molecular weight increases above 500 Da absorption through normal human skin declines rapidly. Lipinski's "Rule of 5" is a recognised framework which correlates the physicochemical properties of a given compound with its membrane permeability and bioavailability in the context of small-molecule drug development (Yang and Hinner, 2015). It postulates that poor absorption or permeation is more likely when: (1) the calculated lipophilicity (clogP) is over 5; (2) the molecular weight is over 500; (3) there are more than five hydrogen bond donors (well represented by the sum of OH and NH bonds); and (4) there are more than ten hydrogen bond acceptors (represented roughly, by the sum of Ns and Os). The Rule of 5 has been generally successful at predicting membrane permeability, but not all compounds that comply with the rules are permeable, and permeable compounds that deviate from the rules are not uncommon. Nonetheless, the Rule of 5 does identify key physicochemical parameters, namely the polarity, size, and lipophilicity of the permeant, that are important for passive diffusion. These interrelated factors can affect the partitioning, diffusion, or both, of the molecule into and across the membrane.

Alternative metrics for these parameters have also been proposed (Yang and Hinner, 2015). The polar surface area (PSA) of a compound has been used in addition to the number of hydrogen bond donors and acceptors as an indicator of polarity. Studies have inversely correlated the permeability of small solutes with molecular volume or cross-sectional area. The number of rotatable bonds has also been suggested (molecules with fewer rotatable bonds and lower PSA have been reported to have better permeability across artificial membranes). Conformationally flexible molecules that are able to form intramolecular hydrogen bonds in a low dielectric environment may adaptively reduce their surface polarity for improved permeation. Localised charge or highly polar groups can significantly decrease the permeability of an otherwise permeable parent compound by orders of magnitude.

ECHA (2019a) reported that the release potential of the additives from the plastic material is correlated with the properties of the polymer matrix, the concentration of the additive and its chemical-physical properties. Release potential is a result of rate of diffusion through the plastic matrix and partition from plastic surface to the contact medium. These two basic mechanisms are driven by the following parameters.

- Molecular volume (weight being used as a proxy) and other intrinsic properties of the additive.
- Diffusivity of the polymer matrix (depending also on particular interaction between additive and polymer-type).
- Relative affinity of the additive to the polymer-matrix compared to the contact medium (e.g. tendency to become airborne driven by vapour pressure; kow).
- Temperature.

The amount of substance released from an article surface in contact is further driven by the following.

- Concentration of the additive in the plastic matrix.
- Dimension of the article and velocity of the contact medium (may be relevant for dynamic contact like water or air flow over a plastic surface).
- The structure of the article itself (e.g. thickness, geometry, number of layers, barrier effect).

In relation to mobility of low molecular weight oligomers within polymer matrices, various models are available to predict migration, particularly related to food contact materials (e.g. ECHA, 2019; JRC, 2010 and 2015). ECHA (2019a) investigated a molecular weight threshold of <600 Da for low molecular weight components that can migrate from plastics. However, recent evidence suggests that for harder plastics with higher glass transition temperature, low molecular weight constituents with molecular weights as low as 200 Da have low diffusivity from food contact materials (Brandsch, 2017).

ECETOC (2019) contains a detailed discussion of the potential for migration from polymers and how this relates to the actual risks from low molecular weight constituents present in polymers. In many cases the low molecular weight constituents present in the external surface layer have the highest potential to migrate from the polymer matrix and diffusion within the polymer matrix is driven by molecular volume, diffusivity, relative affinity of the constituent to the matrix and temperature.

In order to ensure unambiguous use of the term "bioavailability" ECETOC (2019) developed the following definitions.

- **Physical availability** means that one or more individual components of the polymer product are released from the polymer matrix e.g. by migration / leaching.
- **External bioavailability** describes the condition that some high molecular weight polymers that are too large to cross biological barriers might nevertheless exert local toxicity in tissues (e.g. skin, eyes, respiratory tract). This toxicity may well be due to low molecular components (i.e. small oligomers, IAS and NIAS[76], including unreacted monomers) that migrate under conditions of contact to the transitional fluid (e.g. sweat, tears, saliva), which are thereby available to be absorbed and exert their toxic effect. The specific mechanisms by which such effects can occur remain to be determined.
- **Internal (systemic) bioavailability** means that the polymer product is absorbed into the blood stream by an organism thereby becoming systemically available and potentially able to cause systemic effects. The internal bioavailability of a polymer is determined by its size (MW) as well as it charge and physical properties such as solubility and partition in water and/or biological media, and physical state.

Conclusion on low molecular weight oligomers

Based on this discussion it is suggested that it is important to include a criterion in relation to low molecular weight constituents present in the polymer when considering polymers requiring registration. In the absence of other information, it is suggested that this is based on the approach considered in COM (2015) whereby the percentage of constituents with molecular weights <500 Da and <1000 Da are considered alongside relevant trigger amounts for when the polymer would no longer be considered to be of low concern.

By analogy it would also be appropriate to consider all polymers with average molecular weights <1000 Da to be polymers requiring registration. A similar approach is being considered by Government Canada/Health Canada.

Thus, the following criteria are suggested based on COM (2015) and the approaches used in other regulatory schemes. The strength of the available evidence to support these criteria is highest for the polymers with MW_n <1000 Da and lowest for the polymers with MW_n ≥10 000 Da.

- Polymers with a number average molecular weight (MW_n[77]) of <1000 Da are considered as polymers requiring registration.
- For polymers with 1000 < MW_n<10,000 Da a polymer is considered a polymer requiring registration if it contains >10% oligomer content of molecular weight below 500 Da or >25% oligomer content of molecular weight below 1000 Da.

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[76] IAS = intentionally added substances. NIAS = non-intentionally added substances. These terms are used in relation to food contact materials.

[77] COM (2012) is not clear whether the criteria proposed is based on the number average molecular weight or the weight average molecular weight; the two measures are not equivalent. The criteria proposed in COM (2012) are based on the USEPA criteria for a polymer of low concern and these use number average molecular weight (e.g. see Boethling and Nabholz, 1997 and USEPA, 1997).

- For polymers with MW_n ≥10,000 Da a polymer is considered a polymer requiring registration if it contains >10% oligomer content of molecular weight below 500 Da or >25% oligomer content of molecular weight below 1000 Da.

It is important to note here that the criteria suggested in COM (2015) and the approaches used in other regulatory schemes use a lower oligomer content cut-offs[78] for polymers with MW_n over 10,000 Da than for polymers with a MW_n of below 10,000 Da. These different cut-offs for the two molecular weight ranges is difficult to reconcile scientifically as there is no reason to suppose that the low molecular weight oligomers present in polymers with MW_n >10,000 Da would be any more hazardous, and thus warrant a lower cut-off content, than the low molecular oligomers present in polymers with MW_n<10 000 Da. Therefore, for the PRR criteria it is suggested that the same oligomer contents are used for both.

In order to apply this, it may be necessary to define "oligomer" within REACH[79]. The suggested criteria are based on oligomer content but, as discussed earlier, other low molecular weight substances may also be present in the polymer, including unreacted monomers, unreacted other reactants, impurities as well as additives. These are considered further below in the section on impurities present in polymers.

It is important to note that the data and argumentation behind the low molecular weight oligomers cut-offs used in other jurisdictions are not readily available, and only very limited data on this area was obtained during the consultation. The limits on the oligomer contents appear to be based on the OECD (2009) study and experience gained in the assessment of polymers within the United States in particular.

As indicated earlier, reliably establishing the amounts of low molecular weight constituents present in polymers may not always be straight forward However, similar criteria are used in many third countries with polymer notification schemes and so they should be implementable in REACH. EFSA (2017) also contains some guidance on this.

Reactive functional groups

Discussion on reactive functional groups

COM (2015) and many of the regulatory approaches for polymers in other jurisdictions considers that polymers of low concern generally have either no reactive functional groups or contain only certain allowable functional groups.

The experimental basis behind the link between the presence of reactive functional groups and hazardous properties of polymers is not clear based on information readily available in the literature. Boethling and Nabholz (1997) report that the USEPA, based on experience reviewing over 10 000 premanufacturing notices for polymers, identified polymers that are considered to be of low concern for human health and the environment generally have no reactive functional groups, or only certain reactive functional groups, for example blocked isocyanates, or a reactive function group equivalent weight no less than a defined threshold (an example of 5,000 Da was given for pendant methacrylates). However, there is no information reported on the hazards associated with polymers where reactive functional groups were present.

COM (2015) reviewed the available information on the possible hazards associated with the presence of reactive functional groups (detailed in Annex 4 of COM (2015)) and considered the following categories, in addition taking account of work conducted in the United States, EU, Australia and Canada.

- Low-concern groups: carboxylic acid groups; aliphatic hydroxyl groups; "ordinary" unconjugated olefinic groups; butenedioic acid groups; conjugated olefinic groups present in naturally occurring fats, oils and carboxylic acids; blocked isocyanates; thiols; unconjugated

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[78] >2% oligomer content of molecular weight below 500 Da and >5% oligomer content of molecular weight below 1000 Da.

[79] The term oligomer is not defined in REACH. The IUPAC definition is: "Oligomer: A molecule of intermediate relative molecular mass, the structure of which essentially comprises a small plurality of units derived, actually or conceptually, from molecules of lower relative molecular mass."

nitrile groups; halogens (except reactive halogen containing groups such as benzylic or allylic halides).

- Moderate-concern groups: conjugated olefinic groups not contained in naturally occurring fats (genotoxicity), oils and carboxylic acid; alkoxysilanes with alkoxy groups >C2 (lung toxicity, ecotoxicity).
- High-concern groups: pendant acrylates and methacrylates (genotoxicity, skin irritation); aziridines (genotoxicity, skin irritation); carbodiimides (genotoxicity, skin irritation); halosilanes (lung toxicity, ecotoxicity); hydrosilanes (lung toxicity, ecotoxicity); hydrazines (genotoxicity, skin irritation, ecotoxicity); alpha or beta lactones (genotoxicity, ecotoxicity); vinyl sulfones or analogous compounds (genotoxicity, ecotoxicity); acid halides (genotoxicity, skin irritation); acid anhydrides (lung toxicity); aldehydes (genotoxicity, ecotoxicity); hemiacetals (genotoxicity, ecotoxicity); methylolamides (genotoxicity, ecotoxicity); methylolamines (genotoxicity, ecotoxicity); methylolureas (genotoxicity, ecotoxicity); methoxy- and ethoxysilanes (lung toxicity, ecotoxicity); allyl ethers (genotoxicity, cytotoxicity); cyanates, iso(thio)cyanate (genotoxicity, skin irritation); epoxides (genotoxicity, skin irritation); imines (genotoxicity); unsubstituted positions ortho or para to phenolic hydroxyl (genotoxicity); any other reactive functional group not in the low or moderate concern groups.

The basis behind the categories is that the low-concern groups are the least reactive in biological and/or aquatic media and are not alkylating agents or do not contain electrophilic groups, whereas the high-concern groups are the most reactive and are known (or suspected) to pose health and/or environmental concerns (generally alkylating agents or those with electrophilic groups).

The experimental information used to inform these categories is not readily available. However, COM (2012) indicates that this categorisation was based on work conducted in the United States, Australia, Canada and the EU, and was justified in COM (2012) by a study considering reactivity of the groups at a molecular level (detailed in Annex 4 of the COM (2012) report and not repeated here). Further, COM (2012) indicates that these categories were considered by ECHA toxicologists at the time and they were considered to be in line with learnings from the United States and to be in line with what is currently known.

An investigation into the possible health hazards associated with common functional groups that are present in common classes of homopolymers and copolymers is presented in Annex G. The functional groups present in these polymers were profiled using the OECD QSAR toolbox. A summary of the main findings from this analysis are given in Table 3.13. Also shown is a comparison with the hazard category groups from COM (2015). Further details of the methodology used, and the results obtained are given in Annex G.

Table 3.13 Summary of findings from our structural alerts analysis in common polymer types carried out in Annex G

Findings	Significance in relation to COM (2015) hazard category groups
No evidence of significant toxicity associated with the following functional groups: **Amides** **Carboxylic acids** **Ketones** **Esters** **Non-reactive halogens** **Unconjugated olefinic groups**	The functional groups associated with these polymers are generally in the low concern category. The exceptions include: Amides Esters Ketones
Aliphatic nitrile groups associated with hepatoxicity/enhanced toxicity.	Unconjugated nitrile groups are in the low concern category.

Findings	Significance in relation to COM (2015) hazard category groups
There is some evidence that halogenated aromatic compounds may be carcinogenic and show specific target organ toxicity following repeated dose exposure, toxicity.	Non-reactive halogens are in the low concern category. Phenyl groups are not included in the list of groups requiring registration and so reactive phenyl groups would be caught be in the high-concern group by default.
Polyhaloolefins and polyhalodienes are associated with structural alerts for genetic toxicity, carcinogenicity and sensitisation.	"Ordinary" unconjugated olefin groups and halogens (except reactive halogen containing groups such as benzylic or allylic halides) are in the low concern category.
Polyhydroxy(meth)acrylates. These have an alkyl chain with pendant groups contained ester and hydroxyl functionality. There is an alert for in vivo mutagenicity related to parts of the chain which have a O-C-C-O structure.	Aliphatic hydroxyl groups are of low concern. Pendant esters are not included in the list of functional groups requiring registration and so would be caught be in the high-concern group by default.
Polyphenylenes. Aromatic hydrocarbons with ≥2 aromatic rings are associated with liver enzyme induction.	
Polyphenylethers. The phenoxybenzene structural features results in an alert for in vivo mutagenicity.	
Polyvinyl alcohols. No general alerts. The phenol group in Poly(4-vinyl phenol) is linked to various alerts.	Poly(4-vinyl phenol) contains an unsubstituted para-phenolic hydroxy group, which is a group of high-concern
Polyvinyl sulphides (Polyvinyl thioethers) give an alert for specific target organ toxicity following repeated exposure, toxicity related to the sulphide (thioether) group.	Thioethers are not included in the list of functional groups requiring registration and so would be caught be in the high-concern group by default.
Polyepoxides (epoxy resins). These structures have an alert for in vivo mutagenicity which relates to parts of the chain that have the structure X-C-C-X, where X is O or N.	The epoxy group is a group of high concern.
Aromatic polycarbonates may have various alerts, particularly those related to sensitisation.	
Polyurethanes. Carbamate structures may have alerts relating to sensitisation, genotoxicity and carcinogenicity.	The carbamate group is not included in the list of functional groups requiring registration and so would be caught be in the high-concern group by default. Alcohols are a low-concern group. Isocyanates are a group of high concern.
Polyesters.	See Section on polyesters below.
Polyanhydrides. No evidence of significant toxicity.	Acid anhydride is a functional group of high concern.
Polyethersulfones. Polymers with the 1-phenoxy-benzene group have an alert for in vivo mutagenicity.	Vinyl sulfones and analogous compounds are functional groups of high concern. An aryl sulfone might be considered analogous to a vinyl sulfone.

Although limited in scope, the analysis carried out in Annex G shows that structural alerts for toxicity are generally associated with functional groups in the high concern category or groups not listed in any of the category (and so would by default be considered to be in the high concern category) from COM (2015). It is also relevant to note that the analysis in Annex G generally suggests no significant toxicity is associated with amides, (non-pendant) esters and ketone groups. These functional groups are not currently listed in the low concern category in COM (2015). Therefore, it is recommended that these functional groups amides, (non-pendant) esters and ketone groups are added to the low concern category from COM (2015). The analysis carried out generally supports the functional groups in the high concern category from COM (2015).

Conclusion on reactive functional groups

The presence or absence of reactive functional groups is potentially an important consideration, in particular, in relation to human health hazards. In the absence of other information, it is suggested that the following criteria are considered in relation to a polymer requiring registration (based on the approach taken in COM (2015)). The criteria in COM (2015) applies to polymers with molecular weights between 1000 and 10,000 Da. For polymers with molecular weights >10,000 Da COM (2015) considered them to be polymers of low concern regardless of the types of reactive functional groups present.

- For polymers with 1000 < MW_n < 10,000 Da:
    - A polymer requiring registration contains reactive functional groups in either the high-concern category and/or moderate-concern category unless the following applies:
        - The combined functional group equivalent weight (FGEW)[80] of these groups is >5,000 Da. Further, each group in the high-concern category has a FGEW >5,000 Da and each group in the moderate-concern category has a FGEW >1000 Da.
        - For polymers containing reactive functional groups in the moderate-concern and/or low concern category only, each moderate-concern group has a FGEW >1000 Da and the combined FGEW is >1000 Da.

In order to apply these criteria it is recommended that the following functional groups are added to the low concern category from COM (2015): amides; non-pendant esters; and ketone groups.

As noted earlier, the experimental data behind the criteria in COM (2015), in particular relating to the molecular weight cut-offs for FGEW, is unclear, and appears to be based on experience gained elsewhere. At present it is not possible to test further the relevance of these cut-off values for identification of polymers requiring registration owing to lack of readily available data.

Impurities present in polymers

Discussion on impurities

Information on impurities present in polymers, and the hazards that they may present to human health or the environment, is scarce. The REACH definition of a substance, and hence polymers, includes any impurity derived from the process used, and any additive necessary to preserve its stability, and hence it is relevant to consider these two aspects (impurity and additive necessary to preserve its stability) in relation to any criteria for identification of polymers requiring registration.

The impurities present in a polymer and additives necessary to preserve stability will be a function of the monomers and other reactants used to make the polymer, and the manufacturing process used. Given the wide range of different combinations of these factors that are possible it is very difficult to derive meaningful criteria specifically for impurities or other reactants used in the manufacturing process.

A pragmatic approach is therefore suggested. This is in part based on the existing REACH requirements for monomers and other substances chemically bound to the polymer (ECHA, 2012), and in part based on the suggested criteria for polymers requiring registration based on molecular weight considerations.

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[80] The Functional Group Equivalent Weight (FGEW) is the ratio of the number average molecular weight of the polymer to the number of functional groups in the polymer and is effectively the weight of polymer that contains one formula weight of the functional groups. It is a measure of how diluted the reactive functional groups are within the polymer and the lower the FGEW the higher the number of reactive functional groups per unit weight of the polymer.

- REACH already has requirements for registration of monomers and additives other than those necessary to preserve the stability of polymers, as substances. These apply in the following cases:
  - Monomers[81]:
    - Manufacturers or importers of monomers have to register their monomers in line with the normal obligations to register substances in Article 6 of REACH.
  - Substances added to improve the performance of the polymer:
    - In this case the polymeric material is considered as a mixture or an article and the substances added to the polymer are subject to the normal registration requirements for substances.
  - Manufacture or import of polymers:
    - Manufacturers or importers must submit a registration for the monomer substance(s) or any other substance(s) that have not already been registered by an actor up the supply chain, if both the following conditions are met:
      - The polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s); and
      - The total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year. In this context, the total quantity is the quantity of monomer or other substances that end up chemically bound to the polymer).

Currently there are no obligations under REACH for a manufacturer or importer of a polymer to register the quantity of additives necessary to preserve the stability of the polymer as these are considered as part of the polymer. However, if such additives are themselves manufactured or imported then the manufacturer or importer of the additive would be subject to the normal REACH requirements and would need to register the additive as a substance.

- ECHA (2012) also notes that whenever it is not scientifically possible to establish either of the following then the substance can be regarded as a UVCB[82] substance. In this case, the registration for the substance can be submitted.
  - Whether the substance falls under a definition of a polymer;
  - The chemical structure of the monomer units (or any other unit) and their concentration in the substance;

Conclusion on impurities

Based on the above discussion monomers, other reactants and additives other than those required for the stability of the product, are already subject to their own registration requirements under REACH. Therefore, it is important that any criteria for polymers requiring registration do not conflict with, or duplicate, those requirements already in place. For the additives required to stabilise the product and impurities, it would be possible to extend the suggested criteria for low molecular weight oligomers[83] to cover these in addition to

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[81] Essentially the same requirements also apply to “other substances” bound into the polymer.

[82] A UVCB substance is a substance of unknown or variable composition, complex reaction products or biological material.

[83] The term oligomer is not defined in REACH. The IUPAC definition is: "Oligomer: A molecule of intermediate relative molecular mass, the structure of which essentially comprises a small plurality of units derived, actually or conceptually, from molecules of lower relative molecular mass."

oligomers i.e. have the same molecular weight requirements for “oligomers, additives required to stabilise the product and impurities” as currently suggested for oligomers. However, at this stage it is proposed not to include additives required to stabilise the product as these would, in many cases, already be subject to their own registration requirements under REACH. For impurities[84], it also needs to be taken into account that they are likely to be difficult to determine and identify, and thus it may be practically difficult to apply any limits based on impurities as a decision point for determination whether a polymer is a polymer requiring registration or not.

Therefore, for practical reasons it is currently suggested that criteria are not specifically included for identification of polymers requiring registration based on the content of additives required to stabilise the product and minor constituents. However, these are relevant, in particular for substance identity issues and the hazard profile of the substance in relation to any future registration requirements under REACH for polymers requiring registration. Thus, it may be necessary, at that later stage, to clarify the amounts and identities of these constituents and impurities present in the polymer requiring registration once identified.

Degradable polymers

Discussion on degradable polymers

The COM (2015) proposal for polymers of low concern excluded polymers that are degradable from being considered as a polymer of low concern. The fact that a polymer is itself degradable, either biologically or by other mechanisms, is itself not a parameter that would lead to a concern over the polymer. Indeed, in many respects, degradability of a polymer in the environment can be seen as a positive attribute.

The real concern here is if a polymer may degrade in the environment forming products that are more stable <u>and</u> hazardous <u>and</u> bioavailable than the parent polymer. A specific example of this is nonylphenol ethoxylates (which, depending upon the actual composition, may meet the REACH definition of a polymer when the number of ethoxylate groups is >3). Nonylphenol ethoxylates are known to degrade in the environment into nonylphenol or nonylphenol derivatives with lower numbers of ethoxylate groups which are more stable and hazardous.

There is also concern for some polymers which contain perfluorinated side chains that may be liberated from the polymer (e.g. USEPA, 2010).

The standard screening methods for biodegradability include the ready biodegradation test. Substances that pass this test are readily biodegradable and are usually assumed to readily be mineralised in the environment. However, when applied to polymers there are additional factors that may be considered.

- Degradation data may not yet be available for many polymers.
- Some polymers may contain parts of the molecule that are biodegraded rapidly and others that are more recalcitrant. The normal pass rate in a ready biodegradability test is 60-70% degradation dependent upon the exact method. Thus, it is theoretically possible for a polymer to pass a ready biodegradation test and still have more stable metabolites if the more recalcitrant part of the polymer constitutes, for example, <30-40% of the carbon in the molecule.
- A possible approach would be to consider the structure of the polymer in terms of the potentially more recalcitrant degradation products. However, this would require some expert knowledge of possible degradation mechanisms and of the properties of the degradation products and so would not be feasible to include in any general criteria for identification of polymers requiring registration prior to registration.

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[84] Impurities deriving from the manufacturing process in line with ECHA (2012).

- In the approach used by the USEPA for the risk assessment of polymers, biodegradability is assessed based on the molecular structure in cases where the available biodegradation data are insufficient (Boethling and Nabholz, 1997). This again requires some expert knowledge. However, Boethling and Nabholz (1997) note that the vast majority of polymers are not degradable and, when the polymer is biodegradable, the supplier is often aware of this and may be using this as a reason to market the polymer in the first place.

Another possible concern related to the degradability of polymers is if a polymer is not biodegradable it may persistent in the environment and, if solid, may break down by physical means in to microplastic particles which can then enter the food chain.

Conclusion on degradable polymers

At this stage, it is not proposed to include any specific criteria based on polymer degradability for polymers requiring registration. This is partly based on practicality issues and partly based on the difficulty in interpreting the information in terms of the potential for formation of stable degradation products and partly based on the fact that, depending on the circumstances, both persistence (e.g. see Cousins et al., 2019) and degradability can both be seen as leading to possible concerns. It cannot be assumed that degradation will re-form the monomer. However, hazards associated with degradability could be considered on a case-by-case in a safety net criterion.

Polyesters

Discussion on polyesters

The COM (2015) proposal for polymers of low concern includes criteria for polyesters. In the COM (2015) approach, if a polyester is a polymer derived from an approved list of reactants, it is considered a polymer of low concern regardless of the number average molecular weight or oligomer content. This approved list is reproduced in Annex H. The basis for the list is unclear but is probably based on experience gained in other regulatory regimes.

A number of polyesters have been considered in the analysis of structural alerts present in polymers in Annex G. The findings are summarised in Table 3.14 below. It should be noted that the analysis carried out in Annex G is based an initial screening of example structural units for relevant structural alerts related to possible health hazards and are subject to a large uncertainty, particularly over whether any potential effects identified would be expressed in the polymers themselves. Nevertheless, the analysis tends to support at least some of the approved list of reactants given in COM (2015).

Table 3.14 Summary of findings for structural alerts analysis in polyesters.

Findings	Significance
In general, very few structural alerts identified in structures associated with the following monomers. • **1,4-Butanediol;** • **Isophthalic acid (1,3-benzenedicarboxylic acid);** • **Sebacic acid (decanetdinic acid); and** • **Succinic acid.**	All are listed on the approved list of reactants.
Very few structural alerts identified in structures associated with the following monomers. • **Terephthalic acid;** • **1,3-Propanediol; and** • **1,6-Hexanediol.**	No listed on the approved list of reactants.

Findings	Significance
Ethylene glycol derived structures have alerts for *in vivo* mutagenicity.	Ethylene glycol is not on the approved list of reactants.
Aryl alcohol (e.g. bisphenol A) derived structures have alerts for sensitisation.	Bisphenol A is not on the approved list of reactants.

The available evidence collected for hazards from polyesters collected during Task 1.1 also suggest that polyesters as a group generally show low hazards, although the amount of information available is still limited. This tends to support the above analysis.

Conclusion on polyesters

The available evidence suggests that polyesters as a group generally show low hazard. Given that the COM (2015) approach identifies polymers of low concern it would be sensible to include a specific exclusion for these polyesters that meet the COM (2015) criteria from being polymers requiring registration. However, it is important to note that the experimental justification behind these exclusions is not clear.

As noted earlier, several important reactants[85] are absent from the list presented in COM (2015) but included in other criteria for polymers of low concern from other jurisdictions. There is no obvious reason for this and it is recommended that these reactants are added to the list presented in COM (2015).

Water-absorbing polymers

Discussion on water-absorbing polymers

The COM (2015) proposal for polymers of low concern has a specific exclusion that excludes water-absorbing polymers (i.e. polymers capable of absorbing their own weight in water) with a molecular weight >10 000 Da. This is based on concerns over carcinogenicity for high molecular weight water-absorbing polymers that have been seen in a two-year inhalation study in rats which used a polyacrylate polymer with a molecular weight >1 000 000 Da (Federal Register, 1995).

The general applicability of this finding is currently unclear, and the available evidence suggests that this may not be an appropriate criterion to apply across all water-absorbing polymers.

Conclusion on water-absorbing polymers

It is suggested that a specific criterion for water-absorbing polymers is not included when considering polymers requiring registration. However, it should be noted that if concerns exist with specific polymers these can potentially be identified using the safety net criterion below.

Elemental limitations

Discussion on elemental limitations

The COM (2015) proposal for polymers requiring registration has criteria based on elemental limitations. The experimental basis behind these criteria is unclear and there are little or not readily available information on the hazards associated with the presence of specific elements within the polymer.

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[85] Terephthalic acid (benzene 1,4-dicarboxylic acid; CAS 100-21-0), monoethylene glycol (ethane-1,2-diol; CAS 107-21-1) and dimethyl terephthalate (dimethyl 1,4-benzenedicarboxylate; CAS 120-61-6)

In this respect it is important to note that Annex A identifies a number of types of inorganic polymers with backbones based on silicon, oxygen, phosphorus, sulfur, boron, nitrogen, germanium, and/or tin for example. Again, little information is currently available on the hazards of these types of polymers.

Conclusion on elemental limitations

At this stage, it is not proposed to include criteria based on elemental limitations when identifying polymers requiring registration. However, it should be noted that if concerns exist with specific polymers these can potentially be identified using the safety net criterion below.

Nanopolymers

Some polymers can be supplied in nanomaterial form. Such nanomaterials could potentially have different characteristics than the non-nanomaterial form of the same material as a result of an increased specific surface area by volume[86]. For example, Endes et al., (2016) reviewed the current state of knowledge of the biological impact of nanocellulose. Overall, it was concluded that, when investigated under realistic doses and exposure scenarios, nanocellulose has a limited associated toxic potential. However, certain forms of nanocellulose may have specific physical characteristics that may be associated with a biological hazard potential.

The need for a specific criterion covering nanopolymers is currently uncertain owing to the lack of data so no criterion is proposed here. However the area of nanoparticles is a currently an active area for research and this could be reconsidered if more information becomes available in the future.

Other possible considerations – A safety net criterion

It is possible that not all polymers requiring registration may be caught by the above criteria. In addition, the criteria suggested are based on our current (limited) knowledge of the hazards of polymers and it is possible that in future years more information comes available to show that polymers could have as yet unidentified hazards. In order to try and cover these possible situations, it is suggested that a safety net criterion is considered in the identification of polymers requiring registration. A suggested criterion is given below:

Polymers that are suspected to present an equivalent hazard as a polymer that meets any of the other criteria for a polymer requiring registration or are suspected that they may possess hazardous properties that may subsequently lead to a relevant hazard classification[87] should be considered as polymers requiring registration.

Such a criterion could cover, for example, polymers where it is known that hazardous degradation products are formed.

Exposure considerations

Discussion of exposure considerations

Although certain polymers may have properties that are hazardous to human health or the environment, this does not necessarily translate into a potential risk to human health or the environment. In order, to determine risk, the exposure potential has also to be taken into account.

For exposure to the environment, Boethling and Nabholz (1997) highlight that significant release to waste water can occur for polymers used in applications such in cleaning products, flocculants for water treatment and in industrial waste water treatment. In broad terms, the polymers used in these types of applications tend to be the water-soluble/dispersible nonionic polymers with surface-active properties, anionic polymers,

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[86] Nanomaterials are chemical substances or materials with particle sizes between 1 to 100 nanometres in at least one dimension. https://echa.europa.eu/regulations/nanomaterials (accessed on 22/01/2020).

[87] The relevant hazard classifications are those suggested for the overarching criterion based on existing hazard classification.

cationic polymers and amphoteric polymers. Although removal during wastewater treatment by adsorption to sludge will occur for these types of polymer (see above) this would then lead to exposure of the terrestrial environment should the sludge be applied to soil as a fertiliser.

Water-soluble/dispersible nonionic, anionic, cationic and amphoteric polymers are included in the criteria suggested for polymers requiring registration, and the relatively high potential for environmental release of these types of polymers would provide further support for inclusion of the criteria for these polymer types when identifying polymers requiring registration.

The suggested criteria for polymers requiring registration include criteria for low molecular weight polymers (<1000 Da) and oligomers (<1000 Da and <500 Da). The exposure potential for these types of polymers is highly dependent on the use, and it is not possible to make generic statements over where they may be used or released to the environment. However, the concern for polymers that meet these criteria is related to the presence of low molecular weight constituents. These may be more soluble or more volatile than the polymer itself and so may have a higher exposure potential (e.g. through leaching or via loss by volatilisation from the polymer) than the higher molecular weight constituents of the polymer. Further, the bioavailability of the lower molecular weight constituents may be different to that of the higher molecular weight constituents. These factors are equally relevant to possible worker exposure as to environmental exposure, and worker exposure can also occur through skin contact which may be governed by different types of use than may lead to significant environmental exposure. Therefore, it is relevant to consider criteria based on the presence of low molecular weight constituents in relation to identification of polymers requiring registration.

As for the low molecular weight polymers, it is difficult to assess generically the exposure potential for the other types of polymers covered by the suggested criteria. These include polymers with certain reactive functional groups. For these, the concerns relate at least in part, to possible effects following human exposure. As noted above, human exposure is difficult to assess based on consideration of generic uses, as skin contact is important along with how the polymer is processed (e.g. forming dusts, in solution, etc.).

Conclusion on exposure considerations

Overall, the suggested criteria for polymers requiring registration are broadly in agreement with exposure-based considerations in that the suggested criteria cover many of the types of polymers where a relatively high exposure potential can be envisaged. However, the exposure based-considerations are stronger for some criteria (i.e. those based on cationic, anionic, amphoteric and nonionic polymers with surface-active properties) than others.

However, it is important to note that there may be other polymers that have a high exposure-potential that are not caught by the suggested criteria. This, in itself, may be considered to be requiring registration, especially if they are produced or used in large quantities and have as yet unidentified hazards. Therefore, it could be considered to have a safety-net criterion for such polymers where the high tonnage and widespread use itself is the concern. The need for such a criterion was discussed in detail at the Workshop and many difficulties and practicalities with having such a criterion were evident. Some examples of these difficulties are given below.

- It would be difficult to define such a criterion without catching a large number of polymers. For example many polymers have widespread uses in articles etc. where potential for exposure is limited.
- Potential registrants may not be aware of all uses of the polymers at the time of registration, and the uses of the polymers could change over time.

The overall view expressed at the workshop was that a criterion for PRR based on high exposure potential alone would be unworkable practically and would lead to many essentially non-hazardous polymers being registered to no benefit.

In terms of any future registration requirements for polymers requiring registration, it is relevant to consider that the information needed for polymers requiring registration where the potential for exposure is known to be very low may be less than that where more significant exposure may occur, taking physical form into account. There is already some precedence for this in REACH in relation to the registration requirements for substances that are used as isolated intermediates only as well as in Annex XI for adaptation to testing requirements, and similar approaches could be considered for polymers for applications where similarly low levels of exposure are expected. Similarly, if the polymer is used as non-isolated intermediate this could be considered as a similar situation as for non-isolated intermediates[88]. The possibility for reduced requirements for applications where low levels of exposure is expected is considered further in Task 2 of the project. Further guidance would need to be developed on when low levels of exposure would be applicable to polymers (the development of such guidance is beyond the scope of the current project).

Information requirements

In order to determine if any polymer meets the criteria for a polymer requiring registration, certain basic information needs to be available in order to verify whether or not the polymer would meet the criteria.

The information that is needed will include the following, although not all information may be needed for all polymers (or groups of polymers) i.e. if it is known that a polymer meets one of the criteria for a PRR, it is sufficient to conclude that the polymer should be subject to registration.

- Existing hazard classification under CLP;
- Molecular weight distribution including:
    - The number average molecular weight (MW_n); and
    - The oligomer content of the polymer as the percentage of oligomers with a molecular mass less than 1,000 Da and 500 D.
- The equivalent weight of any reactive functional groups;
- The equivalent weight of any cationic or anionic groups;
- Properties including:
    - Physical form;
    - Particle size distribution;
    - Water solubility or dispersibility; and
    - Surface activity in water.
- In the case of polyesters, the reactant used to make the polymer.

If this information is not available for a polymer, or a group of polymer, it may need to be generated before the criteria can be applied.

3.2.6 Outcome

As discussed in the previous sections, the following criteria are suggested as being appropriate for identification of polymers requiring registration in relation to possible registration needs under the REACH regulation. In the previous section, the criteria were ordered in terms of strength of evidence behind the criteria. The criteria in this section have been ordered more logically as presented in Figure 3.1 and Figure 3.2,

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[88] Non-isolated intermediates are exempt from REACH.

to reflect a streamlined approach to the application of the criteria for the identification of a potential polymer requiring registration.

It is taken that any polymer classified under CLP in any one or more of the following hazard classes should be considered as a PRR unless that classification is due to the residual monomer content or, if a mixture, due to the component substances other than the polymer. This is an overarching criterion. However, it is recognised that unreviewed self-classifications may not be definitive.

Relevant hazard classes

- Acute toxicity (Acute Tox. 1 to Acute Tox. 4);
- Germ cell mutagenicity (Muta. 1A, Muta. 1B or Muta. 2);
- Carcinogenicity (Carc. 1A, Carc. 1B or Carc. 2);
- Reproductive toxicity (Repr. 1A, Repr. 1B, Repr. 2 or Lact.);
- Aspiration hazard (Asp. Tox. 1);
- Respiratory/skin sensitisation (Resp. Sens. 1, 1A or 1B or Skin Sens. 1, 1A or 1B);
- Specific target organ toxicity – single exposure (STOT SE1 to SE3);
- Specific target organ toxicity – repeated exposure (STOT RE 1 and STOT RE 2);
- Eye Dam. 1 or Skin Corr. 1, 1A, 1B or 1C;
- Hazardous to the aquatic environment (Aquatic Acute 1, Aquatic Chronic 1 to 4); and
- Hazardous for the ozone layer (Ozone).

In this report, there is considerable reliance on the understanding of molecular weight distribution. The authors of this report consulted standard sources (e.g. DIN 55672) and several expert analysts. It is clear that the use of criteria based strongly on molecular weight is consistent with achievable science. However, although the most common method (gel permeation chromatography, GPC) is a well-developed technique, it has limitations which mean that experimental results should not be over-interpreted, and that clear guidance for any registration process will be needed. Reliable GPC data can be difficult for ionic polymers.

Low molecular weight polymers and oligomers

- Criterion MW1: Polymers with number average molecular weight (MW_n) of <1000 Da are considered as polymers requiring registration.
- Criterion MW2: For polymers with 1000 < MW_n <10,000 Da a polymer is considered a polymer requiring registration if it contains >10% oligomer content of molecular weight below 500 Da or >25% oligomer content of molecular weight below 1000 Da.
- Criterion MW3: For polymers with MW_n ≥10,000 Da a polymer is considered a polymer requiring registration if it contains >10% oligomer content of molecular weight below 500 Da or >25% oligomer content of molecular weight below 1000 Da. There are no restrictions on the nature and content of reactive functional groups.

As indicated earlier, reliably establishing the amounts of low molecular weight constituents present in polymers may not always be straight forward.

Cationic polymers

- Criterion C1: The polymer is a polymer requiring registration if it is a cationic polymer. Exceptions to this are:

  - Polymers with low cationic density, i.e. a polymer whose cationic group has a combined equivalent weight greater than 5,000 Da.

Anionic polymers

- Criterion AN1: The polymer is a polymer requiring registration if it is an anionic polymer. The highest priority would be for such polymers that are surface active. Exceptions to this are:
  - Polymers with low anionic density, i.e. a polymer whose anionic group has a combined equivalent weight greater than 5,000 Da.
- Criterion AN2: The polymer is a polymer requiring registration if it is expected to become an anionic polymer, i.e. if it contains groups reasonably anticipated to become anionic (e.g. acid groups or salts of acid groups) and/or be anionic in a natural aquatic environment ($4 < pH < 9$). The highest priority would be for such polymers that are surface active. Exceptions to this are:
  - Polymers with a low anionic density, i.e. a polymer whose anionic group as a combined equivalent weight greater than 5,000 Da.

Amphoteric polymers

- Criterion AM1: The polymer is a polymer requiring registration if it is an amphoteric polymer. Exceptions to this are:
  - Polymers with low cationic and anionic density, i.e. a polymer whose cationic and anionic groups each have a combined equivalent weight greater than 5,000 Da.

Nonionic polymers with surface-active properties.

Criterion NI1: The polymer is a polymer requiring registration if it is a nonionic polymer with surface active properties. *Reactive functional groups*

- Criterion RFG1: For polymers with 1000 < MWn < 10,000 Da. A polymer requiring registration contains reactive functional groups in either the high-concern category and/or moderate-concern category unless the following applies:
  - The combined functional group equivalent weight (FGEW) of these groups is >5,000 Da. Further, each group in the high-concern category has a FGEW >5,000 Da and each group in the moderate-concern category has a FGEW >1000 Da.
  - For polymers containing reactive functional groups in the moderate-concern and/or low concern category only, each moderate-concern group has a FGEW >1000 Da and the combined FGEW is >1000 Da.
    - Low-concern groups: carboxylic acid groups; aliphatic hydroxyl groups; "ordinary" unconjugated olefinic groups; butenedioic acid groups; conjugated olefinic groups present in naturally occurring fats, oils and carboxylic acids; blocked isocyanates; thiols; unconjugated nitrile groups; halogens (except reactive halogen containing groups such as benzylic or allylic halides). These groups are not of consequence for identification of polymers requiring registration.
    - Moderate-concern groups: conjugated olefinic groups not contained in naturally occurring fats (genotoxicity), oils and carboxylic acid; alkoxysilanes with alkoxy groups >C2 (lung toxicity, ecotoxicity).
    - High-concern groups: pendant[89] acrylates and methacrylates (genotoxicity, skin irritation); aziridines (genotoxicity, skin irritation); carbodiimides (genotoxicity,

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[89] A pendant group or side group is a small group of atoms that is attached to the main polymer backbone.

skin irritation); halosilanes (lung toxicity, ecotoxicity); hydrosilanes (lung toxicity, ecotoxicity); hydrazines (genotoxicity, skin irritation, ecotoxicity); alpha or beta lactones (genotoxicity, ecotoxicity); vinyl sulfones or analogous compounds (genotoxicity, ecotoxicity); acid halides (genotoxicity, skin irritation); acid anhydrides (lung toxicity); aldehydes (genotoxicity, ecotoxicity); hemiacetals (genotoxicity, ecotoxicity); methylolamides (genotoxicity, ecotoxicity); methylolamines (genotoxicity, ecotoxicity); methylolureas (genotoxicity, ecotoxicity); methoxy- and ethoxysilanes (lung toxicity, ecotoxicity); allyl ethers (genotoxicity, cytotoxicity); cyanates, iso(thio)cyanate (genotoxicity, skin irritation); epoxides (genotoxicity, skin irritation); imines (genotoxicity); unsubstituted positions ortho or para to phenolic hydroxyl (genotoxicity); any other reactive functional group not in the low or moderate concern groups.

Specific exclusion for polyesters

- Criterion PE1: Polyesters – if the candidate polymer is a polyester from an approved list, it is not considered a polymer requiring registration regardless of the number average molecular weight or oligomer content:
    - A proposed list of approved polyester reactants was given in Table 7 in COM (2015); the list is reproduced in Annex H.

It is important to note that the experimental justification behind these specific exclusions for polyesters is not clear and the general applicability of this criterion will need to be considered further in the next stage of the project.

Safety net

- Criterion SN1: Polymers that are suspected to present an equivalent hazard requiring registration as a polymer that meets any of the other criteria for a polymer requiring registration or are suspected that they may possess hazardous properties that may subsequently lead to a relevant hazard classification should be considered as polymers requiring registration.

The need to consider high exposure potential itself as a criterion for a polymer requiring registration was discussed at length at the workshop. This was questioned on a number of counts, in particular in relation to definition of such a criterion and the need to understand exposure in terms of internal exposure of an organism, involving consideration of both physical availability and internal (systemic) bioavailability. In addition incorporation of elements of usage into such a criterion was questionable as the uses may not always be fully known by any potential registrant and may be subject to change in the future. Overall, whilst it was recognised that a high exposure potential could be in itself a reason to require registration, the workability of such a criterion would be extremely difficult and may inadvertently lead to a large proportion of polymers (including many non-hazardous polymers) requiring registration.

Finally, a safety clause is added: a polymer which as any other property which suggests the possibility of it containing bioavailable constituents. This is needed in case scientific knowledge develops, or experience of use of the scheme suggests the need.

Flow charts showing the suggested approach to identifying polymers requiring registration are provided in Figure 3.1 (overall approach) and Figure 3.2.

In order to apply these criteria, detailed guidance would need to be developed on how to interpret them; writing guidance is beyond the scope of this report.

In order to determine whether a polymer meets these criteria or not, the following information would need to be available for the polymer:

- Number average molecular weight (MW_n) of the polymer. ECHA (2012) considers the analytical methods that can be used to determine the identity of polymer substances. The preferred method for MW_n is Gel Permeation Chromatography (GPC) using OECD TG 118[90]. Alternative methods for the determination of MW_n are given in an Annex to OECD TG 118. Methods for determining the low molecular weight content of polymers using GPC are given in OECD TG 119[91].
- Water solubility/dispersibility. Methods for determining the water solubility include OECD TG 105[92]. The solution/extraction behaviour of polymers can be determined using OECD TG 120[93]. A draft OECD TG for dispersibility of nanomaterials in aquatic media is under development[94].
- Charge (e.g. anionic, cationic and amphoteric polymers) and charge density. Methods for estimation of charge and whether a polymer has a low charge density are outlined in NICNAS (2017).
- The reactive functional groups present in the polymer. Methods for calculation the functional group equivalent weight are given in USEPA (1997) and Government Canada (2005).
- Physical form of products placed on the market.

The same information would also be important for any subsequent registration and/or risk assessment of the polymer.

When considering the criteria it is important to bear in mind that the criteria are intended to provide a pragmatic approach for identifying polymers that could possess properties that may present hazards to human health and the environment. The criteria are developed taking into account existing experience and the available evidence on properties or features of polymers that are potentially associated with hazards to health or the environment. The criteria are necessarily generalised and if a polymer meets one or more of these criteria it does not necessarily follow that the polymer will possess hazardous properties (or indeed uncontrolled risks), but rather that the polymer could be considered as a candidate for subsequent registration whereby information on the actual hazards presented by the polymer are provided, documented and, if necessary, are assessed in more detail should hazards be identified.

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[90] https://www.oecd-ilibrary.org/environment/test-no-118-determination-of-the-number-average-molecular-weight-and-the-molecular-weight-distribution-of-polymers-using-gel-permeation-chromatography_9789264069848-en (accessed 26th February 2019).

[91] https://www.oecd-ilibrary.org/environment/test-no-119-determination-of-the-low-molecular-weight-content-of-a-polymer-using-gel-permeation-chromatography_9789264069862-en (access 26th February 2019).

[92] https://www.oecd-ilibrary.org/environment/test-no-105-water-solubility_9789264069589-en (accessed 26th February 2019).

[93] https://www.oecd-ilibrary.org/environment/test-no-120-solution-extraction-behaviour-of-polymers-in-water_9789264069886-en

[94] http://www.oecd.org/env/ehs/testing/draft%20TG%20on%20agglomeration%20behaviour%20of%20NM-15-11-2016.pdf (accessed 26th February 2019).

Figure 3.1 Suggested overall approach to identifying polymers requiring registration

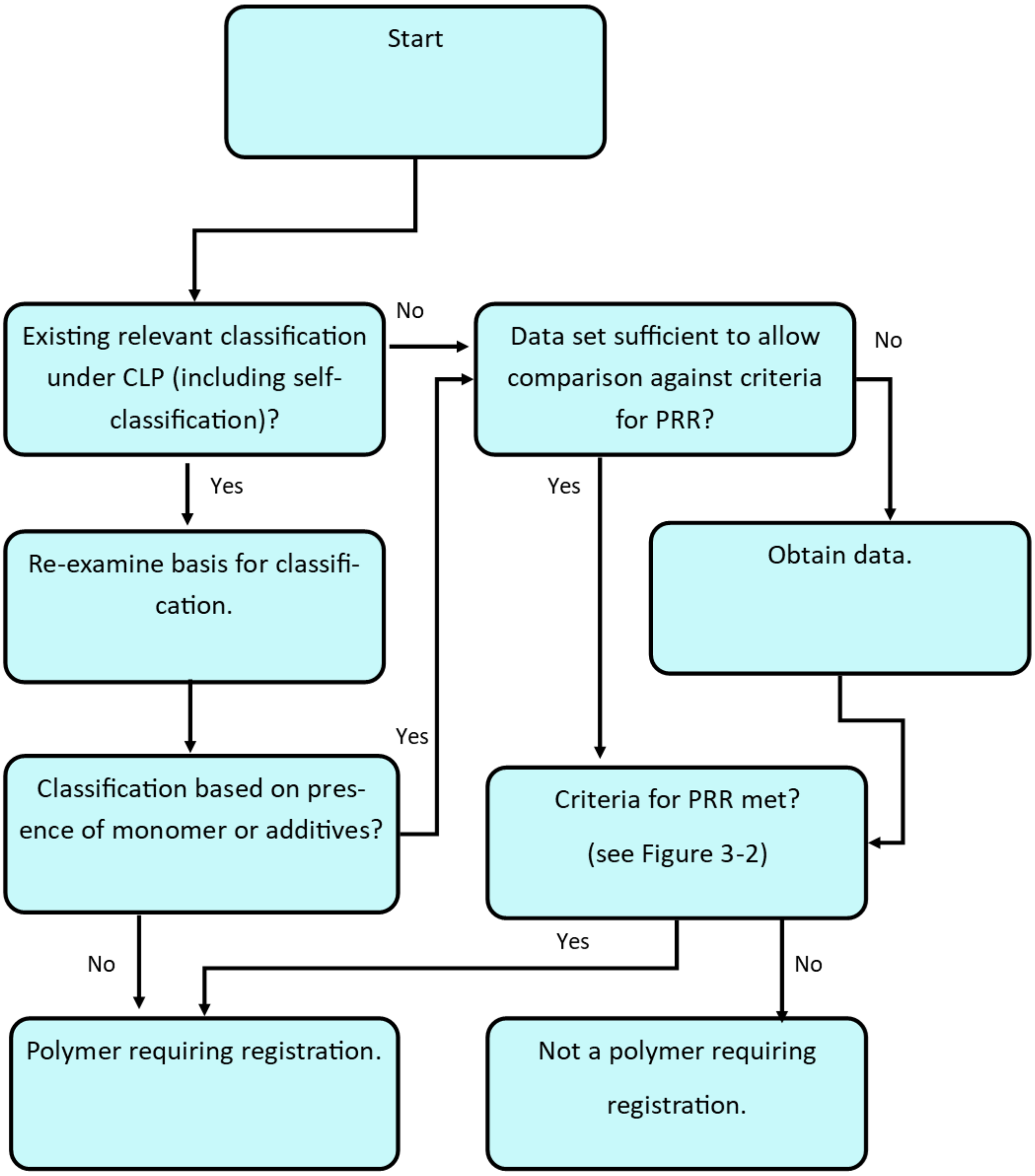
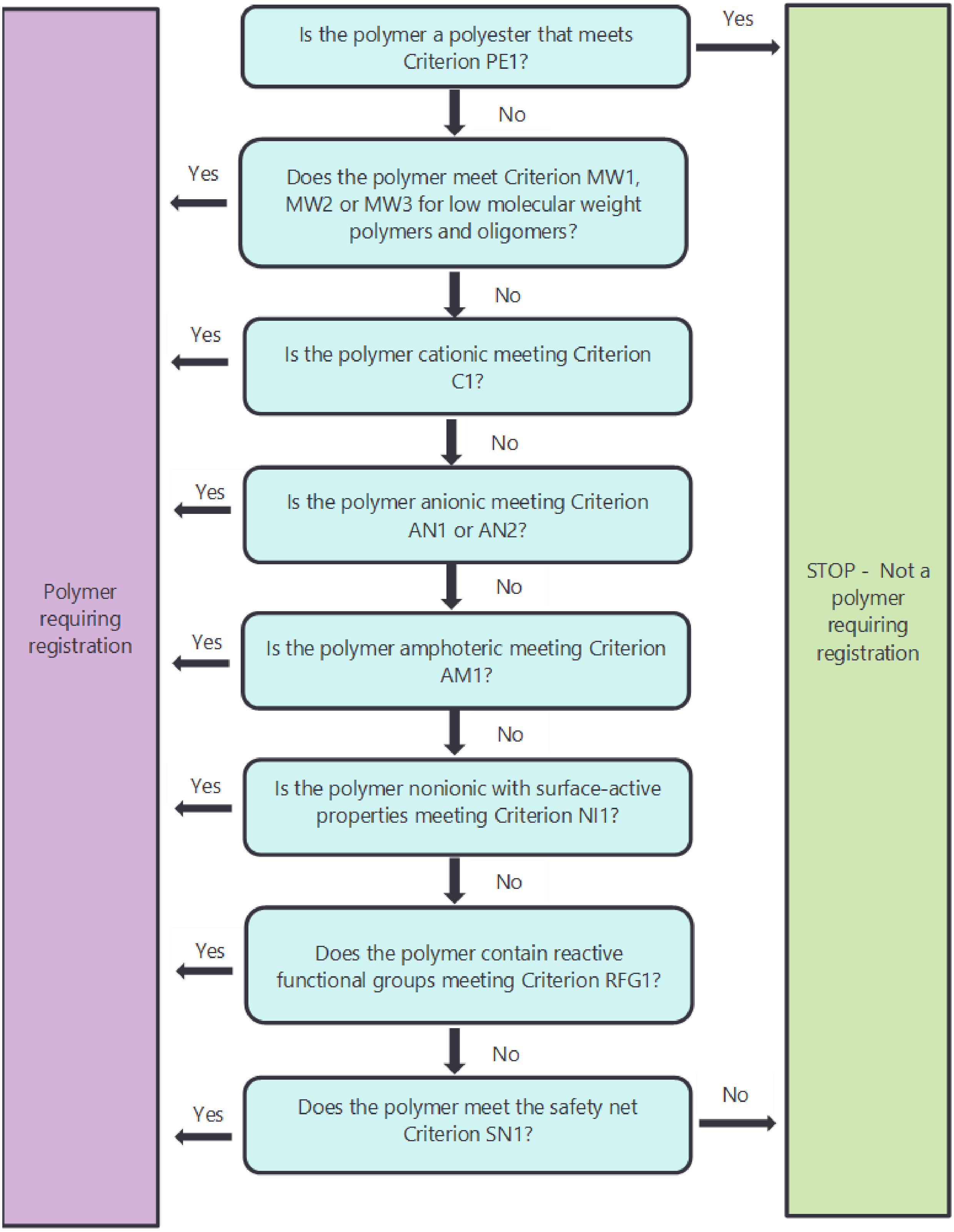


Figure 3.2 Suggested criteria for identifying polymers requiring registration



3.3 Task 1.3 Proposed solutions for grouping of PRRs

In very basic terms, polymer macromolecules can be either linear or branched and may be cross-linked (COM, 2007). Polymers may be manufactured from one monomer (homopolymer) or may be based on two or more different monomers (copolymer). Further, the repeat groups within copolymers may be arranged randomly, arranged in blocks, or may alternate along with polymer backbone. Branched copolymers can also be produced, for example, by grafting sidechains derived from one monomer onto a linear homopolymer. Further details are given in Annex G. It is also important to note that as well as organic polymers, Annex G identifies types of inorganic polymers with backbones based on silicon, oxygen, phosphorous, sulfur, boron, nitrogen, transition metals, germanium, and/or tin for example.

It is also important to note that polymers with apparently similar composition can differ in physical form, which may be very important in respect of the hazard.

COM (2007) indicates that synthetic polymerisation reactions are statistically driven processes and so the polymer products show a distribution of molar mass.

Given the large number of polymers that are on the market within the EU (estimated at <70,000 to 400,000 in COM, 2012) grouping approaches need to be considered to take into account commonalities and cross-overs between polymers in order to best manage the burden on industry against attaining the desired outcomes of registration under REACH. In this respect, two main uses of grouping can be identified.

1. Grouping of polymers to identify which polymers meet the criteria for polymers requiring registration.
   - The main purpose of this grouping would be for a manufacturer/importer of polymers to decide which polymers may meet the criteria for a PRR.
   - A secondary purpose of this grouping would be to allow the manufacturers/importers of similar types of PRR to start a dialogue with other manufacturers/importers in relation to future collaboration in relation to any subsequent registration requirements (see Task 2).
2. Grouping of polymers in relation to any subsequent registration requirements. The main purposes of this grouping would be:
   - To facilitate cost-effective registration of PRR in line with the one substance, one registration principle.
   - To reduce testing costs and avoid unnecessary testing.

The two main uses of grouping are related in that the first grouping identifies the main groups of polymers that may meet the criteria for polymers requiring registration and then the second grouping identifies the specific polymers or groups of polymers within each main group that may be subject to subsequent registration requirements. The focus of this section is on possible approaches for the initial identification of the main groups of polymers that may meet the criteria for polymers requiring registration. Grouping approaches for subsequent registration requirements is considered later in Task 2.

Approaches to grouping of polymers in relation to the REACH Regulation have been considered previously in the COM (2012) and COM (2015) studies. The COM (2015) study also reviewed grouping approaches used in other jurisdictions. These approaches are summarised in the following Sections.

3.3.1 Existing approaches to grouping of polymers from other jurisdictions

The approaches to grouping of polymers in the United States, Australia and Canada, and the grouping provisions under Annex VIID of the former Dangerous Substances Directive[95] (DSD) have been reviewed previously in COM (2015). These grouping approaches are based on the following rationale: polymers that have similar molecular structure, composition or use, show a similar physical and chemical behaviour, and this similarity eliminates the need to distinguish each of the individual polymers within the group in the assessment required during registration. This is, in effect, a read-across approach which has the advantage of reducing the number of submissions (a single submission covers several polymers), reduces the number of test results required, and reduces the costs to companies.

A summary of the existing grouping approaches is given below (based on COM, 2015).

United States – Consolidated Notice

The approach used to group polymers in the United States is summarised below.

- Group size is limited to 2 to 6 polymers;
- Sameness/similarity is determined in terms of:
  - Exposure;
  - Environmental release; and
  - Test data.

No specific criteria are available to determine the sameness/similarity. COM (2015) indicates that the responsibility for determining sameness/similarity lies with the regulators and that procedure used by the regulators to assess sameness/similarity relies on the expertise of staff at the USEPA.

COM (2015) reports that around 208 consolidated notices for polymers are approved per year in the United States, compared with around 514 polymer notifications in total per year. Thus, COM (2015) estimated that the consolidated approach leads to a reduction in the total number of notifications by a factor of 2 to 2.5. The most common grouping issues are reported to relate to variations in the monomers/initiator used in the polymer manufacture.

Canada – Consolidated Notification

The approach used to group polymers in Canada is summarised below.

- Group size is limited to 2 to 6 polymers; and
- Sameness/similarity is determined in terms of:
  - Substance class.

No specific criteria are available to determine the sameness/similarity. COM (2015) suggests that a similar approach to that used in the United States based on staff experience is used by regulators in Canada to assess sameness/similarity.

Australia – Group Assessment

The approach used to group polymers in Australia is summarised below.

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[95] Council Directive of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (67/548/EEC).

- Group size is 2 or more polymers;
- Sameness/similarity is determined in terms of:
    - Similarity of use, taking into account the following:
        - Industry sector in which the polymer is used;
        - Routes of human exposure;
        - Types of workers exposed and the extent to which they are exposed;
        - Routes of environmental release;
        - Potential for public exposure;
        - Volume range:
            - <1 tonne;
            - 1-3 tonnes;
            - 3-10 tonnes;
            - 10-30 tonnes;
            - 30-60 tonnes;
            - 60 to 100 tonnes; and
            - a use would not be considered similar if the increase in volume would lead to a change in the original risk assessment.
        - Mode of introduction, e.g. import or manufacture.
    - Similarity of polymer. A similar polymer is considered as follows:
        - Notified polymer contains one polymer constituent less than the primary polymer;
        - Notified polymer contains a polymer constituent which is similar to a polymer constituent in the primary polymer, with all other polymer constituents the same;
        - Notified polymer is structurally identical to the primary polymer. This allows similar polymers manufactured by different pathways to be grouped;
        - Notified polymers contain the same linkages and functional groups; and
        - The water solubility of the notified polymer is in the range 50% to 200% of the water solubility of the primary polymer.

COM (2015) notes that responsibility for determining sameness/similarity lies with the applicant and that applications for a group assessment must be justified based on the above criteria and parameters. Furthermore, polymers notified under the same procedure must be in the same volume range, have the same potential for exposure and the same toxicity (applicants assess acute oral toxicity and acute aquatic toxicity). Where read-across data are used the suitability of the data for other polymers within the group also needs to be assessed and reported in the application for a group assessment.

COM (2015) reports that the group assessment approach was applied to eight polymers within the 2012 to 2014 time period (one of these was a polymer of low concern) out of a total of 200 polymer notifications.

Dangerous Substances Directive – Narrow range and wide range (or family approach)

The approach used by the former Dangerous Substances Directive for grouping of polymers is outlined below.

- Group size is two or more polymers;
- Sameness/similarity is determined in terms of:
  - Narrow range: a narrow group of (co)polymers of similar composition and/or similar MW_n is considered a single "substance". Small variations are allowed in the following:
    - For homopolymers, MW_n can vary up to three-fold;
    - For copolymers the following two cases are allowed:
      - MW_n remains approximately constant (variation up to 2-fold allowed) while the composition varies by ±10% absolute; and
      - The composition remains approximately constant (variation up to 3% absolute allowed) while MW_n varies by up to 3-fold.
  - Wide range or family approach. This is used when the group of polymers varies too widely in composition or MW_n to be considered a single substance based on the criteria above:
    - A family is defined by a group of polymers where one parameter (e.g. MW_n) is fixed within a narrow range and the other parameter (e.g. composition) varies over a larger range; and
    - Information is provided on representative members of the family, usually representative of the extremes of the parameter that varies over a larger range.

COM (2015) notes that responsibility for determining sameness/similarity lies with the applicant and reports that only 1 family (consisting of 6 polymers) was notified under the family approach out of a total of 265 polymer notifications. The main reason given for not using the family approach was that the guidance was considered too complex and attempts to simplify the guidance were unsuccessful owing to different opinions about polymer notification requirements.

3.3.2 Previous proposals for grouping of polymers in relation to REACH

Two previous studies (COM (2012) and COM (2015)) have considered possible approaches to grouping of polymers in relation to REACH. These are discussed and considered below.

Proposal in the COM (2012) study

COM (2012) reports the results of consultation with Industry over the factors or scientific qualifiers that would be sufficient for the purposes of polymer identification and grouping. These are summarised below:

- Number average molecular weight (MW_n);
- Molecular weight range;
- Molecular weight distribution;
- Kind of monomer chemical group (e.g. acrylate);
- Type of monomer (mono-constituent, multi-constituent or UVCB);
- Identification and number of different monomers;

- Sequence of monomer (isotactic, atactic, syndiotactic);
- Kind of other reactant (for example aliphatic alcohol) including identification of chemical group;
- Identification and number of other reactants;
- Identification and percentage of each stabiliser;
- Degree of branching in the polymer (e.g. percentage of linear polymer and percentage of branched polymer);
- 3D-configuration;
- Identification of functional groups in the polymer;
- End-group modification;
- Intentional monomers present. Identification and percentage of each monomer; and
- Unintentional monomers present. Identification and percentage of each monomer.

COM (2012) proposed a series of options for screening polymers into groups based on the likely properties requiring registration and the downstream use of the polymer. These were effectively broad, high level groups that would contain the polymers for which registration would be required. Such high-level approaches are appropriate for identification the broad groups of polymers that may require registration but are of limited value when subsequently deciding which specific polymers can be grouped in relation to a single registration.

Proposal in COM (2015)

The COM (2015) study considered the OECD guidance for read-across methods and read-across justification and identified the following elements as being relevant for the grouping of polymers.

- Chemical structure:
  - Size of the polymer;
  - Types of linkages; and
  - Linear versus branched polymers.
- Composition:
  - Same monomers used to synthesise the polymer.
- Impurities:
  - Residual monomer and oligomer contents.
- Functional groups:
  - Presence of reactive functional groups.
- Physico-chemical and other molecular descriptors:
  - Charge (ionicity) of polymers;
  - Particle size; and
  - Swellability.

The grouping approach developed in COM (2015) was based on the approaches implemented in third countries and on the approach implemented previously in the EU under the DSD. The main aim of the grouping approach considered in COM (2015) was for similar polymers to be registered within one application. The grouping approach proposed was divided into two main categories.

- Groups of polymers with the same constituents, i.e. the same monomers and other substances belonging to the polymer structure, e.g. counter-ions; and
  - Case 1: Structurally identical polymers.
  - Case 2: Polymers which were considered as one substance under the DSD (narrow range). These are polymers with similar composition and similar MW_n where small variations in composition or MW_n are allowed.
  - Case 3: Polymers with incremental and constant change across the group. This allows homologous series of polymers to be grouped.
- Groups of polymers with different constituents:
  - Case 4: Change in counter-ion (if the polymer is a salt).
  - Case 5: Change with a similar monomer:
    - Monomers which are isomers (positional and stereoisomers) except if the isomerism is known to change the toxicity profile.
    - Monomers with a slight change in structure e.g. acrylate/methacrylate.

3.3.3 Other information related to grouping

Existing ECHA guidance on grouping approaches

A certain amount of guidance for grouping approaches for substances within REACH is already available and it is relevant to consider this guidance, and developments of this guidance, in relation to possible grouping approaches for polymers. In this report grouping can refer to the identification of related polymeric substances either for joint registration or for data-sharing and read-across. Task 2 emphasises the difficulties inherent to development of joint registrations in a context of there being no sufficient indexing system (such as CAS or EC numbers) for all polymers.

ECHA (2008) provides guidance for grouping approaches for substances in relation to Annex XI of REACH. Annex XI states the following in relation to the adaptation of the standard testing requirements.

> “Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or ‘category’ of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read across approach). This avoids the need to test every substance for every endpoint. The Agency, after consulting with relevant stakeholders and other interested parties, shall issue guidance on technically and scientifically justified methodology for the grouping of substances sufficiently in advance of the first registration deadline for phase-in substances.
>
> The similarities may be based on:
>
> (1) a common functional group;

(2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals; or

(3) a constant pattern in the changing of the potency of the properties across the category.

If the group concept is applied, substances shall be classified and labelled on this basis.

In all cases results should:

— be adequate for the purpose of classification and labelling and/or risk assessment,

— have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3),

— cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter, and

— adequate and reliable documentation of the applied method shall be provided."

ECHA (2008) considers a chemical category to be a group of chemicals whose physico-chemical and human health and/or environmental toxicological properties and/or environmental fate properties are likely to be similar or follow a regular pattern as a result of structural similarity (or other similarity characteristic). ECHA (2008) notes that as the number of category members increases the potential for making generalisations about the trends within the category for specific endpoints increases. ECHA (2008) uses the term analogue approach when the grouping is based on a very limited number of chemicals where trends in properties are not apparent.

ECHA (2008) suggests that in many cases members of a chemical category can be based on a presumption of a common mechanism of action. This concept is equally relevant to grouping considerations for polymers as for non-polymeric substances.

In terms of read-across between members of a category using the analogue approach, COM (2008) identifies that a fundamental aspect is that the chemical structures are sufficiently close for there to be reasonable expectation of similar effects. The structural similarity and purity and impurity profiles are important for this.

ECHA (2008) indicates that in some cases similar chemicals are produced for similar uses by the same company or by several companies.

ECHA (2008) notes that it may be challenging for industry to include all relevant substances within a chemical category approach as different priorities may exist between different registrants, related to different uses and different risk assessment needs.

Confidentiality issues over, for example, substance identity and uses may be an issue for grouping approaches. Several of the suggested criteria for PRR (see Section 3.2) require information on the polymer related to the molecular weight distributions, the presence of low molecular weight material, or the nature and number of reactive functional groups, and may relate to the production processes used. These may be considered confidential by some manufacturers/importers.

OECD Guidance on grouping of substances

The OECD has also published guidance for grouping of chemicals (OECD, 2014). The basis for the approach recommended in OECD (2014) is that closely related chemicals can be considered as a group or category. The idea is then that not every chemical within the category needs to be tested for every endpoint provided that the overall data available for the category is adequate to support a hazard assessment for all members of the category. Where comparison or read-across is made between a very limited number of chemicals this is considered in OECD (2014) to be an analogue approach rather than a category approach. The following rationale underpins both the OECD analogue and category approach:

- Common functional group(s);
- Common mode or mechanism of action or adverse outcome pathway;
- Common constituents or chemical classes, similar carbon range numbers. This is often the case with UVCBs and may also be relevant for polymers);
- The likelihood of common precursors and/or breakdown products via physical or biological processes that result in structurally similar chemicals; or
- An incremental and constant change across the category, often observed in physical chemical properties.

OECD (2014) recommends that the structural elements that the category members have in common need to be described, along with the structural differences that may occur in the category. Differences which are not expected to affect the endpoint of interest are then considered to be “allowed differences”.

ECHA Guidance on substance identification

ECHA (2017b) provides guidance for identification and naming of substances under REACH and CLP. Substance identification is a key aspect in deciding whether substances can be regarded as being the same in the context of REACH and CLP, and with regard to the one substance, one registration principle in REACH.

In practical terms there are some similarities between polymers and some types of UVCB substances (and in some cases multi-constituent substances[96]), in that both polymers and UVCBs may have unknown or variable composition or be complex reaction products or biological materials. Indeed ECHA (2017b) gives “biopolymers” as an example of a UVCB. However, it is important to note that a major difference between the REACH definition of a UVCB and a polymer is that the term impurities is not relevant to a UVCB[97] whereas impurities are relevant to a polymer. However, taking this into account, some relevant similarities (and multi-constituent substances) may exist between UVCBs and polymers in terms of potential grouping considerations, and so it is relevant to take into account the available guidance on substance identification from ECHA (2017b).

According to ECHA (2017b), UVCB substances cannot be sufficiently identified by their chemical composition as:

- The number of constituents is relatively large; and/or
- The composition is, to a significant part, unknown; and/or
- The variability of composition is relatively large or poorly predictable.

Therefore, in addition to whatever is known about the chemical composition, the following types of information are usually considered when considering the identity of UVCBs.

- Name;
- Origin or source;
- Relevant steps taken during synthesis and/or processing; and
- Any other relevant identifiers such as generic description of chemical composition, chromatographic or other fingerprint, physico-chemical parameters such as boiling point), colour index number, etc.

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[96] E.g. in cases where the composition is known, and the main constituents identified.

[97] ECHA (2017b) states that ‘due to the lack of differentiation between constituents and impurities, the terms “main constituents” and “impurities” should not be regarded as relevant for UVCB substances’.

ECHA (2017b) gives criteria for checking if substances are the same. These include the following.

- For multi-constituent substances, different purity/impurity profiles are allowed. However, the substances should contain the main constituents and the only impurities allowed are those derived from the product process and additives which are necessary to stabilise the substance.
- Hydrated and anhydrous forms are regarded as the same substances for the purposes of a registration.
- Acids or bases and their salts are regarded as different substances.
- Individual salts (e.g. sodium or potassium) are regarded as different substances.
- Branched or linear alkyl chains are regarded as different substances.
- Substances with alkyl groups using additional terms like iso, neo, branched, etc, are not to be regarded the same as the substances without that specification.
- A UVCB substance with a narrow distribution of constituents is not regarded as equal to a UVCB substance with a broader composition and vice versa.

If a manufacture substance is identified as a multi-constituent substance, the substance may be derived from a different source and/or different process as long as the composition of the final substance remains within the specified range and would not require a new registration (ECHA, 2017b).

There will be a need to check that the guidance is fully-applicable to polymers.

3.3.4 Summary of existing approaches

COM (2015) notes that a common concept behind the grouping approaches in existing regulatory schemes from other jurisdictions is that the members of a group must not differ in terms of environmental and health risks, i.e. they have similar hazard and exposure profiles as exemplified below.

- Similarity of hazards:
  - This could be based on, for example:
    - Common functional group(s)
    - Common precursors
    - Common lower molecular weight oligomers and/or impurities
  - The key question is how similar do the hazards have to be before the polymers can be grouped? This has fundamental consequences for the development of possible groups of polymers for any subsequent registration requirements and also the amount and types of information that may be needed to be provided on the members of the group during the registration process.
- Similarity of exposure.

As noted earlier, two possible uses of grouping can be identified in relation to polymers requiring registration.

1. Grouping of polymers to identify which polymers meet the criteria for polymers requiring registration.
2. Grouping of polymers in relation to any subsequent registration requirements.

The following Sections consider possible approaches to grouping that could be used in relation to the first of these options; grouping of polymers to identify which polymers meet the criteria for polymers requiring registration.

Guidance already exists within the REACH context on approaches for grouping of substances. This is closely linked with substance identity and read-across/filling of data gaps in relation to the second of these two options. Grouping of polymers in relation to subsequent registration requirements is considered further in Task 2 of the project.

3.3.5 Approaches to grouping suggested during the workshop and consultation

Examples of approaches to grouping currently used or being developed within the polymers industry have been provided during the workshop and wider study consultation. These are summarised below. Some of the details of the approaches are considered to be confidential and so only brief details are provided in those cases.

During the workshop, there was much discussion over grouping and identifying polymers that would require registration. The discussions are documented in the workshop report and the main points are summarised below.

CESIO (2017) are grouping surfactants for classification and labelling based on surfactant family: alcohol ethoxylates, alkyl ether sulfates, alkyl sulfates, other anionic surfactants and other surfactants (see also Section 3.2[98]). Within each family, the surfactants are further sub-grouped based on chemistry (for example chemical name, carbon chain length, degree of ethoxylation or propoxylation etc as relevant). In general terms the CESIO (2017) data shows hazard is dependent upon the surfactant family, the alkyl (or hydrophobic group) chain length and the number of ethoxylate groups present. Using this approach surfactants within each sub-group that have similar classifications/hazards are identified and this appears to be a reasonable basis for any subsequent grouping under REACH.

The CESIO (2017) report does not specifically distinguish between polymer and non-polymer surfactants. Not all members of the families and subgroups considered in the CESIO (2017) report will meet the REACH definition of a polymer and so will have already been registered under REACH, presumably using similar grouping considerations.

The Epoxy Resin Committee (ERC, 2019) have developed a suggested grouping approach based on the chemistry used. For example, epoxy resin polymers can be produced out of a prepolymer intermediate BADGE[99], which is REACH registered, with further addition of bisphenol-A or are directly produced out of bisphenol-A and epichlorohydrin. The epoxy resins produced by either method are linear polymeric substances which differ only in the number of BADGE links in the chain and in the BADGE ratio. ERC (2019) suggests a grouping approach based on grouping epoxy resins that fall under the polymer definition depending on epoxy equivalent, average molecular weight and BADGE content.

In terms of hazard, historically epoxy resins have considered three molecular weight ranges.

- Domain A. Molecular weight <700 Da – liquid resins and the harmonised classification and labelling for BADGE applies. A full REACH data set is available for BADGE.
- Domain B. Molecular weight 700 -<1100 – semi-solid resins. Classification and labelling is intermediate between Domain A and Domain B. A limited data set is available (irritation, skin sensitisation and studies with algae, daphnia and fish).

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[98] As discussed in Section 3.2, the CESIO (2017) report does not specifically distinguish between polymer and non-polymer surfactants. Not all members of the families and subgroups considered in the CESIO (2017) report will meet the REACH definition of a polymer and so will have already been registered under REACH.

[99] BADGE is 2-{[4-(2-{4-[(oxiran-2-yl)methoxy]phenyl}propan-2-yl)phenoxy]oxirane which is an oligomeric reaction product of 4,4’-isopropylidenediphenol (bisphenol-A) and 1-chloro-2,3-epoxypropane (epichlorohydrin).

- Molecular weight >1100 Da – solid polymer resins. Not classified based on expert judgement. A limited dataset is available (irritation, skin sensitisation and studies with algae, daphnia and fish).

ERC (2019 then suggests using a tiered approach for evaluating the risk and hazard of these polymers to determine the limits of when a polymer can be considered a PRR similar to that discussed at the workshop (see above). ERC (2019) suggests that this approach could be extended to other families of epoxy resins based on different starting substances.

A confidential study of the potential hazards from polymers used in amino resins has been made available for this study (ERC, 2018). This considered eight broad groups of amino resins based on similarity of manufacturing process, chemical composition and properties.

3.3.6 Suggested approach for grouping of polymers to decide if the polymers meet the criteria for a PRR

This type of grouping can be at a reasonably high level as the main aim is to identify the main groups of polymers that may meet the criteria for a PRR. Such grouping may be easier for some polymer types than others. Such grouping could be carried out at an individual company level or potentially at a cross-sector level using relevant sector groups if confidentiality issues allow.

The suggested criteria that could be considered for grouping are given below. In line with the approach outlined in COM (2015) the criteria are considered in relation to similarity of hazard and similarity of exposure and in line with the approach outlined in COM (2012) the criteria are closely related to the suggested criteria for identification of PRR. Some of these considerations for grouping are also considered in ECETOC (2019).

- Similarity of hazards:
  - This could be based on the following:
    - Common lower molecular weight oligomers:
      - This may be related to the similarity of the production process chemistry.
    - Common reactive functional group(s);
    - Ionicity:
      - Cationic polymers with common cationic group(s);
      - Polymers with common group(s) that can, or can be expected to, become cationic in a natural environment
      - Anionic polymers with common anionic group(s) or similar surface tension;
      - Polymers with common group(s) that can, or can be expected to, become cationic in a natural environment
      - Amphoteric polymers with common cationic and anionic group(s)
      - Polymers with common group(s) that can, or cab be expected to, become cationic and anionic in a natural environment
      - Nonionic polymers with surface-active properties with common nonionic groups or similar surface tension.

It is important to note that some polymers may meet more than one of the criteria for a PRR and there may be more than one way to consider grouping of the polymers. In such cases, it is useful to consider the available options for grouping as this may inform possibilities for grouping PRR in terms of any subsequent registration requirements (see Task 2 of the project).

A suggestion from a polymer producer was received during the consultation for an additional identification code to be used alongside the CAS Number for registration purposes. This code could be used to specify, for example, specific MW ranges, functional group equivalent weight ranges and water solubility ranges.

3.3.7 Suggested approach for grouping of PRR for subsequent registration requirements

This approach to grouping is considered further in Task 2 of the project.

3.3.8 Other considerations related to registration requirements

When considering any registration requirements for polymers it is important to take into account that certain applications of polymers are already subject to their own legislation, and some uses may be exempt from REACH under Article 2(5). Some examples were raised during the consultation and these are summarised below.

The pharmaceutical industry uses are broad range of polymers, generally as downstream users. Examples of uses of polymers within this sector include in medical devices, as processing aids in pharmaceutical manufacture (e.g. chromatographic resins, surfactants) and excipients[100]. In addition, a small number of polymers may be used as active pharmaceutical ingredients (e.g. Li et al., 2015). Article 2(5) of REACH provides exemptions from registration for certain of these uses.

Polymers used in off-shore applications in the oil and gas sector have to be registered according to the OSPAR Harmonised Mandatory Control System (HMCS). This requires a basic set of environmental data to be provided on all polymer substances to allow for the hazard and risk assessment of such substances. The following basic information has to be provided (with the noted exceptions) (OSPAR, 2014 and 2015).

- Partitioning and bioaccumulation potential - Log Pow (OECD 107 or 117) (Log Pow data may be exempted for surfactants and other surface-active substances, however these substances will be assumed to bioaccumulate unless data to the contrary is provided).
- Biodegradability - Aerobic/ biodegradability (OECD 306 or Marine BODIS, or OECD301 A-F) (Harmonised Offshore Chemical Notification Format (HOCNF) guidelines allow submission without biodegradation data for polymers, however these substances will be assumed to persist and receive a substitution warning).
- Aquatic toxicity – Generally marine species for Algae, Crustacean, Fish and Sediment reworker where applicable (to ISO and OSPAR protocols) (sediment reworker study is only required for materials meeting a number of criteria which may make them of concern to sediment dwelling organisms).
- Solubility of the product is reported as part of the HOCNF data; however other physico-chemical properties are not required.

Within the agricultural seed industry, polymers are used in plant protection formulations and in film coatings and binders for pelleting and encrustment (ESA, 2019). The polymers used provide a variety of functions including emulsifiers, dispersing agents, surfactants, rheology modifiers, etc. Studies conducted on the finished formulation (mixtures) are requirements of Regulation (EC) No. 1107/2009 set out in Regulation (EC) No. 284/2013 . Polymers are thus also indirectly covered by these tests covering both toxicology and ecotoxicology. Seed companies also carry out germination testing and performance testing. Because these

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[100] In active substances used as vehicle or media for drug delivery.

studies are carried out on mixtures, it is not usually possible to determine the contribution from any one substance.

Polymers used in food contact applications are subject to their own regulatory framework under Regulation (EC) No 1935/2004 and Regulation (EU) No 10/2011[101, 102].

3.4 Task 1.4 Estimate of the potential risk posed by PRRs in comparison with other chemicals

3.4.1 Introduction

Article 138 (2) of REACH requires that any legislative proposals for selecting polymers for registration the prior publication of a report considering the risks posed by polymers in comparison with other substances. This Section considers what is known about the risks associated with PRRs in comparison with other non-polymeric substances.

Consideration of risk requires both the hazards of PRR and the potential exposure to be considered.

The exposure potential of PRRs is dependent upon several factors, including:

- The manufacturing process;
- The use pattern of the polymer;
- The type of system in which the polymer is used (e.g. closed or open);
- The form of the polymer (e.g. bulk solid, powder, dust, liquid, solution); and
- Whether the polymer comes into contact with water etc.

The same factors also relate to the exposure potential for non-polymeric substances. The extent to which the potential risks posed by PRRs can be estimated is dependent to a large extent on the data available, and clearly it is not possible to carry out an in-depth quantitative risk assessment of all PRRs as part of this project. Simplified approaches to exposure assessment (for example based on use pattern, wide dispersive use, tonnage etc.) do not provide sufficient distinction between polymers or between non-polymeric substances to allow a meaningful assessment of exposure to be undertaken (for example many polymers will have wide dispersive uses). This effectively rules out more simplified approaches to risk assessment as a method to estimate the potential risk posed by PRRs in comparison with other chemicals. Therefore, more qualitative approaches have to be considered.

Recently, a framework for risk assessment of polymers has been developed by ECETOC (2019). The approach is based on the eight steps below and provides a useful structure for the issues that will need to be considered in a detailed risk assessment of a polymer (as may be required for a registration). However, as noted above, such detailed risk assessments are beyond the scope of this study.

- Step 1 Problem formulation
- Step 2 Identification of the polymer
- Step 3 Polymer component strategy
- Step 4 Grouping approach
- Step 5 Determination of exposure scenarios

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[101] https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation_en

[102] https://www.efsa.europa.eu/en/topics/topic/food-contact-materials

- Step 6 Exposure characterisation
- Step 7 Hazard assessment
- Step 8 Risk characterisation

3.4.2 Consideration of classification and labelling

As a first estimate, the potential risks posed by PRRs has been determined in this project based on a simple hazard comparison based primarily on the number (or percentage) of PRRs with classification and labelling reported under the DSD and CLP Regulation, and also the number (or percentage) of substances with similar classifications. However the small number of data currently available from the polymers notified under the DSD limits the conclusions that can be drawn (see Section 3.1). This is not a subtle method at the first stage.

As discussed in Section 3.1, the ECHA C&L database contains classifications for polymers that have been submitted under the CLP Regulation. It is currently difficult to search the ECHA C&L database in a way that will unambiguously retrieve data for all polymers, and it is frequently unclear whether the entry relates to the polymer itself or other constituents that may be present within the polymer, or if the conclusions are reliable.). Nevertheless, it is relevant to note that searches of the database for the terms "poly" or "polymer" revealed that around 70% of the entries were classified for health hazards and 30% of the entries were classified for environmental hazard, with the proportion classified for their physical hazard being relatively low (<4%; see Section 3.1 for further details).

In order to, compare the available classification data for polymers with that for non-polymeric substances, the following broad categories have been considered.

- PBT substances;
- CMR substances[103];
- Substances classified for human health effects; and
- Substances classified for environmental effects.

The ECHA Classification and Labelling Inventory (as of 20 November 2018) contains a total of 146,162 entries.

- 12,411 entries (8.5%) classified for physical hazard;
- 122,305 entries (83.7%) classified for human health effects:
  - 8,888 entries (6.1%) classified for CMR;
  - 68,592 entries (46.9%) classified for specific target organ toxicity[104];
  - 14,999 entries (10.3%) classified as sensitisers[105];
  - 61,080 entries (41.8%) classified for acute toxicity[106];
  - 2,142 entries (1.5%) classified for aspiration hazard[107]; and
  - 96,779 entries (66.2%) classified for corrosivity or irritancy[108].

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[103] Carcinogenic, mutagenic or toxic to reproduction. Substances classified as Carc. 1A, Carc. 1B, Carc. 2, Muta. 1A, Muta. 1B, Muta. 2, Repr. 1A, Repr. 1B and/or Repr. 2.

[104] Substances classified as STOT SE 1, STOT SE 2, STOT SE3, STOT RE 1 or STOT RE 2.

[105] Substances classified as Resp. Sens. 1, Resp. Sens. 1A, Resp. Sens. 1B, Skin Sens. 1, Skin Sens. 1A and/or Skin Sens. 1B.

[106] Substances classified as Acute Tox. 1, Acute Tox. 2, Acute Tox. 3, Acute Tox. 4 or Acute Tox. 5.

[107] Substances classified as Asp. Tox. 1 or Asp. Tox. 2.

[108] Substances classified as Eye Dam. 1, Eye Irrit. 2, Eye Irrit. 2A, Eye Irrit. 2B, Skin Corr. 1, Skin Corr. 1A, Skin Corr. 1B, Skin Corr. 1C, Skin Irrit. 2 and/or Skin Mild Irrit. 3.

- 38,052 entries (26.0%) classified for environmental effects:
  - 16,613 entries (11.4%) classified for acute aquatic toxicity[109]; and
  - 33,503 entries (22.9%) classified for chronic aquatic toxicity[110].

These statistics cover all substances (including polymers) present in the ECHA C&L database. These can be compared with the similar statistics obtained from a search of the C&L database for the term "poly" carried out in Task 1.1 (see Section 3.1).

The percentage of the number of entries in each category considered out of the total number of entries considered is shown in Figure 3.3 for the search for "poly". Also shown for comparison are the same data for total entries minus the "poly" results. This approximates to the number of non-polymeric substances in the C&L database. As discussed in Section 3.1, there are considerable uncertainties inherent in this comparison, not least that not all entries retrieved by the term "poly" will be polymers and there may be other polymers within the database that are not picked up by this term, and it is not clear from the entries in the C&L inventory whether the classification relates to the polymer itself or other constituents or components present within the polymer.

Given the above uncertainties, the firm conclusions that can be drawn from this comparison are limited. However, with these limitations, the following trends can be seen.

- The percentage of the total entries with one or more of either a physical hazard classification, a health hazard classification and/or an environmental hazard classification is broadly similar across the two groups.
- The percentage classified as CMR, aspiration hazard and corrosive or irritant is broadly similar across the two groups. Similarly, the percentage classified for acute aquatic toxicity or chronic aquatic toxicity is broadly similar across the two groups.
- The group of all substances minus "poly" shows a higher percentage of substances classified for specific target organ toxicity or acute toxicity than the "poly" group.
- The "poly" group shows a higher percentage classified for sensitisation than the group of all substances minus "poly".

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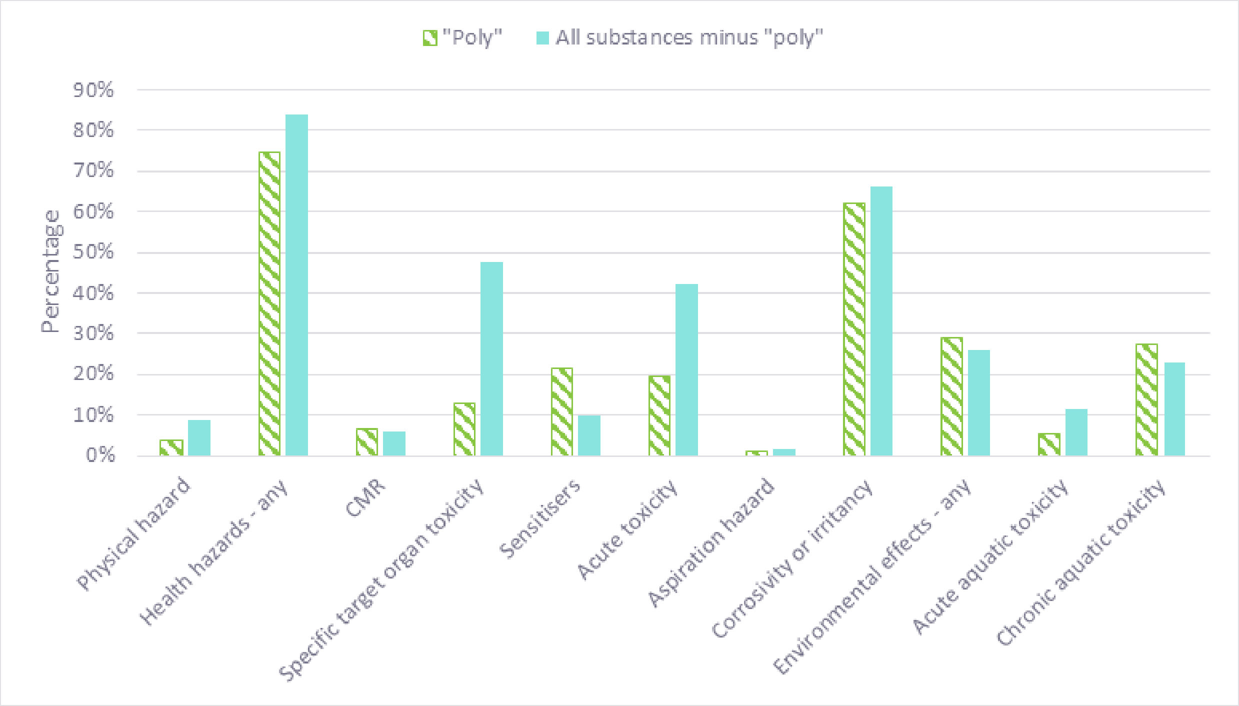
[109] Substances classified as Aquatic Acute 1, Aquatic Acute 2 or Aquatic Acute 3.

[110] Substance classified as Aquatic Chronic 1, Aquatic Chronic 2, Aquatic Chronic 3 or Aquatic Chronic 4.

Figure 3.3 Comparison of the percentage of entries in the C&L database within selected hazard categories



Note: The bar chart indicates the percentage of the total entries (y axis) for polymers, searched as and referred to as “poly”, and of all substances in the C&L database minus “poly”, with one or more of either hazards presented on the x axis. Considerable uncertainties are inherent in this comparison: not all entries retrieved by the term “poly” will be polymers, there may be other polymers within the database that are not picked up by this term, and it is not clear from the entries in the C&L inventory whether the classification relates to the polymer itself or other constituents or components present within the polymer.

It is important to note that reliable statistics on the hazards of polymers are not currently available, and the above comparisons are of a tentative nature.

3.4.3 Specific examples

It is also informative to consider specific examples where the risks from polymers may be similar to those from non-polymeric substances. One such example is alcohol ethoxylates.

Alcohol ethoxylates are non-ionic surfactants that are widely used in laundry detergents, household and industrial cleaners, cosmetics, agriculture and in certain processing industries.

The group of alcohol ethoxylates covers both substances that meet the definition of a polymer and substances that do not meet the definition of a polymer, and therefore have been registered under REACH. Examples of non-polymer alcohol ethoxylates for which REACH registrations currently exist are given below (the list is not comprehensive).

- (Z)-9-Octadecen-1-ol ethoxylated, 1-2.5 moles ethoxylated. EC No. 500-016-2;
- Alcohols, C12-15, ethoxylated, 1-2.5 moles ethoxylated. EC No. 500-195-7;
- Alcohols, C9-11 ethoxylated, < 2.5 EO. EC No. 614-482-0;
- Alcohols, secondary C11-15, ethoxylated (with EO ≤3). EC 614-295-4;
- Dodecan-1-ol, ethoxylated, 1-2.5 moles ethoxylated. EC No. 500-002-6;
- Isotridecanol, ethoxylated, 1-2.5 moles ethoxylated. EC No. 500-241-6;

- Alcohols, C12-14, ethoxylated, 1-2.5 moles ethoxylated. EC 500-213-3;
- Octadecano-1-ol, ethoxylated, 1-2.5 moles ethoxylated. EC 500-017-8;
- Alcohols, C10-12 (even numbered), ethoxylated (1-2.5 EO). EC 939-592-9;
- Alcohols, C12-13, branched and linear, ethoxylated, 1-2.5 moles ethoxylated. EC 500-457-0;
- Alcohols, C12-13, ethoxylated, 1-2.5 moles ethoxylated. EC 500-165-3;
- Alcohols, C12-18, ethoxylated, 1-2.5 moles ethoxylated. EC 500-201-8;
- Alcohols, C13-15 (odd numbered, branched and linear), ethoxylated. EC 931-662-7;
- Alcohols, C16-18 (even numbered), ethoxylated, < 2.5 EO. EC 939-518-5;
- Alcohols, C16-18 and C18-unsatd., ethoxylated, 1-2.5 moles ethoxylated. EC 500-236-9;
- Alcohols, C16-20 (even numbered, linear), ethoxylated (< 2.5 EO). EC 600-724-2;
- Alcohols, C6-C8-(even numbered, linear)-ethoxylated (<2.5 EO). EC 800-182-9;
- Alcohols, C8-10 (even numbered), ethoxylated (<2,5 EO). EC 615-247-5;
- Alcohols, C8-18, ethoxylated, 1-2.5 moles ethoxylated. EC 500-349-3; and
- Alcohols, C9-11, branched and linear, ethoxylated, 1-2.5 moles ethoxylated. EC 500-446-0.

All of the above alcohol ethoxylates are classified for one or more health and/or environmental hazard.

A detailed risk assessment of alcohol ethoxylates used in household cleaning products has been conducted by HERA (2009). The HERA (2009) assessment gave the basic structure of alcohol ethoxylates as Cx-yAEn, where x-y relates to the alcohol chain length range and n is the number of ethoxylate groups polymerised to the alcohol chain. HERA (2009) indicates that alcohols used in production of alcohol ethoxylates typically have alkyl chain lengths in the C8 to C18 range and the average value of n is commonly between 3 and 12 units in alcohol ethoxylates used in household products. Typically, the level of reaction by-products such as unreacted alcohol is around 5%.

As marketed, the alcohol ethoxylates usually contain a distribution of both alkyl chain lengths and ethoxylate groups. In addition, the alcohol group may contain a mixture of linear and (mono) branched chains. In terms of when alcohol ethoxylates will meet the definition of a polymer, this depends upon the actual composition of the products produced. However, it is evident that most of the substances already registered have relatively low numbers of ethoxylate groups (typically <3). Presumably at least some of the products marketed with high numbers of ethoxylate groups would therefore meet the REACH definition of a polymer. It is relevant to note that HERA (2009) estimate that around 97% of alcohol ethoxylates used in household cleaning products have an average of more than 3 ethoxylate groups.

HERA (2009) noted the following trends in properties for alcohol ethoxylates as a group.

- The K_{oc} is expected to increase as the alcohol chain length increases and the number of ethoxylate groups increase.
- The alcohol ethoxylates are generally readily biodegradable.
- Removal during sewage treatment (by primary biodegradation and adsorption) is generally high (>99%).
- Human health:
  - No evidence that alcohol ethoxylates are genotoxic, mutagenic or carcinogenic.

  - No adverse reproductive or developmental effects observed.
  - Majority of available toxicity studies give NOAELs in excess of 100 mg/kg bw/day.
  - The lowest NOAEL was 50 mg/kg bw/day (with a C14-15 alkyl chain and 7 ethoxylate groups and a C12-14 alkyl chain with 6.5 ethoxylate groups).
  - Alcohol ethoxylates are not contact sensitisers but neat alcohol ethoxylates are irritating to eyes and skin. Irritation potential of aqueous solutions is concentration dependent.
  - Skin irritation appears to be related to the degree of ethoxylation with the irritation potential decreasing with ethoxylate content (up to 20 ethoxylate units). No trend in irritation potential with alkyl chain length was found.
- Environment. The assessment considered 230 different homologues with hydrocarbon chain lengths between C8 and C18 and with between 0 to 22 ethylene oxide groups:
  - Acute ecotoxicity has been seen in laboratory studies across the range of structures, generally in the 0.1 mg/L to low hundreds of mg/L range.
  - Chronic aquatic toxicity data are also available, generally ranging from <0.1 mg/L to low tens of mg/L range.
  - Increasing alkyl chain length tends to increase the toxicity to aquatic organisms whereas increasing number of ethoxylate groups tends to decrease the toxicity to aquatic organisms.

Given that the exposure potential of alcohol ethoxylates in domestic cleaning products is broadly similar (the uses are essentially down-the-drain uses) regardless of the carbon chain length and number of ethoxylate groups, or whether or not the substance is considered a polymer, it can be concluded that the risks from polymeric alcohol ethoxylates will be broadly similar, or will overlap with, those from non-polymeric alcohol ethoxylates. Given that the non-polymeric substances already have to be registered under REACH this suggests that there is no obvious reason why the polymeric substances should not also be subject to registration requirements under REACH.

Similar detailed risk assessments have also been carried out on alcohol ethoxysulfates (HERA, 2003 and 2004) Details of these studies are not reproduced here, but again the approach did not distinguish between substances considered as polymers and those that were not polymers but rather considered the hazards related to different carbon chain lengths and the number of ethoxylate groups. The conclusions of these risk assessments are valid for both polymers and non-polymer substances.

CESIO (2017) gives recommendations for the harmonised self-classification and labelling of surfactants (see Annex D). The report considers surfactants with broad families (alcohol ethoxylates,alkyl ether sulfates, alkyl sulfates, other anionic surfactants and other surfactants). The report makes no distinction between non-polymeric surfactants and polymeric surfactants but rather considered the classification for sub-groups of these families based on chemistry (e.g. carbon chain length, degree of ethoxylation or propoxylation, etc. as relevant). Thus the same classification would be recommended for both polymeric surfactants and non-polymeric surfactants that fall within the same subgroup.

3.4.4 Gaps and limitations from the information available

The estimation of the risks posed by polymers requiring registration in comparison with other chemicals is currently limited in its extent owing to the lack of useable data.

The analysis carried out suggests that, in terms of numbers and types of classification and labelling, polymers requiring registration may present similar hazards as other chemicals but there are large uncertainties associated with the available data. In particular, it is frequently unclear whether the reported classification relates to the polymer itself or some other constituent or components that may be present in the polymer and this has potential to skew the analysis.

It is also relevant to consider that it is currently not possible to distinguish in the classification and labelling database between polymers that would meet the suggested criteria for a polymer requiring registration and those that would not meet the criteria. This also compromises any analysis that can be undertaken. It would be expected that the polymers meeting the suggested the criteria for polymers requiring registration would have a generally much higher incidence of relevant hazard classifications than in those polymers that do not meet the suggested criteria for a polymer requiring registration. It is not currently possible to test this fully within the data currently available although the analysis carried out in Task 1.1 on the DSD data set are suggestive that this is the case.

3.5 Conclusions

The conclusions from the work carried out on Task 1 are summarised in Table 3.15.

Table 3.15 Conclusions from the work carried out on Task 1

Main conclusions
Information on the hazardous properties of polymers is generally not readily available. An analysis of 57 safety data sheets (SDS) found that the SDS are of variable quality and are not always clear as to which constituents the data refer to. Basic information on polymer properties such as molecular weights and water solubility is not always available. Similarly, it is not clear if the CLP classification relates to the polymer itself, constituents or components.
No specific criteria are currently agreed for identification of polymers requiring registration. A number of polymer types that may be requiring registration have been identified. • Cationic polymers; • Anionic polymers; • Amphoteric polymers; • Nonionic polymers with surface-active properties; • Low molecular weight polymers; • Polymers containing low molecular weight oligomers; • Polymers with reactive functional groups; and • Some types of degradable polymers. Suggested criteria have been developed to cover these areas.
Much of the available information relates to organic polymers. There are a number of types of inorganic polymers and the general applicability of the approach to these is currently unclear.
Most current approaches to grouping are based on the following. • Similarity of hazards; and • Similarity of exposure/use.
The estimation of the risks posed by polymers requiring registration in comparison with other chemicals is currently limited in its extent owing to the lack of useable data. The analysis carried out so far suggests that, in terms of numbers and types of classification and labelling, polymers requiring registration may present similar hazards as other chemicals but there are large uncertainties associated with the available data.

Based on the available information, these criteria seem to be the most relevant ones. Registration of PRR will provide more data that could, in the future, help to identify additional criteria or to review/refine the ones proposed.

4. Task 2 – Propose registration requirements for PRRs

4.1 Overview

It is outside the scope of this report to set policy, but it is appropriate to consider the strengths and weaknesses of possible options for registration processes, which could affect policy. That is done in this section.

Some statements of principle follow.

- It is taken throughout that a PRR is considered to be such on the basis of the properties of constituents that contain the repeat units characteristic of a polymeric molecule, and additionally any essential stabilisers.
- Should a polymer possibly meet any of the PRR criteria as defined under Task 1, but there are insufficient data to be sure, then it is necessary to obtain those data.
- It has been set out by the Commission that Registration of all polymers would not be a cost-effective use of resource, and the implications of that is not for discussion here. However, if only the PRRs are registered, then producers need to make a decision about whether PRR criteria are met for their products on the basis of evidence, not supposition. It might be useful for there to be a listing of all polymers produced commercially, but that is not considered here.
- It has been concluded that it is highly desirable for PRR to be treated in a way that is broadly consistent with how non-polymers have been treated under REACH to date. Not all aspects of the registrations need be identical in terms of data requirements or timing of registration; even for non-polymers exact data requirements for a substance are subject to discussion.
- The implementation of polymer registration in terms of schedules is outside the scope of this report. However, the criteria for PRR are relatively untested and therefore regulatory measures which allow a staged process, with time allowed for review of the criteria and submissions, might be prudent. This is discussed below, but a full discussion of that is likely to follow after the completion of this study. Additionally, the work in draft form has been shared with the Commission during the consultation stages, and the probable need for some detailed pilot studies of groups of polymers has been identified by stakeholders. Issues of CBI will need to be taken careful account of; producers will, for example have differences in composition that are important to them and generally not known by competitors.

4.2 Understanding of Task 2 - Assess appropriate registration requirements for PRRs under REACH

The options suggested in the COM (2012) study align strongly with the existing REACH Regulation, and that is a good starting point. There is a need to develop methods, terminology and registration steps in a format that industry in general is well familiar with, and already has experience of. Alongside this, the database of registered REACH substances provides a valuable global resource of chemical information, and any form of registration or chemical safety assessment for polymers should add to that dataset in a consistent way. The criteria proposed in this report are intended to be consistent and proportionate with need, but they need to be tested against data.

However, the available dataset for polymers is much less comprehensive than that for non-polymers and, although sharing of data was a high priority in the consultation, the number of datasets contributed confidentially was small, and insufficient for there to be complete confidence in the workability of proposals. The review of hazard and risk for non-polymers has been made in many ways over many years, and REACH is in part based on that experience. Polymer data sets are less widely-available, and therefore there is planned ongoing consultation with industry even after the completion of this report.

In this report, the options available for Registration are set out, but a preferred approach is identified in each case. The basis of choice is not cost alone, but also the need for information aligned with general REACH principles which are already well-established. In addition, the details of the mechanism of any future Registration requirement is subject to the information gained during the consultation process and to the views and decisions of Member States, ECHA and the Commission.

This section does not make comparisons with regulatory methods used in other jurisdictions, since the purpose is to set out proposals for the EU. Earlier sections of the report provide such information, and ECETOC has provided a very thorough review (ECETOC, 2019).

With the assumption of the development of modified or additional requirements for polymers under the existing REACH regulation, the COM (2012) report foresaw three possible and progressive levels of registration based on the type of polymer:

1. PLCs – exempt / no registration. This seemed to be a realistic proposal given the large number of polymers on the market; REACH does already include criteria for the exemption of substances;
2. Non-PLCs – data requirements matched to REACH Annex VII; and
3. Non-PLCs – data requirements matched to REACH Annex X, for those of most concern, (e.g. carcinogens).

This report is aimed at PRRs, and it cannot be stated that 'non-PLC = PRR', which is also pointed out in ECETOC (2019). The above conclusions from the COM (2012) report are not accepted here, nor reconsidered in detail in this report, since they have very large steps (i.e. differences) in the requirements for data in the three stages described above, which is not justifiable. Fundamentally, it cannot easily be predicted whether a non-PLC should be in group 2 or 3 in advance of doing studies. The recommendations of COM (2012) do not seem to take account of the fact that the amount of data available is low, and it cannot be judged whether Annex X is really necessary for many PRRs; in other words, it cannot be judged in advance what constitutes 'most concern'. A different approach is proposed in this report. Also, not all non-PLCs will require registration. However, the principle of progressive steps is accepted.

In addition, whilst reference to the current REACH Annex requirements is arguably necessary for consistency, it is not likely that all the endpoints listed in the Annexes will be necessary for a PRR in every case and, in some cases, other endpoints not currently listed in the Annexes may be more relevant for PRR.

In this report, it is recognised from Task 1 that there are specific hazards and risks associated with PRRs and the way PRRs should be grouped. This has consequences for the data requirements under registration and any polymer-specific issues that must be handled in a different way to how REACH manages other substances.

Therefore, as part of Task 2, possible registration requirements for PRRs and the possible mechanisms for their implementation are addressed. However, as part of these considerations it is a priority to align the proposed system as closely as possible to current REACH requirements, but without a requirement to collect data of little relevance for some PRRs.

It is noted that, in REACH, Registration is only the first stage, and that the proposals must facilitate Evaluation, based primarily on hazard but also potential for exposure to humans or the environment.

However, polymers are not excluded from the Authorisation or Restriction stages of REACH – this is a further reason to treat polymers and non-polymers in a similar way.

It should be noted that some PRRs may already have been considered under other Regulations. However, as in REACH at present, such substances will need to be assessed due to any non-REACH-exempt uses. Alignment between Regulations is outside the scope of this report.

4.3 Task 2.1 – Adaptation of information requirements for polymers (Evaluate existing registration requirements in REACH against hazard/risk assessment of PRRs)

4.3.1 Introduction

Task 1 has established the basis of what is considered as a PRR. The development of sound regulation now requires proposals for formal regulatory steps to be set out for scrutiny.

The approach for the regulatory content of this report is, as far as reasonably practicable, expected to follow the fundamentals of any new REACH registration for non-polymeric substances. It is not intended to propose a new Regulation, but to deal with polymers as far as reasonably practicable within the REACH Regulation. REACH will need amendments, as will the supporting Guidance, IUCLID, REACH-IT, etc, but the aim is to present options within a model of minimum divergence from it. The reasons for that are:

- Polymers are described in REACH already;
- To make maximum use of the principles already established, which will benefit all stakeholders; and
- To have a 'level playing field' that does not give polymers any undue commercial advantage or disadvantage compared to non-polymers with regard to enforceable regulatory requirements.

However, the data required for certain types of PRR may be considerably reduced compared to non-polymers for strictly scientific reasons, for example bioavailability properties which would make certain studies of no benefit. That is not a new concept – REACH already allows for adaptations for these reasons.

4.3.2 High-level strategy

The report on Task 1 has established the basis of what is considered as a PRR.

COM (2012) considered different data requirements for different types of non-PLCs, but this report <u>does not follow the ideas</u> set out in that document.

With regard to prioritisation, options could include:

1. A tonnage-based system as in REACH at present, covering <u>all</u> PRRs in the same way. This is not considered to be useful, firstly because almost all existing polymers are at high tonnage, and secondly the bioavailability of polymers varies with molecular weight and solubility properties in a marked way and it is not a useful parameter to distinguish which polymers have the potential to pose a higher risk (see point 3).
2. A hazard-based system. This is considered to be of little value for the reasons already explained – data need to be available in order to assess the level of hazard.
3. A system based on physical availability and bioavailability as expressed by molecular weight distribution, or other scientific information. This builds upon the PRR criteria themselves. This could

be seen as a proportionate approach in that uptake by organisms is lower for higher molecular weight.

Therefore, it is proposed here to explore prioritisation of polymers as well as the likelihood of data requirements and derogations thereof according to option 3. The working proposal is to follow the PRR criteria from Task 1 and then to consider the polymers identified as PRR using those criteria in broad *types* based on the dominant number average molecular weight[111]:

- Type 1: < 1000 Da[112]
- Type 2: 1000-10,000 Da
- Type 3: >10,000 Da

For these three types, the testing requirements will also take into account chemical composition issues in addition to molecular weight. The consultation has shown that availability of reliable techniques such as gel permeation chromatography for determination of molecular weight range is sufficient to make this a workable proposal. However, there is inherent variability between laboratories of up to 10% in MW, which will need to be accounted for when guidance is developed.

Matters such as the timing of dossier submission are not considered to be within the scope of this work. However, it should not be assumed that types 2 and 3 possess less hazardous properties than type 1. In view of this and to retain a similar level-playing field amongst polymers and non-polymeric substances, data requirements ought to be in accordance with the tonnage band a substance falls in, as is done in REACH today. Based on the properties of the polymer, an assessment will be made on an initial dataset to determine which data can be generated further (see Section 4.4.10).

The banding of molecular weight will need to be refined[113] in respect of those polymers which span more than one range (and indeed the ranges may need review), and those for which the molecular weight is ‘transient’, i.e. that changes down the supply chain or due to degradation. It is important to note that molecular weight is a simplistic surrogate for bioavailability; additionally, it presupposes that molecules are not physically trapped in the polymer. For example, lower molecular weight constituents could be trapped and unable to diffuse out of a matrix of higher molecular weight constituents, both present in the same polymer. Therefore, experimental evidence of lack of availability could over-ride considerations based solely on molecular weight. Whilst this is not explored further in the report, guidance on this will be needed. ECETOC (2019) also discusses this point.

- Substances of molecular weight below 1000 Da are considered initially, at least in principle, to be potentially bioavailable (Type 1). The proposal is that these require a full data set in alignment with the standard REACH Annexes, subject to provisos described below.
- For Type 2, of intermediate molecular weight, a testing strategy is set out in this chapter.
- For the polymers with high molecular weight (Type 3), bioavailability is believed to be low; however, if the polymer is degradable then a lower molecular weight product could be generated. The basis of assignation of ‘PRR’ would only be on some structural feature, and therefore any studies to be performed initially would be justifiable on the basis of that feature, e.g. cationicity or a reactive functional group.

Before consideration of detailed test requirements, the general REACH registration context needs to be considered.

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[111] Criterion MW1 = Type 1; MW2 criterion would be part of Type 2, and the MW3 criterion would imply Type 3.
[112] This value is also discussed in ECETOC (2019).
[113] Once there are sufficient data available on which to base a judgement.

4.3.3 The REACH process applied to PRR

It is important to state that absence of information about whether PRR criteria are met necessitates finding that information, experimentally or with the use of QSAR, read-across and grouping if necessary. For many substances, consideration and knowledge of composition alone will be sufficient to rule out the need for registration. Sections 4.4.10 and 4.4.11 also offer some guidance on how this assessment can be achieved for polymers where molecular weight and composition do not conclusively indicate whether a substance may be considered a PRR or not, and limited data are available.

The development of sound regulation now requires proposals for formal regulatory steps to be set out.

The fundamentals of REACH registration are, for substances in general:

1. A process to identify the substance; the exact details for PRR are discussed further below
2. Establishment of co-registrants managing a joint submission, if required
3. Sharing of relevant data
4. Development of a data set at the required Annex level (though there are proposed adaptations for PRRs)
5. Collection of use information and then performance of chemical safety assessment in accordance with the existing methods (though there may be adaptations for PRRs)
6. Registration according to the general principle of one substance-one-registration which REACH has set out
7. Hazard assessment, risk characterisation – including exposure assessment, management and communication of safe use

This sequence is broadly applicable to polymers, with provisos, and to non-polymeric substances. There is a possible difference between polymers and non-polymeric substances: polymer groups are likely to play a particularly important role when deciding whether substances are similar enough to be registered as one group of substances. Therefore, the stage where co-registrants come together to manage a joint submission covers also the formation of groups of polymers with potential for registration. These groups may be further split, based on the process illustrated in Figure 4.1.

The details of any substance sameness and identity processes are outside of the scope of this report and would be further developed by the European Commission, Member States and ECHA in any amendments to REACH, other implementing legislation or guidance[114]. However, technical details relating to the data that may be useful to gather at this initial stage of the registration are discussed in the report. Furthermore, the exact timeline for the implementation of PRR registration requirements is not required to be established here.

In the following paragraphs, discussion of how the seven steps of REACH registration summarised above may be adapted for polymers is given. Task 2.2 and 2.3 give some specific details.

4.3.4 Polymer identity and sameness

It is recognised that the establishment of sameness and groups will be very demanding, given the following observations:

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[114] It should be noted that the USEPA has written guidance on polymer identity (USEPA, 1997).

- Many existing CAS and EC numbers may not be fit for the purpose of a registration process, because they may not uniquely identify a polymer substance, although any such numbers which are useful should be retained;
- Many polymers do not have CAS numbers; and
- There is no long history of polymer assessment (whether voluntary or mandatory) from which to draw on, when proposing methodologies.

It is important to have clear inclusion and exclusion criteria, as described under Task 1, in order to avoid the registration of 70,000 – 400,000 polymers (the exact number is not known, this figure is Taken from COM (2012) and supported during the Workshop, see Task 3), most of which would not be PRR. Potential registrants would need detailed guidance about whether they could meet PRR criteria. After that, inquiry-like processes, similar to those performed already for non-polymeric substances under REACH, are considered to be a familiar and sensible first step toward the establishment of groups of co-registrants for PRR. It is possible that producers and importers should be asked to retain or submit their assessment of polymers considered to not be a PRR for transparency.

The administration of many PRRs coming under REACH will require careful planning because of the amount of data to be shared and discussed, and availability of resources.

Therefore, the data that need to be gathered to aid the formation of groups of co-registrants are proposed to be the following:

Descriptor	Comment
Any formal descriptor of the polymer	Name, CAS and EC Number if appropriate.[1]
Registrant	Manufacturer/Importer
Desire to be a Lead Registrant?	Yes/No question
Type of polymer	Synthetic polymer, or a natural polymer that has been chemically modified.
Nature of the polymer	Organic/inorganic, natural where not exempt, post-reacted, homopolymer/co-polymer, etc.
Identification and proportions of the starting materials, and manufacturing methods	To include: monomers, cross-linking agents, end blockers, stabiliser and others chemically bound to the polymer. This can be developed from current guidance on UVCBs.
Elemental composition of the polymer	The percentage of elemental present.
Molecular formula for each of the repeat units, cross-linking agent and end blocker present	Non-polymeric components such as pigments, plasticisers and fillers do not need to be stated as these are already covered under REACH.
Repeat units present	The repeat units and their sequence, if more than one, define a polymer. Identification and quantification of each constituent with defined repeating units. It could probably be aligned with current SID requirements for UVCB substances.

Descriptor	Comment
Physical form of the polymer (usually at RTP rather than use temperature)	For example, solid/liquid, particle sizing/granulometry of solids. Viscosity could be useful. This is critical given that polymers of similar composition could have different physical form and therefore of different hazard profile. Therefore, even for the same molecular description, different PRR status (including not being PRR) is possible for different sources of the polymer.

[1] It is understood that there may be very few suitable EC and CAS numbers for polymers, or these may be too broad in scope to be useful. It is probably necessary, and simpler, to assign EC Numbers after the inquiry stage.

[2] For the purposes of the Chemical Abstracts Registry file, broad polymer class types have been listed (American Chemical Society, 1995).

Based on these descriptors, criteria for polymer sameness and grouping approaches for registration need to be established. It is understood that these endpoints or parts of them can be considered as CBI. During the workshop it was indicated that data sharing is typically managed by Sector Groups or Industry Associations. A mechanism for data sharing respecting CBI under REACH for polymers may require additional considerations beyond typical current practice for non-polymers.

4.3.5 Establishment of groups of co-registrants and other fora for sharing information

It is assumed that groups of co-registrants would be formed to enable one registration per substance or registration group, taking into consideration the variable nature of polymers and changes that can occur down the supply chain.

The groups of co-registrants could be formed by two different procedures.

1. Companies which know that they manufacture or import the same polymer based on composition or market use could form groups of co-registrants. This could be facilitated by official guidance on sameness of polymers.
2. In certain cases, co-registrant groups based on specific hazard as expressed by compositional or physical data alone might be useful. For example, this could include different mainly non-bioavailable polymers but which could contain the same constituents or functionalities which possess a particular hazard. For some polymers, there will be only one application area, which could also be a way to establish the identity of co-registrants.

ECHA could, after receiving the SID information as given above, require the formation of groups of co-registrants in accordance with the REACH Inquiry procedures and the principle of one registration per substance. The information present in the IT system would be useful to identify groups of co-registrants. Also, groups of closely-related polymers could be registered together if the hazard properties are the same.

At this stage, the group of co-registrants should agree upon the following:

- Whether closely related group members could be registered together (following criteria for polymer sameness, discussed below);
- The Lead Registrant;
- The name of the substance under ECHA guidance; and
- A name (description of the substance) that would include certain criteria (e.g. molecular weight range, solubility, biodegradability, >1% w/w below 1000 Da, etc).

After the formation of the group of co-registrants, ECHA could provide new EC Numbers to identify the substance, if necessary. Change from previous numbers, although undesirable, could be necessary.

Consultees did not wish to abandon all existing registration numbers. Some classes have useful CAS or EC numbers (but many do not).

It is relevant to note that there is a large difference between polymers and non-polymers in respect of widely-available data and experience. In the development of chemical regulations around the world over many years, data submission processes into IUCLID in 2000, and the OECD/ICCA HPV process, much knowledge of the non-polymers has been disseminated. The data have been subject to in-depth analysis all this time. No such overview is available for polymers requiring registration. Therefore, every effort should be made to encourage the sharing of data, subject to the principles of compensation to data owners and minimisation of animal testing.

4.3.6 Polymer sameness and grouping of polymers in relation to registration requirements

The starting point is the existing REACH registration requirements. Based on this, further specific requirements necessary for PRRs are developed. The following will need to be considered, and also other needs in the preceding analysis for Task 1, Task 2.1 and Task 2.2.

- Information on production and use e.g.:
    - Manufacturing method; and
    - Use pattern and known end use;
- Information on identity of the substance specific to polymers:
    - Number average molecular weight;
    - Molecular weight distribution;
    - Identity and concentration of starting monomers and other substances which become bound into the polymer;
    - Identity and content of any hazardous non-reacted monomers (and other substances); and
    - Identity of reactive functional groups.
- Physicochemical properties including physical form and characteristics such as glass transition temperature;
- Degradation data;
- Toxicological data; and
- Ecotoxicological data.

It is essential to note here that sameness is not just a question of composition or structure. Experience with UVCBs has shown that differences in properties between two substances can be exhibited even when composition appears on first examination to be very similar; if the properties are different then the composition or physical bioavailability must be different, even if it may not be obvious why.

The approach to polymer sameness will need to be developed further, probably through guidance development.

4.3.7 Process of sharing of relevant polymer data

Companies that have identified their substance as being a PRR, that possess data on the substance, and for which other registrants have been identified, will need to share the property data available on their substance in order to carry out the shared chemical safety assessment.

Confidential Business Information (CBI) and compensation for use of data will need to be managed. The approaches developed under REACH so far will be applicable to polymers. These include Non-Disclosure Agreements, Letters of Access, removal of CBI data from reports and use of third parties.

The existing Implementing Regulation (EU) 2016/9[115] and Guidance on data-sharing (ECHA 2017) will also apply to polymers.

4.3.8 Development of a data set at the required Annex level

This is discussed extensively in sections following.

4.3.9 Performance of chemical safety assessment

Chemical safety assessment (CSA) involves first the identification of hazard and then exposure must be assessed quantitatively or qualitatively. Thereafter risk may need to be characterised quantitatively. Polymers requiring registration may not all possess hazard. However, existing approaches should be applicable in broad terms.

4.3.10 Registration of polymers

Each registrant will need to submit an IUCLID dossier, which provides information relevant to the registrant's legal entity only, e.g. legal entity name and contact details, legal entity composition, and an assessment of how their substance meets the PRR criteria. It is subject to further consideration by the Commission and others as to whether companies whose polymers do not meet any of the PRR criteria as set out in Task 1.2 will need to provide their assessment to the authorities, and if this is the case, how it will be provided and evaluated.

A joint submission part of the dossier submitted by the Lead Registrant is also envisaged for polymers (as is the case for non-polymer substances in REACH as it currently stands) containing information on the substance that covers the whole SIEF-type group of registrants, e.g. boundary composition, classification and labelling, properties data, PBT assessment, shared CSR, etc. The IT-methods will need development, almost certainly including amendments to IUCLID, and, as already mentioned elsewhere in the report, guidance specific to polymers will be required to steer the registration process, data requirements or derogations thereof.

For the first steps following PRR identification, Figure 4.1 proposes an indicative overall scheme, which sets the context for discussion of sameness of polymeric substances. The diagram attempts to show the considerations a potential registrant needs to go through, once it has been established that their substance meets the definitive criteria to become a PRR. Just as in REACH to date, it is very important to establish that joint registrations are valid in respect of composition, hazard, and thereby, risk. The "Stages" (described below) are those where compositional/sameness issues may apply.

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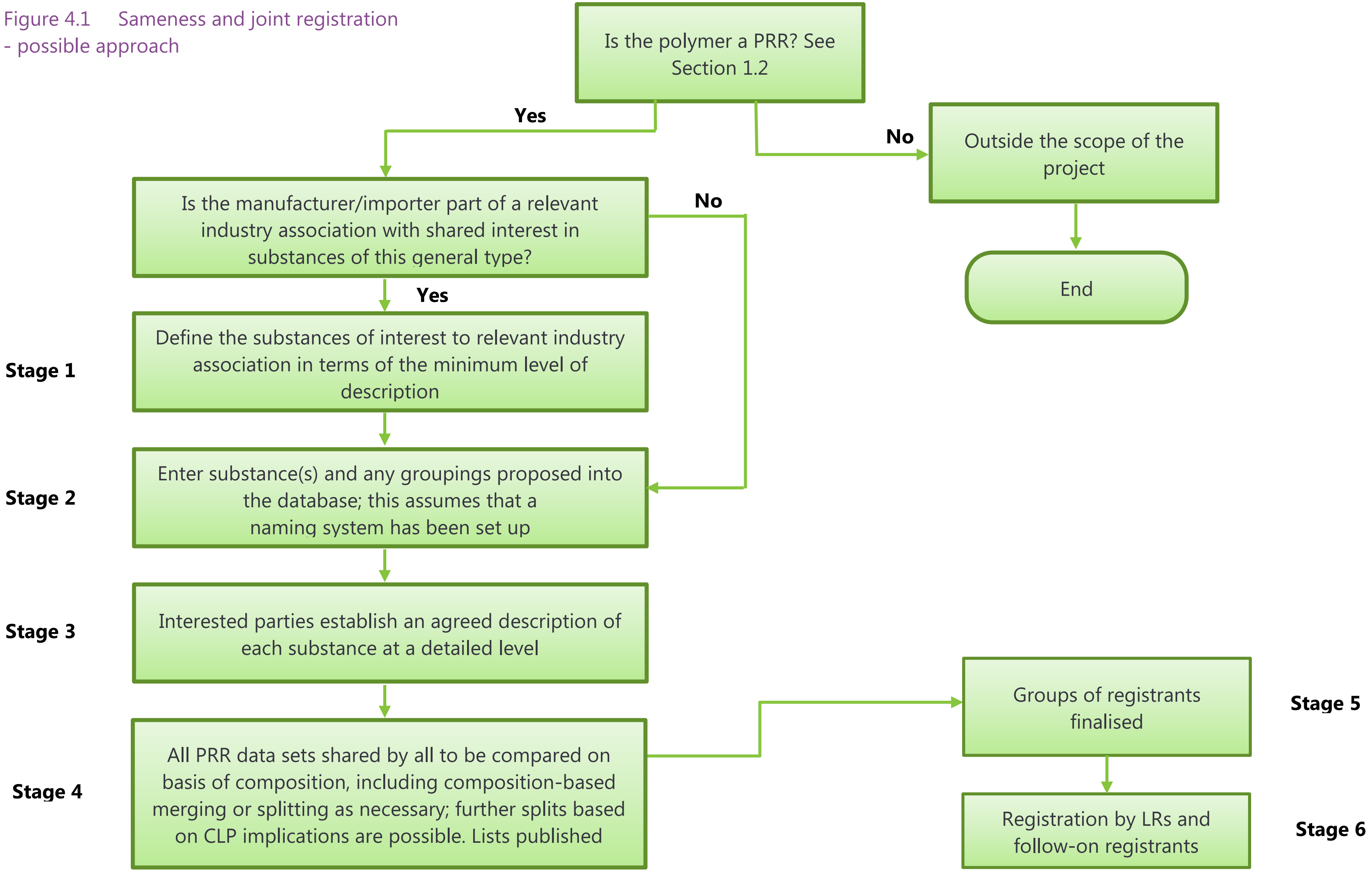
[115] Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing in REACH https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0009

Figure 4.1 Sameness and joint registration - possible approach



- Stage 1 requires a partial description of the substance (see Table on Minimum Level below).
- Stage 2 requires there to be a database set up by ECHA, presumably following the development of guidance on naming.
- Stage 3 is the start of a co-registrants' process of discussion.
- Stage 4: Discussion of properties implies that each data holder can describe adequately the substance for which data are available.
- Stage 5 implies that a suitable substance identification profile is written for the joint submission.

The stages are aimed to help potential registrants come together prior to registration taking place. They also aim to address the issue of confidential business information (CBI), which is also a problem for many non-polymer substances under REACH at present. At some later date, an Inquiry process[116] could be used.

Therefore, the data that need to be gathered to allow the identification of PRR and to aid the formation of joint submissions is presented in Table 5.1 for the early discussions in Stages 1 to 4, i.e. sufficient information to establish whether potential registrants have a shared interest. It is likely that the type and level of information needed for this stage will be determined at a later stage within industry associations and EU authorities and will be dependent on the type of polymer. A dialogue between the Commission and ECHA will be needed to establish suitable grouping and hazard profiles.

Table 4.1 Minimum level of data to allow identification and formation of joint submissions

Descriptor	Comment
Names in IUPAC nomenclature[117] or other international chemical name(s)	IUPAC nomenclature is possible for homopolymers, but is more complex for copolymers and blends
Numbers where available	CAS and EC Number if appropriate.[1 Note]
Registrant	Manufacturer/Importer
Type of polymer	Synthetic polymer, or a natural polymer that has been chemically modified
Nature of the polymer	Organic/inorganic, natural where not exempt, post-reacted, homopolymer/co-polymer, etc.
Manufacturing description	Currently required for UVCBs only under REACH. CBI will need to be respected.
Identification and proportions of the starting materials	To include: monomers, cross-linking agents, end blockers, stabiliser and other reactants chemically bound to the polymer.
Elemental composition of the polymer	The percentage of elements present at for example >0.1%
Repeat units present	The repeat units and their sequence, if more than one, define a polymer. Identification and quantification of each constituent with defined repeating units. It could probably be aligned with current SID requirements for UVCB substances.

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[116] Inquiry-like processes, similar to those performed already for non-polymeric substances under REACH, are considered to be a familiar and sensible first step toward the establishment of SIEF-like consortia for PRR.
[117] IUPAC nomenclature for polymers may not be applicable for the full needs of REACH. It is described in Hiorns et al, (2012).

Descriptor	Comment
Molecular weight or molecular weight range	
Molecular formula and molecular weight for each of the CRUs, cross-linking agent and end blocker present	Additives such as pigments, plasticisers and fillers do not need to be stated as these are already covered under REACH
Functional group % concentration	Not routinely measured by some polymer producers but it is for reactive resins and monomers used for example in thermosets.
Physical form of the polymer	For example, solid/liquid, particle sizing/granulometry of solids. Viscosity could be useful. This is critical given that polymers of similar composition could have different physical form and therefore of different hazard profile. Therefore, even for the same molecular description, different status (including not being a polymer requiring registration) is possible for different sources of the polymer.

[1] It is understood that there may be very few suitable EC and CAS numbers for polymers, or these may be too broad in scope to be useful. It is probably necessary, and simpler, to assign EC Numbers after the inquiry stage.

Note that the work has been severely limited by the lack of data sets on which to test the principles.

For Stages 5 and 6 further information would be needed at a more detailed level for a representative sample. The purpose of a second phase is to avoid an excessive analytical burden on all registrants. It is likely that the type and level of information needed for this stage will be determined within industry associations and EU authorities and will be dependent on the type of polymer. Table 5.2 shows the data that could be required for these stages.

Table 4.2 Further information to allow identification and formation of joint submissions

Properties	Notes
Number average and weight average molecular weight	-
GPC data (or equivalent) and molecular weight distribution (MWD)	This is particularly important. The standard DIN 55672 is the most modern source for regulatory standard measurements. However, some classes of polymer such as those with high charge density can be difficult to analyse.
Distribution of repeat units or groups of repeat units	Representation of this may be difficult.
Degree of crosslinking	This will be affected by the curing and post-cure regime in thermosets and elastomers. Can be considered in terms of glass transition temperature or similar.
Polydispersity	Not all polymer manufacturers measure MWD or polydispersity.
Constituents of note	Discussion about which constituents are relevant to PRR decision.
Nature and order of magnitude of any additives	-
Spectral data (UV, IR, Raman, NMR or MS)	-
High pressure liquid chromatogram, gas chromatogram	Unlikely to be necessary in every case.

Properties	Notes
Description of analytical methods	-
Identity of nonreacted monomers	May be relevant if the monomer cannot be removed.
Weight percentage of non-reacted monomers	This will be dependent on the degree of reaction and, for thermosets, the cure regime.

In order for grouping for registration purposes to work in practice, the grouping approach must be comprehensive but not duplicative. All substances must be part of a group, but criteria must be narrow enough to avoid the possibility of double grouping. The information required in Tables 4.1 and 4.2 supports this principle.

In the development of guidance, it will be important to establish the principles behind grouping, for registration purposes, of polymers that are subject to transformation down the supply chain.

4.4 Task 2.2– Propose specific requirements necessary for PRRs

4.4.1 Introduction and overview

The existing registration requirements in REACH are considered with the hazard/risk assessment needs for PRRs and this is used as the basis for adaptation (if necessary) of the information requirements for polymers. This consideration takes into account the following aspects.

- Availability of test methods;
- Limitations on what can be meaningfully tested:
  - E.g. solubility cut-off for ecotoxicity, biodegradation and bioavailability[118]; and
  - Relevant existing adaptation criteria.
- Many polymers could be considered as similar to UVCBs, which poses substance identity issues for registration.

Two fundamental aspects of the development of data sets are fully exemplified:

- Endpoints that cannot be met experimentally in a scientifically meaningful way should be waived or met by validated prediction, e.g. solubility in water for constituents likely to be of immeasurably low solubility; and
- The testing of vertebrates should be minimised.

This section sets out the (possible) approach to registration requirements included in REACH in the context of polymers, and is based on the principles developed in Task 1. It is useful at this point to set out some principles of how to approach the REACH Annexes to PRRs.

In all cases, the necessity and relevance of this information is justified and, where appropriate, its use for the assessment of the risks of PRRs is explained. The specific requirements must also consider the following:

- Test methods that may be suitable for generating the necessary information.

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[118] For the sake of brevity, in this Task, lack of bioavailability is taken to refer to molecules which may not penetrate into cells due to molecular size. That does not exclude the possibility of effects due to adsorption e.g. of cationics, or over other surface-mediated effects caused by specific functional groups.

- Data (but not registration) exemptions or specific adaptations that may apply, for example based on low water solubility, high number average molecular weight, physical form, etc..
- The need for vertebrate testing should take into account the potential benefit of the study: is there a good chance that valuable information will be obtained, i.e. useful data concerning hazard? If not, the study should not be done (a principle that also applies to non-polymers). There may be some benefit in testing a material not on the market if it can produce useful data for many regulatory purposes.

The specific requirements of other jurisdictions are not listed here given the differences from any probable implementation method in REACH.

4.4.2 Performance of polymer chemical safety assessment

The basic principles of current safety assessment for non-polymers can be followed for PRRs, although some additional guidance may be needed. The principles that underpin the assessment of multi-constituent substances and UVCBs may be applicable to PRRs.

The chemical safety assessment should therefore align with the existing REACH chemical safety assessment requirements and should include: a review and assessment of the hazard properties according to the relevant Annex requirements (see Data requirements tables below) and an assessment of the life-cycle of the polymer (see Data requirements concerning uses and exposure further below). The assessment should also contain a PBT assessment and derivation of the classification and labelling according to the CLP, Regulation (EC) No 1272/2008[119].

In certain cases, an assessment of the endocrine disrupting properties of polymers may also be required.

The following tables have been developed from COM (2012) and are based on the REACH Annex data requirements. The table indicates data requirements for polymers, and does **not** indicate whether the endpoints would be applicable specifically to polymers requiring registration or to all polymers.

It is possible that standard test guidelines will require adaptation or modification in order to obtain results with different classes and groups of polymers.

In the tables, requirements do refer to tonnage band, so as to be consistent with REACH for non-polymers.

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[119] Classification, labelling and packaging of substances and mixtures (CLP Regulation, EC No 1272/2008).

4.4.3 Data requirements concerning identity of PRRs

Table 4.3 Table of identity data requirements for polymers requiring registration

Properties	Annex[1] (Tonnage Threshold)	Relevant to Polymers[2]	Notes
Name or other identifier of each substance	VII (≥1tpa)	Y	-
Names in IUPAC nomenclature[Note 3] or other international chemical name(s)	VII (≥1tpa)	C	IUPAC nomenclature is possible for homopolymers but is more complex for copolymers and blends.
Other names (usual name, trade name, abbreviation)	VII (≥1tpa)	Y	-
EINECS or ELINCS number	VII (≥1tpa)	C	Will be available in a minimal number of cases.
CAS name and CAS number	VII (≥1tpa)	C	Unlikely to be useful in some cases.
Other identity code	VII (≥1tpa)	Y	-
Molecular and structural formula (including SMILES notation)	VII (≥1tpa)	C	This may be complex for copolymers and blends.
Molecular weight or molecular weight range	VII (≥1tpa)	Y	-
Number average and weight average molecular weight	P (≥1tpa)	Y	-
GPC data (or equivalent) and molecular weight distribution (MWD)	P (≥1tpa)	Y	
Identity of repeat units	P (≥1tpa)	Y	-
Proportion of different repeat units	P (≥1tpa)	Y	-
Distribution of repeat units or groups of repeat units	P (≥1tpa)	C	Representation of this may be difficult.
Chain length mean and distribution	P (≥1tpa)	C	Network and cross-linked polymers may be too complex for this parameter.
Degree of crosslinking	P (≥1tpa)	C	This will be affected by the curing and post-cure regime in thermosets and elastomers Can be considered in terms of glass transition temperature or similar.
Functional group molar concentration	P (≥1tpa)	Y	Not routinely measured by some polymer producers but it is for reactive resins and monomers used for example in thermosets.
Availability of monomeric functional groups for further chemical reaction or interaction with surrounding media	P (≥1tpa)	C	This will be affected by the degree of reaction and the need in some polymers for residual monomer to confer certain properties or performance.

Properties	**Annex[1] (Tonnage Threshold)**	**Relevant to Polymers[2]**	**Notes**
Polydispersity	P (≥1tpa)	Y	Not all polymer manufacturers measure MWD or polydispersity
Degree of purity (w/w %)	VII (≥1tpa)	C	Not all polymer manufacturers measure purity routinely.
Nature of impurities, including by-products	VII (≥1tpa)	Y	-
Weight percentage of main impurities	VII (≥1tpa)	Y	-
Nature and order of magnitude of any additives	VII (≥1tpa)	Y	-
Spectral data (UV, IR, Raman, NMR or MS)	VII (≥1tpa)	Y	
High pressure liquid chromatogram, gas chromatogram	VII (≥1tpa)	C	Unlikely to be necessary.
Description of analytical methods	VII (≥1tpa)	Y	-
Identity of nonreacted monomers	P (≥1tpa)	Y	Useful but not relevant to PRR identification.
Weight percentage of non-reacted monomers	P (≥1tpa)	C	This will be dependent on the degree of reaction and for thermosets the cure regime.
Manufacturing description	VII (≥1tpa)	Y	Currently required for UVCBs only under REACH.

[1] Relevant REACH Annex number or "P" to indicate a polymer specific requirement.

[2] Relevance of property to polymers: "Y" = Yes, "N" = No, and "C" = Certain polymers only, determined by COM (2012) and the current study team.

[3] IUPAC nomenclature for polymers may not be applicable for the full needs of REACH. See Baron et al (2009) for a description of class names, structure and molecular architecture. (IUPAC, 2009), and Jones et al (2008) for a naming guide.

4.4.4 Maximum data requirements for Type 1

This section sets out requirements that would apply where a full data set was considered necessary. That applies initially to the lowest molecular weight substances, referred to as 'Type 1' above (see page 9). It could apply to higher molecular weight polymers (Type 2 and Type 3) if their initial assessment showed that more data was needed. Polymers may need adapted methods of measurement to be used.

4.4.5 Data requirements concerning physicochemical properties

Table 4.4 Table of physicochemical property data requirements for polymers

Properties	Annex[1] (Tonnage Threshold)	Relevant to Polymers[2]	Notes
Cure regime	P (≥1tpa)	Y	This information should be given as it will affect a number of the properties reported.
Physical form	VII (1-10tpa)	Y	-
Melting/freezing point	VII (1-10tpa)	C	Values below normal environmental temperatures would be of little use.
Boiling point	VII (1-10tpa)	C	Consider omitting.
Decomposition temperature	P (≥1tpa)	Y	Assumed same cost as other temperature/state transition tests.
Relative density	VII (1-10tpa)	Y	-
Vapour pressure	VII (1-10tpa)	C	Molecular weight could suggest that no measurement is necessary. An estimate for any PRR constituents could be useful.
Surface tension of an aqueous solution	VII (1-10tpa)	C	Consider whether testing is necessary.
Solubility (water, solvents, oils)	VII (1-10tpa)	Y	Solubility in water should be provided and estimates could be sufficient in some cases; see also discussion under Type 2. Should include discussion of ionisation and / or surfactancy, including measurements where beneficial.
Partition coefficient	VII (1-10tpa)	Y	Unlikely to be useful in many cases; should not be attempted for surfactants.
Water extractivity	P (≥1tpa)	Y	Based on NONS requirements (see comment on long term extractivity).
Flash-point	VII (1-10tpa)	C	Consider omitting.
Flammability	VII (1-10tpa)	C	Following usual adaptation rules, consider whether testing is necessary.
Explosive properties	VII (1-10tpa)	C	Use prediction initially.
Self-ignition temperature	VII (1-10tpa)	C	Consider omitting.
Oxidising properties	VII (1-10tpa)	C	Use prediction initially.
Granulometry/morphology (solids only)	VII (1-10tpa)	Y	-
Stability in organic solvents and identity of relevant degradation products	IX (100-1000tpa)	Y	-

Properties	Annex[1] (Tonnage Threshold)	Relevant to Polymers[2]	Notes
Dissociation constant	IX (100-1000tpa)	C	Important
Viscosity	IX (100-1000tpa)	C	-

[1] Relevant REACH Annex number or "P" to indicate a polymer specific requirement.
[2] Relevance of property to polymers: "Y" = Yes, "N" = No, and "C" = Certain polymers only; to be determined by expert judgement, as for non-polymers.

4.4.6 Data requirements concerning environmental fate and behaviour

Table 4.5 Table of environmental fate property data requirements for polymers

Properties	Annex[1] (Tonnage Threshold)	Relevant to Polymers[2]	Notes
Degradation (ready biodegradation)	VII (1-10tpa)	Y	This parameter will only be relevant to the bioavailable lower MW polymers and oligomers.
Fate and behaviour in the environment (adsorption/desorption screening)	VIII (10-100tpa)	Y	This parameter will only be relevant to the lower MW polymers and oligomers.
Degradation (abiotic hydrolysis as function of pH)	VIII (10-100tpa)	C	Unlikely to be scientifically achievable in many cases, but existing guideline derogations are sufficient.
Degradation (further abiotic testing if need identified by CSA)	VIII (10-100tpa)	Y	Current approaches in REACH to assess need are adequate.
Degradation (biotic simulation – ultimate degradation in surface water)	IX (100-1000tpa)	Y	Current approaches in REACH to assess need are adequate.
Degradation (biotic soil simulation testing (for substances with a high potential for adsorption to soil)	IX (100-1000tpa)	Y	Current approaches in REACH to assess need are adequate.
Degradation (biotic sediment simulation testing (for substances with a high potential for adsorption to sediment)	IX (100-1000tpa)	Y	Current approaches in REACH to assess need are adequate.
Degradation (biotic identification of degradation products)	IX (100-1000tpa)	Y	Current approaches in REACH to assess need are adequate.
Degradation (further biotic testing if need identified by CSA)	IX (100-1000tpa)	Y	Current approaches in REACH to assess need are adequate.

Properties	**Annex[1] (Tonnage Threshold)**	**Relevant to Polymers[2]**	**Notes**
Fate and behaviour in the environment (bioaccumulation in aquatic species, preferably fish)	IX (100-1000tpa)	Y	This parameter will only be relevant to the lower MW polymers and oligomers. May be very difficult to achieve experimentally; not applicable to surfactants.
Fate and behaviour in the environment (further adsorption/desorption if warranted from screening under Annex VIII)	IX (100-1000tpa)	Y	Current approaches in REACH to assess need are adequate.
Fate and behaviour in the environment (further environmental fate and behaviour of substance or degradation products if need identified by CSA)	X (≥1000tpa)	Y	Current approaches in REACH to assess need are adequate.

[1] Relevant REACH Annex number or “P” to indicate a polymer specific requirement.
[2] Relevance of property to polymers: “Y” = Yes, “N” = No, and “C” = Certain polymers only; to be determined by expert judgement, as for non-polymers.

4.4.7 Data requirements concerning mammalian toxicology

Arguments regarding potential for absorption are particularly important in order to avoid performance of studies that would give no useful information. A discussion of toxicokinetics is a key part of that consideration.

Table 4.6 Table of toxicological property data requirements for polymers

Properties	**Annex[1] (Tonnage Threshold)**	**Relevant to Polymers[2]**	**Notes**
Skin irritation or skin corrosion (*in vitro*)	VII (1-10tpa)	Y	-
Eye irritation (*in vitro*)	VII (1-10tpa)	Y	-
Skin sensitisation (*in vitro/in chimico*)	VII (1-10tpa)	Y	From R7a (ECHA 2016) guidance: Contact allergens are reactive substances (usually organic substances or metal ions) of low molecular weight (<500-1000 Da) and have a lipophilicity that favours dermal penetration.
Mutagenicity (*in vitro* gene mutation in bacteria)	VII (1-10tpa)	Y	-
Acute toxicity (oral)	VII (1-10tpa)	Y	-
Mutagenicity (*in vitro* cytogenicity study in mammalian cells or in vitro micronucleus study)	VIII (10-100tpa)	Y	-

Properties	Annex[1] (Tonnage Threshold)	Relevant to Polymers[2]	Notes
Mutagenicity (*in vitro* gene mutation study in mammalian cells, if other tests negative)	VIII (10-100tpa)	Y	-
Acute toxicity (inhalation OR dermal)	VIII (10-100tpa)	C	Inhalation is unlikely to be applicable for many polymers unless as a respirable dust.
Repeated dose toxicity (*in vivo* short-term (28 days))	VIII (10-100tpa)	Y	See note above the table.
Reproductive toxicity (*in vivo* screening (OECD 421 or 422))	VIII (10-100tpa)	Y	See note above the table.
Toxicokinetics (assessment of available information)	VIII (10-100tpa)	Y	
Repeated dose toxicity (*in vivo* sub-chronic (90 days)	IX (100-1000tpa)	Y	See note above the table.
Reproductive toxicity (prenatal developmental toxicity) in one species	IX (100-1000tpa)	Y	See note above the table.
Reproductive toxicity (Extended 1 generation reproductive, with exceptions)	X (≥1000tpa)	Y	See note above the table.
Reproductive toxicity (prenatal developmental toxicity) in a second species	X (≥1000tpa)	Y	See note above the table.
Mutagenicity (*in vitro* somatic cell study if positive genotoxicity study)	X (≥1000tpa)	Y	-
Repeated dose toxicity (*in vivo* sub-chronic (≥ 12 months), if justified from other studies)	X (≥1000tpa)	Y	See note above the table.
Carcinogenicity study	X (≥1000tpa)	Y	See note above the table.

[1] Relevant REACH Annex number or "P" to indicate a polymer specific requirement.
[2] Relevance of property to polymers: "Y" = Yes, "N" = No, and "C" = Certain polymers only; to be determined by expert judgement, as for non-polymers.

4.4.8 Data requirements concerning ecotoxicology

Table 4.7 Table of ecotoxicological property data requirements for polymers

Properties	Annex[1] (Tonnage Threshold)	Relevant to Polymers[2]	Notes
Aquatic toxicity (*in vivo* short-term invertebrate)	VII (1-10tpa)	C	This parameter will only be relevant to substances with sufficient solubility.
Aquatic toxicity (*in vivo* short-term fish)	VIII (10-100tpa)	C	This parameter will only be relevant to substances with sufficient solubility.
Aquatic toxicity (Activated sludge respiration inhibition testing)	VIII (10-100tpa)	Y	-
Aquatic toxicity (long-term invertebrate)	IX (100-1000tpa)	Y	Current approaches in REACH to assess need are adequate, i.e. solubility in water, organic matter, and adsorption properties.
Aquatic toxicity (*in vivo* long-term fish)	IX (100-1000tpa)	Y	Current approaches in REACH to assess need are adequate, i.e. solubility in water, organic matter, and adsorption properties.
Aquatic toxicity (*in vivo* fish early-life stage (FELS) toxicity test)	IX (100-1000tpa)	Y	Current approaches in REACH to assess need are adequate, i.e. solubility in water, organic matter, and adsorption properties.
Aquatic toxicity (*in vivo* fish short-term toxicity test on embryo and sac-fry stages)	IX (100-1000tpa)	Y	Current approaches in REACH to assess need are adequate, i.e. solubility in water, organic matter, and adsorption properties.
Aquatic toxicity (*in vivo* fish juvenile growth test)	IX (100-1000tpa)	Y	Current approaches in REACH to assess need are adequate, i.e. solubility in water, organic matter, and adsorption properties.
Effects on terrestrial organisms (short-term toxicity on invertebrates)	IX (100-1000tpa)	Y	Current approaches in REACH to assess need are adequate, i.e. solubility in water, organic matter, and adsorption properties.
Effects on terrestrial organisms (effects on soil micro-organisms)	IX (100-1000tpa)	Y	Current approaches in REACH to assess need are adequate, i.e. solubility in water, organic matter, and adsorption properties.
Effects on terrestrial organisms (short-term toxicity on plants)	IX (100-1000tpa)	Y	Current approaches in REACH to assess need are adequate, i.e. solubility in water, organic matter, and adsorption properties.
Effects on terrestrial organisms (long-term toxicity on plants)	X (≥1000tpa)	Y	Current approaches in REACH to assess need are adequate, i.e. solubility in water, organic matter, and adsorption properties.

Properties	Annex[1] (Tonnage Threshold)	Relevant to Polymers[2]	Notes
Effects on terrestrial organisms (long-term toxicity on invertebrates)	X (≥1000tpa)	Y	Current approaches in REACH to assess need are adequate, i.e. solubility in water, organic matter, and adsorption properties.
Long-term toxicity to sediment organisms (long term toxicity on sediment organisms)	X (≥1000tpa)	Y	Current approaches in REACH to assess need are adequate, i.e. solubility in water, organic matter, and adsorption properties.
Long-term or reproductive toxicity to birds	X (≥1000tpa)	Y	Current approaches in REACH to assess need are adequate, i.e. solubility in water, organic matter, and adsorption properties.

[1] Relevant REACH Annex number or "P" to indicate a polymer specific requirement.

[2] Relevance of property to polymers: "Y" = Yes, "N" = No, and "C" = Certain polymers only; to be determined by expert judgement, as for non-polymers.

4.4.9 Data requirements concerning uses and exposure

Assessment of exposure will apply to PRRs only where a hazard is present. A substance identified as PRR should be registered with all the information concerning the whole use pattern and life cycle that apply in REACH in the relevant Annex.

A key issue that will require attention is that during the life cycle of a polymer there is potential for it to change its physical form (ECETOC, 2019)

Some of the considerations in this section also apply to non-polymers, but attention is drawn to the issues here without making inferences for non-polymers.

During the consultation process some participants indicated that the present REACH system for description of exposure may need adaptation, and it may be necessary to conduct some research before the system of registration is finalised. This view is also stated by ECETOC (2019).

Where assessment of exposure is necessary (due to hazard) the methods used in REACH for non-polymers are relevant, although there will be some limitations.

To make the requirements proportionate to need, it is considered that only the constituents[120] which possess a hazard need to have exposure assessment performed. That is no different to the approach that can be applied for multi-constituent or UVCB substances, where there are many examples of substances with some constituents possessing hazard and other constituents not. The potential for exposure to only a fraction of constituents can also be seen for certain non-polymers, although this may require some adaptation compared to non-polymeric substances. The fraction of the hazardous constituent in a non-hazardous matrix (i.e. the remainder of the substance) will need to be known.

All the exposure endpoints assessed under REACH, as fully described in existing guidance, must be assessed, i.e. environment, health and physicochemical hazards in their entirety.

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[120] As indicated under Task 1.1: ECHA (2017) defines as "constituent" any single species present in a substance that can be characterised by its unique chemical identity. For this report a polymer constituent means any constituent which falls within the REACH definition of a polymer. For the purpose of risk assessment, polymeric constituents may need to be further divided according to MW ranges and bioavailability in relation to hazard potential as is done for UVCBs and multiconstituent substances.

It should be recognised that some constituents of polymers, although hazardous, can in many (but not all) cases have relatively extreme properties, such as:

- Very low water solubility;
- Very high partition coefficients;
- Very high adsorption to solids and to interfaces;
- Very low vapour pressure and volatility;
- Low rate of mobility between 'compartment' in the environment or the human body;
- Extreme stability; and
- Very low mobility within the matrix of the whole substance.

These extremes may apply singly or in combination.

Therefore, standard models for human and environmental exposure can be used, but they may be impossible to apply quantitatively in every respect. Existing defaults in standard models could be reconsidered. For example, the EUSES models for estimation of environmental concentrations[121] include default values for the movement of molecules which may need to be made more sensitive to the molecular properties than in the current implementation. Therefore, for polymers, the assumptions in EUSES about attainment of steady states could very well not be valid.

Alternatively, realistic qualitative assessment of the potential for exposure can be performed in terms of the known properties. Part E of the REACH guidance should be followed. For example:

- For high molecular weight molecules, exposure of humans via the air is unlikely except when aerosols could be formed, or respirable dusts are present;
- For high molecular weight molecules of very low solubility and low degradability, it could be assumed that 100% will pass to sewage sludge in a biological waste water treatment plant; and
- For high molecular weight molecules of very high solubility and low degradability, it could be assumed that 100% will pass to water in a biological wastewater treatment plant (which is not the case for many non-polymers).

Assessment of releases arising during service life and waste disposal may be particularly difficult and the need for new or revised guidance should be considered. This is particularly important given that many polymers are intended to have a long service life. There will need to be clarity about how to treat microplastics, which are being addressed in numerous other initiatives.

4.4.10 Reduced requirements for PRRs of Type 2

This Type 2 could include many PRRs, although numbers are not known. Test methods would draw upon those listed under the discussion of Type 1.

This section looks at the steps that may be required when:

- There is a need to determining whether further testing is necessary and which tests are required; and
- Identifying what is needed for their initial assessment , bearing in mind that for some studies, testing proposals are required before their performance.

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[121] Also CHESAR which uses the EUSES model.

The following assumptions were made:

- The need to test would require careful consideration, in case:
    - The only samples available contain a non-removable monomer, additive and/or stabilisers which could dominate the test results.
    - The substance contains a low fraction of potentially hazardous constituents, so the study design needs to take that into account, or the need to test at all should be considered.

In order to assist the process of formulation of a realistic initial registration strategy in the absence of existing data, the following charts (Figures 4.2 to 4.4) suggest a possible way forward in broad terms. The suggestions are in line with current guidance; however, it must be understood that the implementation of registration of PRRs will need significant amounts of new guidance development. However, polymeric surfactants could pose difficulties in that aggregates are often formed in solution (see also ECETOC, 2019).

Figures 4.2 to 4.4 cover:

- Physicochemical properties, for which volatility and solubility properties are particularly important;
- Human health, for which the need to test vertebrates is a particularly sensitive issue, especially for polymers where there are many products on the market but with much overlap in composition; the chart has some similarities in one produced by ECETOC (2019); and
- Environment, for which poor solubility in particular is a strongly-limiting factor and needs to be well-understood.

These charts have been drawn to address the fact that polymers present different challenges compared to non-polymers.

The abbreviations used are explained after the figures.

Figure 4.2 Illustrative Type 2 testing Strategy: Physicochemical Properties

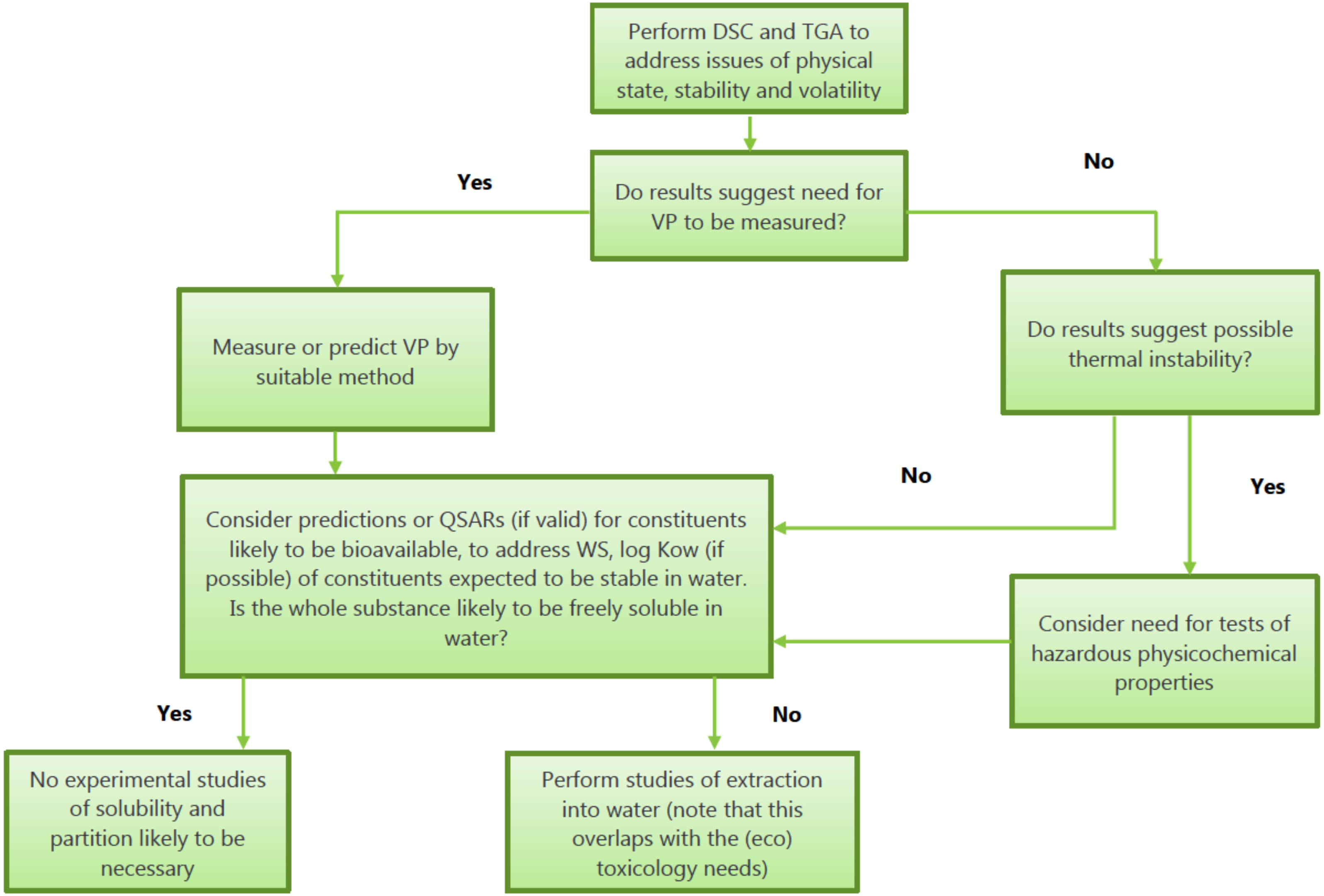


Figure 4.3 Illustrative Type 2 testing Strategy: Human Health

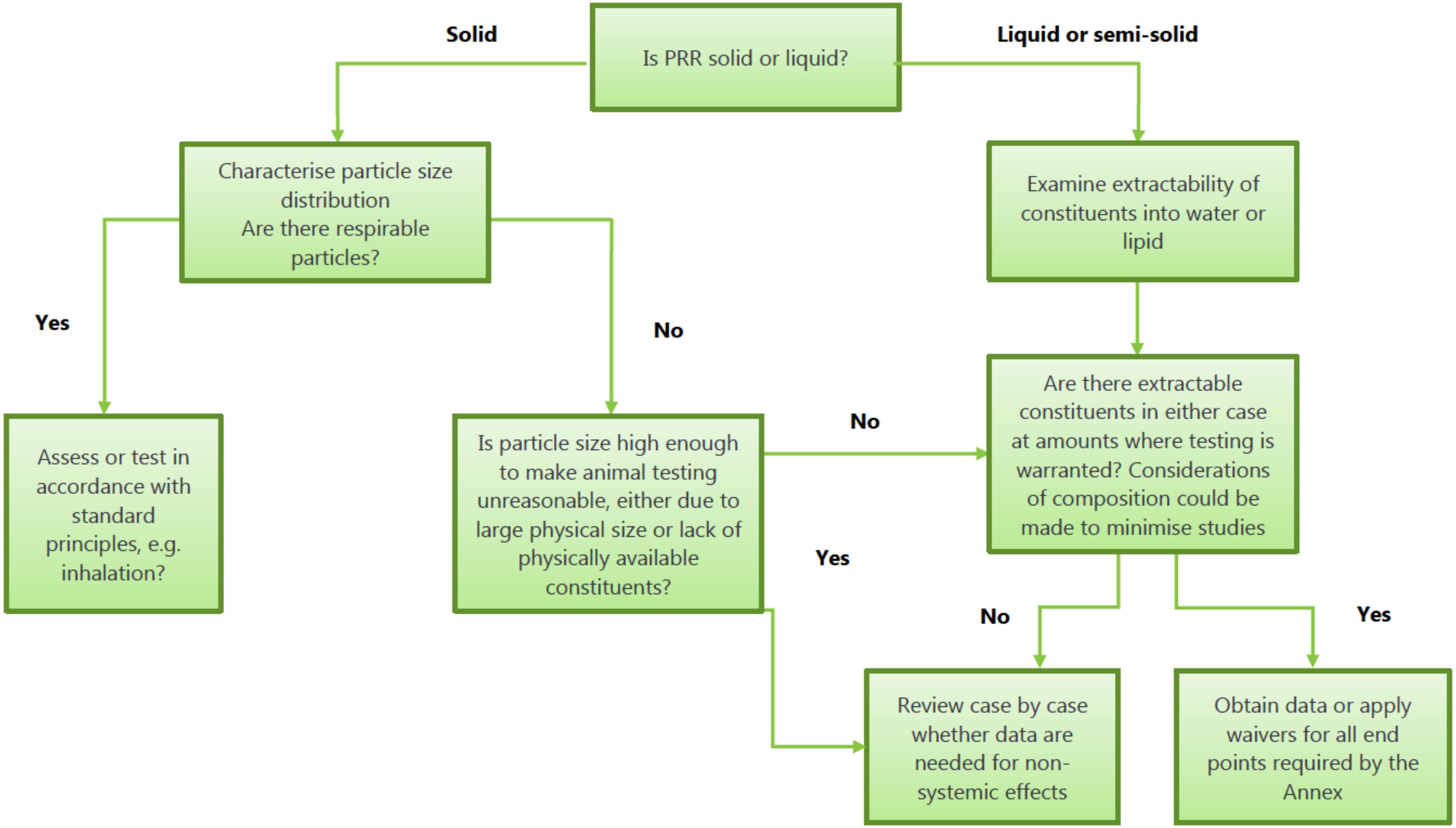
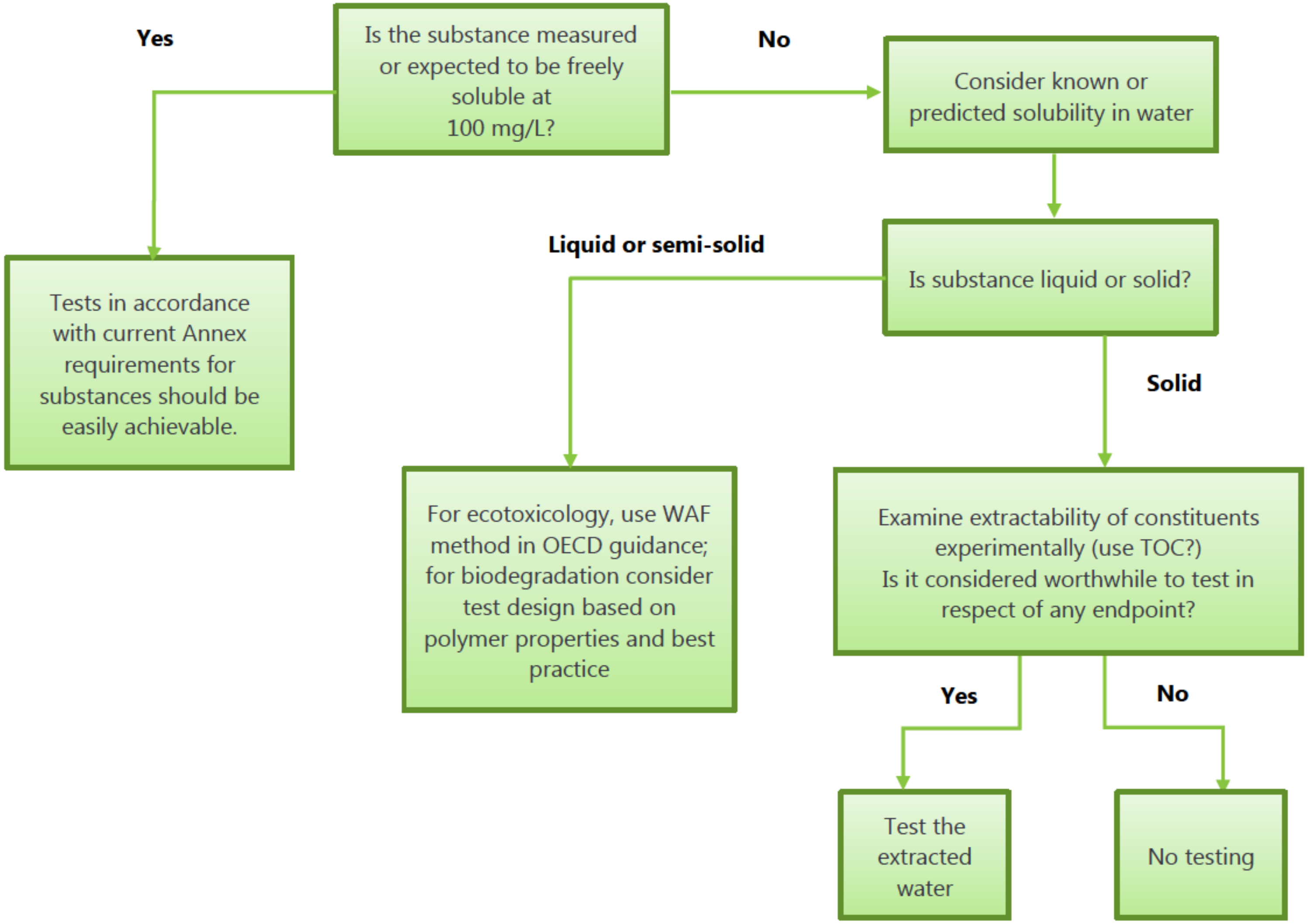


Figure 4.4 Illustrative Type 2 testing Strategy: Environment (not including discussion of degradation products)



Abbreviations used in the figures:

DSC	Differential scanning calorimetry	A standard method to detect thermal events during heating of a sample, such as melting, boiling, phase change, instability.
TGA	Thermogravimetric analysis	A standard method (usually used with DSC) to detect mass loss during heating of a substance; loss can be due to volatility, instability.
VP	Vapour pressure	Vapour pressure measurements usually represent the total pressure from all constituents, although special techniques or predictive methods give results for each constituent. QSAR can usually be used, including for limit values.
WS	Water solubility	True solubility refers to pure substances; for multi-constituent substances (UVCBs, polymers) the amount dissolved depends on the experimental conditions such as amount of excess substance present.
Log K_{ow}	Logarithm of the octanol-water partition coefficient	Standard method used to compare the relative affinity of a substance for an organic environment to an aqueous environment.
TOC	Total organic carbon analysis	A standard method to measure the total amount of a substance in water, from solubility or ecotoxicology studies, for example. It does not discriminate between different constituents.
WAF	Water accommodated fraction	A standard method of preparation of aqueous test media for UVCBs. It is a method to prepare a solution maximising the amount of constituents that will dissolve under specified conditions appropriate to media preparation.
QSAR	Quantitative structure-activity relationship	A computational method to predict intrinsic properties of (almost always) pure substances/constituents. Methods have limitations and require careful validation.
UVCB	Substance of Unknown or Variable composition, Complex reaction products or Biological materials	Fully defined in REACH.

In order to assess the potential costs of PRR registration options, it is useful to explore what the likely reasonable data requirements will be according to the proposals. There may be polymers that will require a full set of test data at the appropriate REACH Annex level, and others where waivers as currently used or reduced testing could apply. The considerations given in the following charts are also particularly applicable to low solubility UVCBs.

It should be clear from these proposals that the potential for polymers to have 'extreme' properties is addressed using appropriate testing strategies. However, there may be polymeric substances for which many or all of the standard Annex requirement tests are needed.

4.4.11 Reduced requirements for Type 3

For Type 3, many of the principles suggested for Type 2 will also apply, but due to the higher molecular weight less experimental work will be needed.

In the table below, some examples of the kind of substances that could be PRR in Type 3 are given. These are illustrative of the principles of responding to the presence of a structural alert. However, definitive test requirements cannot at present be given.

Table 4.8 Examples of the types of polymers that could fall within Type 3 and recommended data-sets

Example	Comment
High molecular weight cationic polymers	Consider solubility in water and ecotoxicity as for Type 2. Genotoxicity tests should be performed. Study irritation and corrosivity if necessary. Mammalian *in vivo* studies should not be performed.
High molecular weight polymers that are surface active	Consider solubility in water and ecotoxicity as for Type 2. Genotoxicity tests should be performed. Study irritation and corrosivity if necessary (which is discussed in ECETOC, 2019).
High molecular weight polymers with >2% oligomers of molecular weight <500 Da or >5% oligomers of molecular weight <1000 Da	Consider procedures as for Type 2 (as in the figures).
High molecular weight polymers with a relevant hazard classification for environment and/or human health	It is assumed that it is the polymeric constituents have been shown to be responsible for the classification. Consider procedures as for Type 2 (see the figures above) having first assessed the available data responsible for the classification.

4.5 Task 2.3 – Define information needed per tonnage band

4.5.1 Introduction and overview

The COM (2012) report assumed the existing REACH tonnage bands would apply to polymers. The same assumption is considered as a possible starting point in the current study, but the appropriate tonnage bands for polymers may not necessarily be the same as those for non-polymeric substances or be applied in the same way.

4.5.2 Tonnage bands: discussion

Tonnage would apply to the individual substance, not to the sum of tonnages in a group.

When a substance has been identified as a PRR, the data requirements for the substance can be derived from the REACH Annexes, but the need for adaptations in respect of polymers should be considered.

Three options regarding the tonnage triggers now could be considered:

1. Registration could be based on the **whole substance tonnage**; polymers could be considered as being similar to multi-constituent or UVCB substances, for which the whole substance tonnage is used to determine the Annex level required for the registration.
2. Alternatively, Registration could be based on the **tonnage only of the constituents which are considered as physically and biologically available at any point in the life cycle,** i.e. taking into account exposure and properties.
3. Finally, Registration tonnage could be based on the **tonnage of the constituents which possess hazard.**

Option 1 is the simplest to apply and is consistent with REACH as it now stands.

Option 2 would be relatively straightforward to apply when molecular weight distribution data are available but could raise several difficulties in respect of substance grouping and co-registrant group formation. Perhaps more important is that this would not be consistent with REACH as it now stands. It could also be problematic if scientific understanding of bioavailability changes. However, physical bioavailability would be a strong basis for waivers of some of the tests.

Option 3 is problematic in that the fraction of the tonnage which possesses the hazard may not be known.

Therefore, it is concluded for consistency with other substances and ease of regulatory methods, that PRRs should be registered in accordance with the registered tonnage band.

It should be noted that exposure assessment does take into account the fraction of the substance possessing the hazard for which exposure and risk are being quantified.

REACH requires that necessary information shall be generated whenever possible by means other than animal tests. Therefore, several ways of replacing or minimising animal testing can be considered. Thus, the approach to minimise testing is to use read-across, prediction, bioavailability considerations, or other scientific criteria to identify the testing needed, and even the constituents to be tested. Polymers could be considered on a very similar basis to non-polymers. Therefore, the 'level playing field' principle would apply. It should be noted that this would raise considerable concerns with registrants in that the weight-of-evidence for read-across could be hard to achieve, given that data sets for polymers are less well-understood than for substances in general.

It is possible that route of exposure arguments could minimise testing requirements due to the (generally) extreme properties of polymers (low volatility, low solubility, etc). Additional guidance on this could be needed, especially given that the life cycles of polymers are generally complex, and given their long service life in some cases.

Some other options are listed below: given that there are both policy and inter-related technical issues involved, there is no immediately obvious best way forward, but consultation and discussion should resolve that.

4.5.3 Registration process: discussion

For the REACH phase-in substances, reporting deadlines were set based on the Annex requirements and hazard (in part). Such a staging does not have to be followed for polymers, largely because tonnages of polymers are likely to be high.

In order to reduce the workload, it is proposed here that any staging of registration should be based on the three types, i.e. type 1, then 2, then 3.

4.5.4 Consideration of the effort involved in registration of polymers

Polymers are on the market in very high quantities, and very little is known about many of them, based on literature surveys conducted to date. The experience of REACH to date, in which much new information came out from the manufacturers' own systems, could be repeated for PRRs, which would be a very significant gain for human and environmental protection. Therefore, any approach to PRRs is expected to provide information that is likely to be of high value.

The recommendations under Task 2 are aimed at consistency with REACH and good use of scientific judgement. The basis of preference of one option over another has not been costed at this stage.

Where will there be costs to registrants? These are likely to be, as outlined in the preceding discussions, as follows:

1. Establishment of composition;
2. Assessment of whether a substance is a PRR;
3. Inquiry process, or equivalent;
4. Establishment of groups of co-registrants; and
5. Data sharing.

And, taking Type into account:

6. Gap analysis, taking use and exposure into account;
7. Commissioning of any tests; and
8. Registration, including chemical safety assessment.

All of these will require resources.

At the time of writing it is not known how many PRR of Type 1, Type 2 and Type 3 exist. Due to the need for producers to comply with their obligations to purchasers, as corroborated by the limited amount of published data, it can be anticipated that significant amounts of unpublished data exist. However, many substances will have rather incomplete information available. Intensive consultation with industry during the project has confirmed that unpublished data are available. However, industry has indicated that significant time and effort will be needed in order to collate this information and so it has not been possible to fully take this into account within the time frame of the current study.

4.6 Conclusions

The proposals in respect of substance identification have been set out. This is a critical topic in respect of possible Registration processes and database needs. The overall conclusions for Task 2 are that:

- Rational hazard-based proposals have been put forward for possible future requirements under a registration system for polymers. Bioavailability and exposure are critical issues, as was the case under the legislation that existed for polymers prior to the introduction of REACH (Dangerous Substances Directive (67/548/EEC)).
- The proposals deal with polymeric substances in a way which is consistent with the non-polymeric substances, but which is proportionate to hazard and risk principles. In summary:
    - prioritisation of PRR assessment is based on its MW range, where lower molecular weight polymers are prioritised (see Section 5.3.2).
    - The data requirements based on volume placed on the market apply equally to polymers and non-polymers in REACH, regardless of the type of substance, which allows for a level-playing field between these substances. Data requirements are therefore tonnage dependent and are independent of the polymer type.
    - however, some data requirements may not be relevant, particularly with regards to higher molecular weight polymers. Therefore, a series of testing strategies are proposed that enable to conduct an initial assessment. The results of this will indicate which further tests will be relevant to derive a meaningful chemical safety assessment, based on the properties a polymer. These are illustrated in Figures 4.2 to 4.4.
- As far as validation is concerned, some useful information was made available by industry and these data are compatible with the proposals.
- However, the data overall on properties of polymers and the nature and scale of the market potentially affected is far more limited than that which was available for non-polymeric substances prior to the introduction of REACH. A process to test the proposed approach and to improve understanding of the impacts is advised before any legislative proposals are taken forward.

5. Task 4 - Carry out a cost and benefit assessment

5.1 Approach

5.1.1 Overview

The purpose of this chapter is to provide a detailed analysis of costs and benefits of the possible registration requirements (set out in Task 2) for PRRs (as defined in Task 1), that could further feed into a possible Impact Assessment carried out by the European Commission.

It should be noted that key elements of the potential registration requirements for polymers are yet to be determined. In particular, following completion of this study, a pilot trial of approaches to grouping of polymers for registration will be carried out, involving industry and the authorities. The extent to which this potential for grouping of polymers for registration is realised has a major effect on the costs of registration (and on the relative benefits in comparison to those costs). The estimates provided in this chapter represent a best estimation of the extent to which polymers could be grouped for registration. However, the results of the pilot trial should ideally be taken into account in revising these estimates within the possible future Impact Assessment.

Various analytical methods exist to compare options, including cost-benefit and cost-effectiveness analysis, multi-criteria analysis, SWOT analysis and least cost analysis, among others[122]. Traditional cost-benefit analysis faces many challenges including, most significantly, the difficulties in quantifying many of the most important costs and benefits. Typically, some elements can be quantified (e.g. costs of a new policy for businesses) while for other aspects methodologies for quantifying impacts are not well developed (e.g. quantifying different chemicals exposure scenarios to levels of harm to the environment or for different health impacts). There are other challenges with cost-benefit analyses, such as the difficulty in taking into account all distributional effects; difficulties in predicting enforcement patterns across the EU; reliance on data availability from all Member States or on assumptions to extrapolate, etc.

Therefore, methods other than a strict cost-benefit analysis may be more appropriate depending on the case at hand and a multi-criteria analysis can be a useful complement or alternative to cost-benefit analysis to provide policy makers with a basis for informed decisions, when the information necessary for a full cost-benefit analysis is not available, is controversial or is volatile, e.g. when there are no robust methods to monetise different impacts. Multi-criteria analysis is also useful for complex interventions with diverse quantified impacts measured in different units and/or qualitative impacts (in particular factors which cannot be expressed in monetary terms). There are several limitations when carrying out a multi-criteria analysis: the outcome can be difficult to communicate as stakeholders may find it difficult to understand how the approach works and it can lead to inconclusive policy rankings given that various optimal orderings of options can exist. Multi-criteria analysis can be complex and rely on subjective judgment.

In light of this and to avoid any ambiguity/complexity in this chapter, the assessment undertaken is a **qualitative analysis in complement to a quantitative/semi-quantitative cost-benefit analysis.** Assumptions and expert opinions are clearly stated in the following sections. Given the very different types of costs and benefits, it was concluded that it would be inappropriate to use a scoring and weighting approach as would typically be done in a formal multi-criteria analysis.

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[122] Better Regulation Toolbox (BRT) (#tool 55 - 57)

To the extent possible, the objective of this task was to collect quantitative data for the various costs and benefits. As agreed with the project steering group, the approach to assessment of costs and benefits draws in part upon the approach in a recent study for the Commission on registration requirements for low-tonnage substances under REACH[123], and is summarised in sections below.

5.1.2 Baseline

Polymers are currently exempted from the provisions on registration of Title II of REACH (Article 2(9)). Therefore, manufacturers or importers of a polymer are not required to provide any information related to the intrinsic properties of the polymer itself to ECHA, with the exception of its hazard classification and labelling, when applicable. Polymers are not exempt from the provisions on authorisation and restriction under REACH. During the consultation, including at the workshop, it was noted that some industry stakeholders are already collecting various hazard data and assessing the potential risks from certain polymers in the absence of any formal requirement for registration; however this was not considered as a widespread and systematic practice.

Under the baseline, key data points for which information and assumptions were required are as follows, including the available estimates from the literature and consultation. Note that, while substantial efforts were made to obtain relevant and recent information, in some cases, no updated information was provided, and the work has instead relied on estimates that are several years old.

Table 5.1 Baseline indicators

Indicator	Estimate	Source
Total number of polymers	Upper bound: 400,000 Lower bound: 60,000 Best estimate: 200,000	Lower and upper bound estimate comes from the Review of REACH with regard to the registration requirements on polymers (COM, 2012). A figure of 1,000,000 polymers has been mentioned in the literature [Note 1], however it was not used in the assessment as it was not substantiated with evidence.
Percentage of polymers of low concern	Approximately 50% of polymers are polymers of low concern	Review of REACH with regard to the registration requirements on polymers (COM, 2012).
Percentage of polymers requiring registration (PRRs)	Upper bound: 20% of polymers Lower bound: 10% of polymers	Project team's best estimate, based on Tasks 1 and 2. This is for polymers meeting the possible criteria proposed for identification of PRR and falling within Type 1, 2 or 3 (see Tasks 1 and 2 for further information). Data from USA and Canada point to e.g. 12-15%, though the situations are not fully comparable.
Percentage of unique polymers amongst PRRs [Notes 2 and 3]	Upper bound: 40% of PRRs Lower bound: 25% of PRRs	Upper bound: according to Health Canada, 4,000 of 10,000 notifications of polymers were unique (see further information in Task 1). Lower bound: based on REACH substance registrations, where there were 20,608 substances in 82,874 completed registrations (as of November 2019). This assumes that the process of grouping and sameness is effective in reducing the number of distinct polymers requiring registration.

[1] https://chemicalwatch.com/register?o=72674&productID=1&layout=main (subscription required). [2] Unique polymers are groups of distinct polymers requiring one registration. They are assumed to be identified through the first stage of grouping (i.e. demonstration of 'sameness') [3] In this report, grouping can refer to the identification of related polymeric substances either for joint registration or for data-sharing and read-across. The first part of this (grouping for joint registration) is assumed to relate to the identification of "sameness" of polymers and hence the identification of unique polymers. The second element of grouping relates to data-sharing for read-across, which is reflected in the assumptions on the potential for data waiving (which includes demonstrating potential for read-across, as well as exemption from certain tests due to e.g. physicochemical properties).

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[123] European Commission (2017).

To illustrate how the above data translate into the number of polymers that would be registered, using the best estimate or central estimate values:

- As a best estimate, it is assumed that there are 200,000 polymers on the market.
- 50% of polymers are assumed to be PLC, meaning that 50% are not PLC, so there are 100,000 polymers that are not PLC.
- However, not all of these will require registration. Only 15% of the total number of polymers (30% of the non-PLC polymers) are assumed to meet the PRR criteria, i.e. 30,000 polymers out of the 100,000 non-PLC polymers.
- Based on experiences from other countries, it has been subsequently found that only around 40% of polymers qualifying for registration (or similar) requirements are actually 'unique'. The grouping process would allow these polymers to be registered together and much of the same data (e.g. on toxicity) could be used for all. Therefore around 12,000 'unique polymers' are assumed to be registered.
- Note that, in the subsequent sections, a Monte Carlo simulation has been used, taking into account the ranges in each of the above values. The best estimates of the above figures – based on the mean average values from the Monte Carlo analysis – are 33,000 polymers that would require registration (compared to 30,000 above), of which 11,000 would be unique polymers subject to registration (compared to 12,000 above).

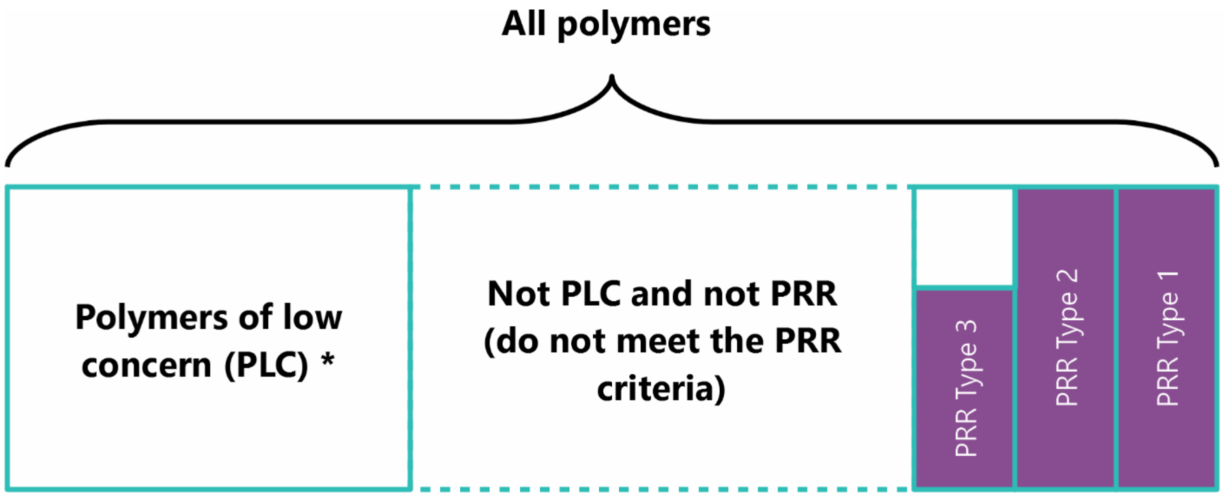
5.1.3 Analysis of options

The suggested criteria for the identification of polymers for registration (under Task 1) and the associated registration requirements and considerations in the approach to grouping (under Task 2) are intended to provide a proportionate and appropriate means of ensuring information is available to allow safe use of certain polymers, while not imposing potentially significant burdens where there is little benefit to be gained. In particular:

- The proposed approach would not apply to all polymers, nor even to those polymers that do not meet the (already well-established) criteria for 'polymers of low concern' (PLC). Instead, criteria are set out for the identification of those polymers with more potential for health or environmental hazards i.e. polymers requiring registration (PRR).
- For most polymers, an appropriate basis for identifying what endpoints are relevant and hence what test data are needed would be applied. In particular, it is assumed that many of the vertebrate tests would not be required for most polymers, reducing the potential for extensive animal testing as well as reducing costs for industry.
- Grouping of similar polymers together for registration (and read-across) would reduce the number of registrations required, and also reduce the number of new tests required for the endpoints set out in the REACH annexes.

The figure below highlights which polymers are concluded to be polymers requiring registration (PRR), based on the approach set out in Task 2. Note that the figure is illustrative and does not provide a quantitative estimate of the fraction of polymers that are PRR.

Figure 5.1 Illustration of which polymers are PRR based on the approach in Task 2



Only purple-shaded areas are polymers requiring registration (PRR)
Type 1: < 1000 Da – Data as for non-polymers
Type 2: 1000-10,000 Da – Testing strategy (reduced testing)
Type 3: > 10,000 Da – Only PRR if include certain structural features e.g. cationicity or reactive functional groups
* Criteria to identify PLC are considered to be already well accepted (e.g. EC 2015, OECD 2009)

Based on the analysis undertaken in previous tasks, it is clear that, for many polymers, imposing registration requirements would not be proportionate. It is not clear that registration of *all* polymers would bring substantial additional benefits to those expected under the main scenario of registering PRR, as described further in this report. Throughout the consultation, it was widely noted that there would be no merit in registering polymers falling under the definition of 'polymers of low concern' and similarly, stakeholders suggested that there would be little to no use in registering certain other types of polymers such as those with a very large molecular size or those without reactive functional groups (see section 22). The experience from the New Substances Assessment and Control Bureau of Health Canada with polymers confirmed that conducting certain testing by default on all polymers was of little value, and generally does not yield new knowledge.

In order to explore the potential implications on the costs and benefits of different registration requirements for polymers, a **number of alternative scenarios have been analysed for the cost assessment**, including:

- Scenario 1: This is the main scenario for registration of PRR described in this report. Only polymers meeting the criteria for PRR would be registered, and there would be significant waiving of vertebrate tests.
- Scenario 2: This would include registration of all polymers that do not meet the PLC criteria. The same degree of testing (and waiving of testing) as in scenario 1 is assumed.
- Scenario 3: This would include registration of all polymers that do not meet the PLC criteria. The waiving of tests set out in Appendix I would not apply in this case.
- Scenario 4: This would include all polymers being registered, but also including those that meet the PLC criteria. Again, the waiving of tests set out in Appendix I would not apply.

On the other hand, it is assumed that the additional benefits from registration of any polymers that are not PRR (i.e. those represented by the non-shaded areas in the figure above) would be marginal. Therefore, it is assumed that, for scenarios 2, 3, and 4, the level of benefits from registration would be broadly the same as for scenario 1 (i.e. there would be very little additional

benefit and hence little merit from an environmental or health perspective in extending the registration requirements. This is because the selection of PRR should identify those most likely to have relevant hazards.

5.1.4 Uncertainty

There is a **significant lack of data on costs and benefits** from the various consultations undertaken for this project and within the literature reviewed. Hence, there is significant uncertainty around data points that are key to the analysis of costs and benefits. In this context, a Monte Carlo simulation model has been used to enable the impacts of this uncertainty to be explored. In addition:

- **Quantitative versus qualitative analysis**: Costs and benefits have been quantified and monetised where possible, based on the best available data at the time of writing. As with any impact assessment, it has been necessary to rely on a number of assumptions, in cases where reliable data do not exist, and the analysis in the present report relies heavily on the approach used in another, similar study. Where quantification was not possible, a qualitative analysis is provided. Impacts that have only been assessed qualitatively may be as important as those that have been quantified.
- **Use of literature in the absence of better primary data from the consultation:** In cases where no information was provided by stakeholders through the various consultation methods, assumptions from previous studies in the field were used. Where applicable, these assumptions were adjusted to reflect the specific characteristics of polymers versus non-polymer substances. A detailed list of assumptions is provided in sections 5.2.2 and 5.3.3.
- **Expert judgement:** in cases where no information was available, the expert judgement of the authors, taking into account discussions with industry and authorities, has been applied to estimate certain data points.

5.1.5 Categories and definitions of costs and benefits assessed

The cost assessment covers the following cost items:

Table 5.2 Type of costs considered in this assessment

Affected stakeholders	Type of cost	Quantitative	Qualitative
Industry	Costs to form groups of pre-registrants (i.e. costs associated with the identification and grouping of polymers)	X	
	Registration fees paid to ECHA	X	
	Registration and SIEF administrative costs (e.g. time spent when companies engage with other registrants on shared information (as part of SIEFs) and on the preparation of the dossier).	X	
	Total costs of submission (e.g. compilation of material for the dossier including physicochemical information, general administration of the submission and liaison with ECHA)	X	
	Costs of testing and generating information	X	

Affected stakeholders	Type of cost	Quantitative	Qualitative
	Costs of revising Safety Data Sheets	X	
	Withdrawal of certain substances from the market due to high cost of registration		X
	Costs of implementing enhanced risk management measures identified as needed to ensure safe use for health and the environment		X
ECHA **Note that the costs to ECHA are not additive to the cost of fees paid by registrants.**	Costs to form groups of pre-registrants (i.e. costs associated with the identification and grouping of polymers) [Note 1]	X	
	Costs for processing registration dossiers (including updates)	X	
	Costs for final dossier evaluation output (compliance checks concluded with no draft decision, decisions on testing proposals and compliance checks)	X	
	Other costs such as IT equipment and update, dissemination of information including on the website, updating manuals, preparing webinars, etc.		X
	It was noted that the registration process has substantial implications in terms of regulatory risk management activities (e.g. CLH, restriction, authorisation) but these were considered out of the scope of this project which focuses on registration and evaluation. These should however be considered should the Commission carry out an Impact Assessment. Some qualitative considerations are therefore provided in this report. There would be both costs and benefits associated with these regulatory risk management processes.		X
Member States [Note 2]	Costs for substance evaluation	X	
	Costs of enforcement		X

[1] At this stage, it is still uncertain whether ECHA would have a facilitation or decision role in helping industry to form groups of pre-registrants. This is likely to have implications in the level of time and resources spent by ECHA. [2] As with ECHA's costs, some of the costs for Member States will not be additional to the costs for industry. For example, registration and other fees contribute towards ECHA's funding, but also towards Member States undertaking substance evaluations. In addition, for enforcement, the extent to which there would be additional costs for Member States is dependent on whether or not they would extend current enforcement activities under REACH, or simply use the existing resources for REACH enforcement to encompass registered polymers as well.

The benefit assessment covers the following items:

Table 5.3 Type of benefits considered in this assessment

Type of benefit	Quantitative	Qualitative
Avoided human health impacts through 1) better and more up to date physicochemical and ecotoxicological information for substances and subsequently 2) through enhanced risk management measures/approaches	X	X
Avoided environmental impacts through 1) better and more up to date physicochemical and ecotoxicological information for substances and subsequently 2) through enhanced risk management measures/approaches	X	X
Encouraging innovation in the chemicals industry		X
Ensuring a level playing field		X

5.2 Task 4.1 Costs for registration/evaluation of PRR

5.2.1 Main steps in the cost assessment

A Commission study on registration requirements for low tonnage substances (2017)[124] identified several (not all) factors likely to impact the costs of registering any substance. These include, for instance, whether there is already toxicological or ecotoxicological information on the substance; the number of companies registering that substance (which influences both the sharing of information costs in a SIEF and also the cost of administering a SIEF); whether the registrants of that substance will all support a joint registration or whether one or more individual registrations will also be submitted; the size of the companies registering that substance (which determines the registration fees due and also allows exploration of the impacts on SMEs versus larger companies); and the volumes produced by each of the companies registering that substance (which has an influence on the impact of the costs on companies and downstream users because it provides an indication of the price increase per unit of manufacture).

The different combinations of the above factors will lead to different results in terms of cost of registering substances. Another key factor driving the costs is the extent to which data on physicochemical, toxicological, ecotoxicological properties and on exposure potential is required; these would be defined through the requirements of any future system for registration of polymers. Some of this data will already exist, so it will not all need to be generated; however, any joint registrants would need to share in the costs of accessing and using that information.

The analysis aimed to build up cost estimates that would reflect the various factors likely to impact the cost of registration of certain polymers under REACH

A Monte Carlo Analysis approach was applied to consider various probability distributions that are associated with the combination of key data and assumptions. The Monte Carlo approach takes samples for each parameter within the range and types of distributions specified for each parameter, and generates estimates for intermediate and final calculations of key output parameters. The analysis involved applying 100,000 iterations, in order to generate estimates of key output parameters along with

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[124] European Commission, 2017, Impact Assessment of potential options, in particular possible amendments of REACH annexes, to modify requirements for registration of low tonnage substances (1-10t/year) and the CSA/CSR requirement for CMR substances in the framework of REACH.

their predicted probability distribution. The mean, and key percentile values (P5 and P95) are presented in this report.

In order to run the analysis, the project team took the following steps:

Table 5.4 Steps in the cost assessment

	Steps	**Indicators**
Input	Estimate the number and nature of unique polymers requiring registration (PRR)	Total number of polymers Total number of polymers of low concern Total number of PRR Total number of unique PRR
Intermediate calculations	Estimate the distribution of PRR per dossier and per tonnage band	Number of PRR per tonnage band Number of dossiers per tonnage band Number of dossiers per tonnage band, per type of PRR (1, 2, 3), per size, and by individual/joint submissions.
Input	Calculate costs of forming groups of co-registrants	Costs of forming groups of co-registrants per dossier
Input	Calculate the costs of testing and information provision per polymer, considering waiving of tests, extent of existing information available and requirements for new tests.	Costs of testing and generating information per unique PRR Costs of revising Substance Safety Data Sheets [Note 1]
Input	Calculate the substance (and dossier) registration costs	Registration fees per dossier Joint registration and SIEF administrative costs per dossier Costs of submission per dossier
Intermediate calculations	For each key data point where there is uncertainty, define the range of expected values and where possible the likely probability distribution function for the data.	n/a
Outcome	The outputs of the analysis are therefore presented as ranges with associated uncertainty levels (e.g. confidence intervals), rather than single point estimates.	Total cost of registration, broken down by size of company, tonnage band, type of PRR (1, 2, 3) and type of submission (joint/individual)

Notes: The extent of testing and waiving of tests assumed is set out in Appendix J and took into account: physicochemical properties, that would further determine the waiving of tests for certain types of polymers; level of existing data available, that would further determine whether there is already information available for certain endpoints; and availability or applicability of QSARs, that would further determine whether new tests should be run.

Detailed assumptions and values used in the Monte Carlo analysis and the assessment overall are presented in the next section.

5.2.2 Assumptions for the cost assessment

The following table presents the main variables, assumptions and indicators for the cost assessment, including current gaps.

Table 5.5 Assumptions for the cost assessment

Indicator	Estimate	Source	Stakeholders
Number and type of polymers/dossiers			
Number of dossiers submitted per polymer per tonnage band	1-10 tonnes: 1.3 dossier per registration 10-100 tonnes: 1.5 dossier per registration 100-1000 tonnes: 2 dossiers per registration Over 1000 tonnes: 4 dossiers per registration	Review of REACH with regard to the registration requirements on polymers (COM, 2012). Values are taken directly despite uncertainty, in the absence of better information being provided following requests during the current study.	All
Percentage of dossiers of PRR per type (1, 2, 3 – see Task 2) [Note 1]	Type 1: 20% Type 2: 40% Type 3: 40% Total: 100%	Project team's best estimate, based on Tasks 1 and 2. The percentages represent the proportion of the total number of PRR that are assumed to fall within each molecular weight range (i.e. of polymers fulfilling the PRR criteria, there are relatively fewer of lower molecular weight, i.e. type 1, than the number of higher molecular weight). This is because the majority of polymers overall are assumed to be dominated by high MW polymers. The number of Type 3 polymers is assumed to be greatest overall, but only a proportion of these would qualify as PRR (the proportion is not known).	All
Percentage of dossiers per tonnage band	1-10 tonnes: lower 5% and upper 64% (best estimate) 10-100 tonnes: lower 13% (best estimate) and upper 15% 100-1000 tonnes: lower 10% (best estimate) and upper 40% Over 1000 tonnes: lower 12% (best estimate) and upper 40%	Best estimate based on substance registrations for non-polymers (ECHA website, 22/11/2019), assuming 0-1t and intermediates included within 1-10t. Other values based on (COM, 2017). Note that lower / upper values do not add up to 100% as they represent ranges. In the Monte Carlo analysis, it was ensured that the values sum to 100% for each trial by varying the 1-10t, 10-100t and 100-1000t values within the range given, and calculating the value for >1000t based on the difference of the sum of these and 100%.	All
Percentage of joint dossiers	1-10 tonnes: 20% joint / 80% individual 10-100 tonnes: 30% joint / 70% individual 100-1000 tonnes: 50% joint/ 50% individual Over 1000 tonnes: 50% joint / 50% individual	Review of REACH with regard to the registration requirements on polymers (COM, 2012).	All

Indicator	Estimate	Source	Stakeholders
Percentage of registration per tonnage band and size of company	1-10 tonnes / Micro 25% 1-10 tonnes / Small 30% 1-10 tonnes / Medium 30% 1-10 tonnes / Large 15% 10-100 tonnes / Micro 10% 10-100 tonnes / Small 20% 10-100 tonnes / Medium 30% 10-100 tonnes / Large 40% 100-1000 tonnes / Micro 3% 100-1000 tonnes / Small 8% 100-1000 tonnes / Medium 40% 100-1000 tonnes / Large 50% Over 1000 tonnes / Micro 3% Over 1000 tonnes / Small 8% Over 1000 tonnes / Medium 30% Over 1000 tonnes / Large 60%	Review of REACH with regard to the registration requirements on polymers (COM, 2012).	All
<u>Time and costs assumptions</u>			
Time to form groups of pre-registrants (stage 2, under Task 2) (i.e. costs associated with the identification and grouping of polymers)	Best estimate: 20.8 hours and upper bound: 83.2 hours	This estimate is based on the effective working time of ECHA staff used per inquiry concluded and applied to industry. The value from the ECHA General Report, 2017 was multiplied by two (best estimate) or eight (upper bound) to reflect the complexity of polymers versus non-polymer substances. This feedback was consistently provided through the consultation and by the steering group. The lower time estimate from the ECHA General Report 2018 was not used as it reflects efficiencies that are only applicable to non-polymer substances. In addition, the type of activities required to form groups of pre-registrants are different than activities under the REACH inquiry process, and the former is likely to take more time.	Industry
Costs of dossier submission	Costs of individual registration: Micro: €2,200-€3,200 Small: €2,000-€3,000 Medium: €2,000-€2,800 Large: €1,500-€2,000 Costs of joint registration: All members are micro enterprises: €2,800-€3,800 Small is the largest member: €2,500-€3,500 Medium is the largest member: €2,500-€3,300 All members are large: €2,000-€2,500	(COM, 2017) as above	Industry
Joint registration and SIEF administrative costs	Costs of engaging on information (for each registrant): €1,000 Costs of engaging on dossier preparation (for each registrant): €750	COM (2017) as above	Industry

Indicator	Estimate	Source	Stakeholders
Costs of revising Substance Safety Data Sheets	€500	COM (2017) as above. (Safety data sheets will already exist for the polymers but these will need to be updated to reflect the information arising from the registration process.)	Industry
Costs (fees) of registration dossiers per tonnage band, per individual/joint submission, per size of company.	See Regulation, in Annex 1.	Commission Implementing Regulation (EU) 2015/864 of 4 June 2015 amending Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).	Industry
Costs of testing and generating information	See Appendix I for the costs of various tests. On average, costs of testing are as follows per registration, for each tonnage band: PRR type 1 € 37,710 for 1-10t € 171,163 for 10-100t € 304,904 for 100-1000t € 703,134 for over 1000t PRR types 2 and 3 € 37,710 for 1-10t € 91,951 for 10-100t € 175,196 for 100-1000t € 220,709 for over 1000t	COM (2017) as above Review of REACH with regard to the registration requirements on polymers (COM, 2012). Estimates from ECETOC (prices from a series of labs). Feedback from the consultation. For those polymers for which test/data waiving would take place, it is assumed that a cost of demonstrating read-across is approximately 5%-10% of the cost of the initial test. The cost to demonstrate read-across will depend on the quality of the existing data that supports the read-across, the endpoint being waived or read across, etc. For all polymers where waiving of tests is assumed, the costs of demonstrating read-across are assumed to apply.	Industry

Indicator	Estimate	Source	Stakeholders
Effective working time of ECHA staff used per inquiry concluded	Best estimate: 20.8 hours and upper bound: 41.6 hours	This estimate is based on the effective working time of ECHA staff used per inquiry concluded. It was also used (by extrapolation) to assess costs associated with the time for industry to form groups for registration, in the absence of better data. The value from the ECHA General Report, 2017 was multiplied by two (best estimate) or eight (upper bound) to reflect the complexity of polymers versus non-polymer substances. This feedback was consistently provided through the consultation and by the steering group. The lower time estimate from the ECHA General Report 2018 was not used as it reflects efficiencies that are only applicable to non-polymer substances. In addition, the type of activities required to form groups of pre-registrants are different than activities under the REACH inquiry process, and the former is likely to take more time.	ECHA
Effective working time of ECHA staff used per processed registration dossier (including updates)	Upper bound: 0.48 person day (3.84 hours, assuming 8h/day) Lower bound: 0.36 person day (2.88 hours, assuming 8h/day)	ECHA General Report, 2017 (actual time used as upper bound) and 2018 (actual time used as lower bound).	ECHA
Effective working time of ECHA staff used per final dossier evaluation output (compliance checks concluded with no draft decision, decisions on testing proposals and compliance checks)	Upper bound: 27.8 person day (222.4 hours, assuming 8h/day)	ECHA General Report, 2017. It was noted that this process of dossier evaluation may take more time for polymers (versus non-polymers) at the start but the difference should even out. In particular, the level of complexity for PRR can be considered comparable to that for UVCBs (in the context of the evaluation of dossiers): while only a third of substances under REACH are currently UVCBs, this complexity would apply to all polymers. Therefore, it was agreed that the 2017-time estimate would be used as a best estimate to reflect the above complexity of PRRs, rather than the lower time estimate of 2018 which reflects efficiencies at ECHA that are only applicable to non-polymer substances.	ECHA

Indicator	Estimate	Source	Stakeholders
Average hours spent for 15 countries for 2014 and 2015 for substance evaluations of single substances	The ECHA report (see right) provides the number of average hours spent for 15 countries for 2014 and 2015 for substance evaluations of single substances: 653 hours in 2014 and 582 hours for 2015, therefore, on average 617.5 hours spent per substance evaluation.	ECHA report on 'Comparison of the time spent for substance evaluation in 2014 and 2015'	Member States
<u>Other assumptions</u>			
Hourly salary industry (including taxes)[Note 2]	Micro: 13.65 €/h Small: 19.96 €/h Medium: 21.33 €/h Large: 25.45 €/h	Average labour costs per size of company in the plastics industry. Eurostat Labour cost, wages and salaries, direct remuneration (excluding apprentices) by NACE Rev. 2 activity) - LCS surveys 2008, 2012 and 2016 [lc_ncost_r2]	Industry
Hourly salary ECHA	30 €/h(+25% overhead)= 37.5€/h	Estimated salary for AD5-AD7 based on ECHA salaries grid. ECHA confirmed that typically, AD5/7 staff work on dossier evaluation. It was discussed that typically, lower grades than AD5/7 process the registration dossier, but given this activity is minor compared to dossier evaluation, it was considered appropriate to use the AD5/7 salaries for all activities. The Better Regulation Toolbox (tool #60) recommends that the hourly pay should correspond to the gross salary plus overhead costs (25% by default)).	ECHA
Hourly salary MS (public sector EU28) (including taxes)	15.71 €/h	Average labour costs for the public sector in EU28 Eurostat Labour cost, wages and salaries, direct remuneration (excluding apprentices) by NACE Rev. 2 activity) - LCS surveys 2008, 2012 and 2016 [lc_ncost_r2]	Member States
Percentage of dossier evaluation among all dossiers	20%	Project team's best estimate taking into account e.g. Review of REACH	ECHA
Percentage of substance evaluation among all substances	2%	Project team's best estimate taking into account e.g. Review of REACH.	Member States

[1] Type 1:< 1000 Da ; Type 2: 1000-10,000 Da; Type 3: >10,000 Da. See the detailed definition of the types in Section 3.
[2] Labour costs refer to the total expenditure borne by employers for the purpose of employing staff. They include employee compensation, which is mainly comprised of gross wages and salaries in cash and in kind and employers' social security contributions, vocational training costs, other expenditure, such as recruitment costs and spending on working clothes, and employment taxes regarded as labour costs minus subsidies received.

A key element of the costs for industry relates to the extent to which data on different endpoints is required for different polymers. The approach taken to assessing these costs was as follows:

- For the different tonnage bands, the endpoints (and hence tests) required were as based on REACH annexes VII to X.
- Data from Table 4.3 to Table 4.7 were used to identify which endpoints are relevant for polymers. Where endpoints are relevant it was assumed that 100% of PRR would require data on the endpoint; where endpoints are relevant to certain polymers (indicated with a "C" in Table 4.3 to Table 4.7 it was assumed that 40% of PRR would require data.
- It was assumed that a certain proportion of substances would already have information relevant to each endpoint, as per Appendix I.
- It was further assumed, based on the approach to identification of PRR, that it would be possible to waive the need for certain tests through e.g. exposure-based waiving, reliance on in vitro tests, use of QSARs, grouping, and exclusions in column 2 of the REACH Annexes, etc. The assumptions are set out in Appendix I and primarily concern endpoints requiring vertebrate animal testing.
- Applying the above factors, the average costs of testing per PRR were estimated, for each tonnage band and for each type (1 to 3) of PRR (see above in the table on assumptions).

5.2.3 Predicted costs of registration for industry under the main Scenario 1

Costs of registration and evaluation

The results below mainly cover costs incurred by registrants (manufacturers, importers and only representatives). The specific costs incurred by distributors are not quantified in this study. The REACH review indicates that 'these costs have been mostly linked to the pre-registration obligation (pursuant to Article 28 of REACH) and the preparation, translation, coordination, update and modification of Safety Data Sheets'[125].

The average cost for industry of registration *per substance* is assessed to be approximately €230,000 (covering activities to form groups of pre-registrants, registration, testing, SIEF administration, fees and SDS). *Per registration (dossier)*, the estimated costs for industry are around €109,000. Note that REACH review (COM, 2018) reports that the average cost per substance under REACH is €153,195 and the Extended Impact Assessment (COM, 2003) anticipated a cost per substance of €193,367.

Similarly to non-polymer substances under REACH, the cost drivers in the registration process are linked to the preparation of registration dossiers, which vary with the complexity of the dossier (e.g. based on the intrinsic properties of the polymer and the volume placed on the market); the level of data sharing between registrants; and the availability of information (e.g. information already available versus new tests to be performed) (COM, 2018). Another driver of registration cost is associated with the fees, which depend on the volume of the substance and the size of the company, assuming fees to register polymers would be similar to those already in place under REACH for other substances. The total costs of generating information and testing (including justifying waiving of tests) is estimated as 85% of the total costs for industry with fees representing 11%. Other costs of submission, SIEF and consortia administration and to form groups of pre-registrants, are estimated to represent together less than 5% of industry costs to register PRRs.

The REACH Review (COM, 2018) highlights that, in the case of simpler registration dossiers and smaller firms, ECHA's fees can represent 50% or more of the total costs companies incur when registering. For more complicated dossiers, the costs of compiling and generating the necessary data were generally the

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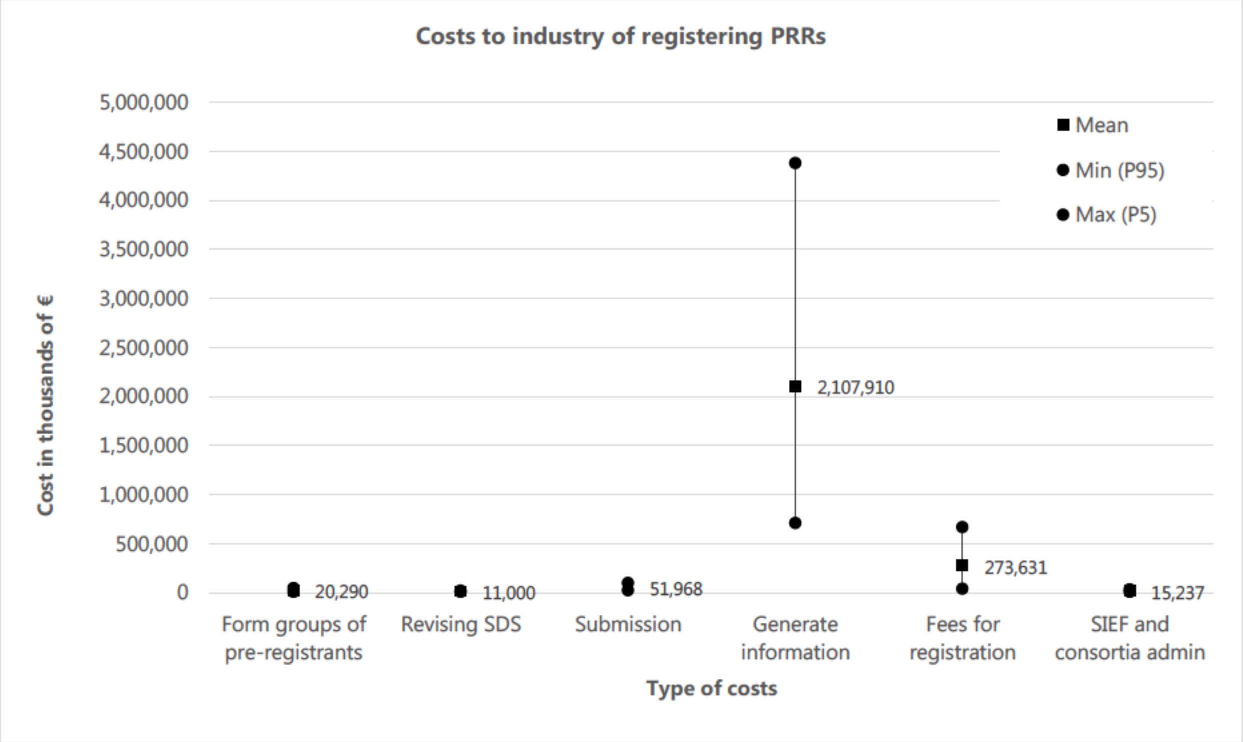
[125] COM, 2018, Commission General Report on the operation of REACH and review of certain elements

main cost element and fees only represented a minor part of the overall cost of registration. This is also expected to be the case for PRRs.

The figure below shows the various cost items for industry to register PRRs, including lower estimate (percentile 5%), upper estimate (percentile 95%) and mean values. Costs of evaluation for industry have not been assessed, as they relate to activities to cover the information gaps due to pending registration obligations or non-compliance'[126].

Figure 5.2 Costs to register PRRs - Industry



Ongoing costs after registration

In addition to the "one-off" costs of registration, there are also expected to be "ongoing" costs. Under REACH, for non-polymer substances, registrants are required to update their dossiers, as registrations must reflect the current knowledge on substances and how they can be used safely at production sites and by users throughout the supply chain. For polymers, there would therefore be an ongoing cost associated with such updates, and this should be taken into account when comparing against the benefits (which are assessed over a period of 40 years, as described later in this chapter).

The costs of such updates have not been quantified in the current analysis (and no comparable data for the costs of such updates for non-polymer substances have been identified). However, the costs are expected to be substantially lower than those for the initial registration. Following a review of previous Impact Assessments for the introduction and amendments to REACH (including the original Business Impact Assessment and an update from 2003[127]), as well as reports on the functioning of REACH (ECHA 2017c, COM 2018d), no quantitative estimates of the ongoing costs associated with REACH compliance have been identified. However, it is possible to conclude the following:

- As set out in ECHA (2017c), there are ongoing costs associated with keeping REACH registrations up to date. However, it is of note that fees are not typically charged for

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[126] COM, 2018, Commission General Report on the operation of REACH and review of certain elements

[127] RPA (2003).

submission of updated dossiers, except where the tonnage band changes (and that is not a direct cost of introducing a registration requirement, but rather an effect of changed market share for a given substance).

- COM (2018d) concludes that "the update of registration dossiers by companies is still a weak point, only 25% of dossier owners conduct a regular routine review of their REACH data and 50% of updates were requested by ECHA". It is clear therefore that the level of activity in updating REACH registration dossiers had – to that point at least – been modest.
- The main costs associated with such updates are likely to relate to the update of the registration dossiers to take into account new information. However, the generation of such new information is not a requirement of REACH, and so the associated costs are not directly linked to registration.

Therefore, while the ongoing costs should not be discounted, they are expected to be significantly smaller than the costs associated with the initial registration.

5.2.4 Predicted costs of registration for ECHA and Member States under the main Scenario 1

Costs for public authorities, mainly driven by ECHA, include costs to carry out dossier evaluations and to process registration dossiers, respectively representing 88% and 7% of public authorities' costs associated with registration and evaluation of PRRs. Note that this quantitative assessment does not cover enforcement activities undertaken by ECHA or Member States, as no data was available to assess those.

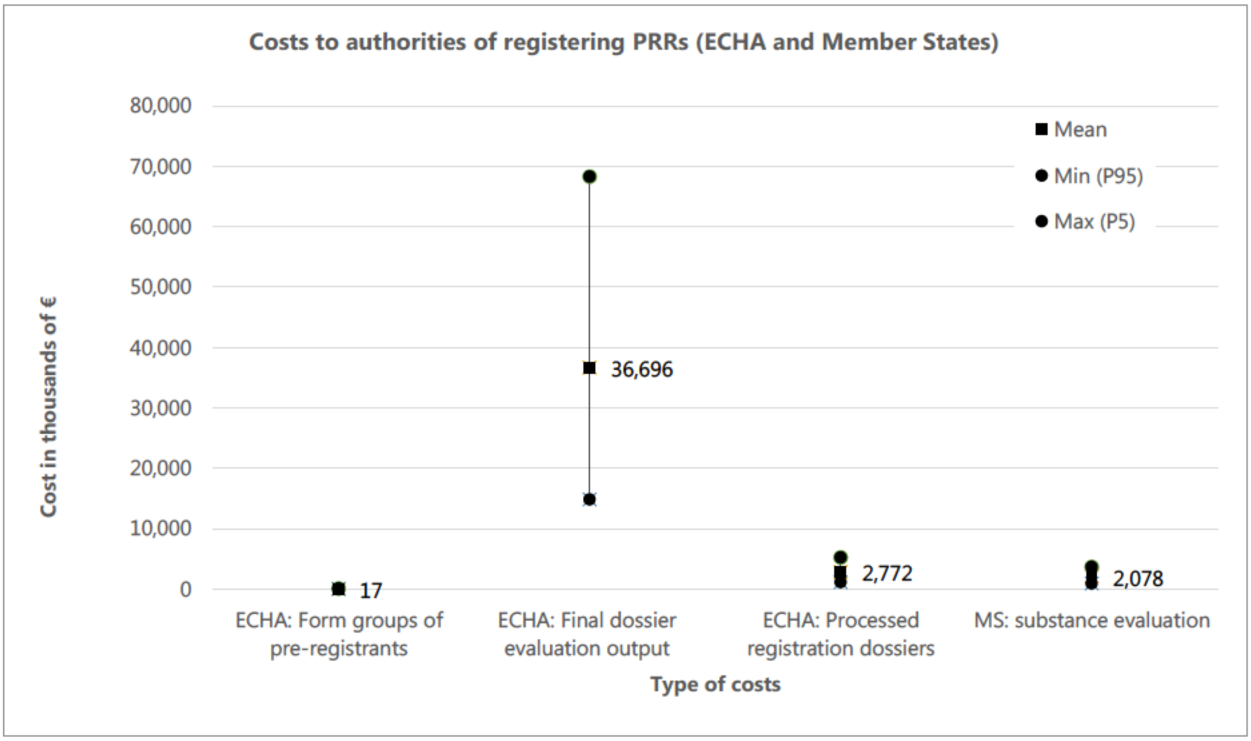
It should be noted that the costs to ECHA are not strictly speaking additional to the costs for industry, as the registration fees form part of ECHA's income which is in turn used to fund ECHA's resources in administering the registration and evaluation processes (along with the general ECHA subsidy from the EU budget).

Likewise, Member States receive financial support to fund (at least in part) the activities involved in substance evaluation, so these costs are not strictly speaking additional to the costs for industry. However, they are both important in the context of understanding both the transfer of resources and also the likely manpower requirements for the authorities.

The figure below shows the various cost items for public authorities (both ECHA and Member States) to register PRRs, including lower estimate (percentile 5%), upper estimate (percentile 95%) and central values. As indicated in the REACH review, fees collected by ECHA will already be included in the estimates of costs of registration for industry.

The above costs are essentially one-off costs, although the substance evaluation (for example) may take place some years after the initial registration. There will also be ongoing costs for authorities associated with enforcement, and other activities associated with administering the regulation at EU and member state level. However, these have not been quantified in the current study.

Figure 5.3 Costs to register PRRs - Public authorities



5.2.5 Breakdown of costs

The table below summarises some of the main cost estimates developed for Scenario 1 (the preferred scenario). All values are the mean average values as generated using the Monte Carlo analysis.

Table 5.6 Costs by type of registration, type of PRR, tonnage band and size of company for Scenario 1

	Industry	ECHA	Member States
Total costs of registration (€) [Note 1]	2,480,035,809	39,484,957	2,077,585
Average costs of registration per unique polymer (€)	231,484	3,686	194
Average costs of registration per registration (€)	108,960	1,795	98
Total costs of registration by type of registration (€)			
Joint	1,126,327,899	15,627,079	705,282
Individual	1,353,707,909	23,857,877	1,372,302
Total costs of registration by type of PRR (€) [Note 2]			
Type 1	720,464,031	7,896,991	415,517
Type 2	879,785,889	15,793,983	831,034
Type 3	879,785,889	15,793,983	831,034

	Industry	ECHA	Member States
Total costs of registration by company size (€)			
Micro	118,867,411	3,779,921	280,904
Small	248,544,658	5,950,004	398,895
Medium	789,518,463	12,625,508	665,432
Large	1,323,105,277	17,129,524	732,354
Total costs of registration by tonnage band (€) [Note 3]			
1-10 tonnes	221,599,975	11,106,862	923,535
10-100 tonnes	194,291,337	3,916,703	282,247
100-1000 tonnes	603,441,103	7,800,211	421,564
Over 1000 tonnes	1,460,703,393	16,661,180	450,238

Notes: [1] All data are mean average values generated in the Monte Carlo analysis and related to Scenario 1 (preferred scenario). [2] Note that, while average registration costs per polymer are much lower for Type 2 and Type 3 polymers (with reduced testing requirements), the total calculated costs are higher than for Type 1 because the number of Type 2 and 3 polymers is estimated to be greater than the number of Type 1 polymers. Assumptions regarding e.g. waiving of testing at different tonnage bands also affect the calculations. The numbers of Type 2 and Type 3 polymers are assumed to be equal (see Table 5.5) and the testing/waiving requirements are assumed to be the same, hence the cost values are also the same. [3] Note that, while the average costs per polymer are lower for the 1-10t range, the total costs are higher, due to the assumed higher proportion of polymers in the 1-10t range (see Table 5.5).

5.2.6 Other non-quantified costs

Overview

Several types of costs have not been quantified due to the lack of publicly available data, practical difficulties in collecting/generating such data or consultation feedback. These include, for example, the costs of enhanced risk management measures to ensure safe use of polymers, and enforcement activities, amongst others. Therefore, the above quantified costs are likely to represent a lower bound estimate and expected costs could be higher than those provided in the above table.

Furthermore, as explained above, the costs considered here are primarily the one-off costs associated with the registration and evaluation requirements. There will also be ongoing costs to industry and authorities, but overall these are expected to be substantially lower than the initial costs of registration.

Costs of enhanced risk management measures needed to ensure safe use

According to the REACH Review, the main cost driver among the REACH processes is registration, and these costs are associated with the fees and preparation of the registration dossier.

It is through improved risk management of chemicals/polymers that benefits will arise, and these risk management measures can be implemented due to the increased knowledge of hazards and risks (hence, the knowledge on how to ensure safe use) as a result of the registration requirement. Some of the risk management measures will be required by other legislation than REACH[128]. Such costs are therefore not directly attributable to a registration requirement for polymers.

It is not practicable within the scope of the current study to estimate the EU-level costs associated with risk management measures introduced following a registration requirement for polymers. To do so would require estimates of not only the number of workplaces (and other activities involving the use of polymers) at which different risk management measures would need to be applied. It would also require understanding of the measures currently applied, across the range of different polymers, followed by estimates of the different risk management measures that could (technically and economically) be applied for those activities.

The present report does not attempt to provide any a quantified estimate of the costs of risk management measures. Similarly, the REACH review report (COM 2018d) does not provide a quantitative assessment of the cost of implementing risk management measures under REACH (as a result of the registration requirement) nor a scale or order of magnitude for those.

Nonetheless, some narrative and examples of the costs of possible risk management measures is provided here, in order to give context to the practical changes that may take place as a result of a registration, albeit often indirectly through requirements of other legislation.

The implementation of risk management measures may range from simple and low/no cost organisational measures, through to major process changes, enhanced containment, ventilation, or indeed regulatory risk management measures. These costs will be specific to individual substances (polymers), individual sites and decisions will be made based on a range of commercial, technical and other considerations. For example, identification of a polymer substance as a CMR might necessitate change to process design, with investments in new plant, etc. At the other end of the scale it could lead to simple organisational changes (e.g. in which people are present in which places of a plant at a given time, with no direct additional costs incurred in some cases).

A recent study to collect information in connection with possible amendments to Directive 2004/37/EC on carcinogens and mutagens (COM, 2018e) provides examples of the scale of such costs. The authors consulted stakeholders on the risk management measures already in place and how effective these were, and what other risk management measures would be required if new occupational exposure limits for various substances were introduced. The study considered several categories of risk management measures, namely:

- Local Exhaust Ventilation (LEV), extraction at source
- Worker enclosures (WE), i.e. physical separation of workers in an enclosure or control room
- Respiratory Protective Equipment (RPE)
- General Dilution Ventilation (GDV)
- Organisational & hygiene measures (OH)

Among those categories, the study identifies the following risk management measures and the table below provides an estimate of costs for some of these risk management measures by company size based, ranging from €300 to €1,700,000 of capital expenditure, with subsequent operating costs worth between 10% and 1000% of the initial amount of capital expenditure, depending on the risk management measure and the size of the company.

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[128] For example, improved information on hazards can lead to changes to harmonised classification and labelling under the CLP regulation, which in turn can trigger new risk management measures in compliance with occupational safety and health legislation.

- Discontinuation
- Substitution
- Rework/redesign of the production process
- Full enclosure
- Partial enclosure
- Open hood
- Pressurised or sealed worker enclosure
- Simple enclosed cabin
- Breathing apparatus
- HEPA filter
- Simple mask
- Organisational and hygiene measures
- General dilution ventilation

Table 5.7 Cost of various risk management measures in the workplace

Risk management measure	Capital expenditure (range)	Operating expenditure [Note 1]
Rework	€25,000 (small company) to €1,000,000 (large company)	Not applicable
Local exhaust ventilation (LEV)	€7,000 (open hood, small company) to €1,700,000 (full enclosure, large company)	10% of capital expenditure
Worker enclosure (WE)	€7,000 (simple enclosed cab, small company) to €650,000 (pressurised/sealed, large company)	10% of capital expenditure
Respiratory protective equipment (RPE)	€300 (HEPA filter, small company) to €100,000 (breathing apparatus, large company)	50% (HEPA filter) 1,000% (breathing apparatus)
Organisational measures	€2,000 (small) to €75,000 (large)	50% of capital expenditure
General dilution ventilation	€6,000 (small) to €100,000 (large)	30% of capital expenditure

Source: COM (2018e) Notes: [1] Operating expenditure is per year, for the lifetime of the risk management measure.

The above relates to measures to reduce exposure in the workplace, but measures to address environmental releases are likely to follow a similar pattern, in that they will range from simple, low-cost organisational measures to rework of processes, and installation of emissions abatement equipment, which may be much more costly.

The specific risk management measures that would be implemented are dependent on the individual polymer, as well as individual circumstances of use (e.g. specific workplaces). It is, therefore, not possible to identify the extent to which specific risk management measures would be applied as a result of a registration requirement and the new information that would generate on ensuring safe use. Those that are currently implemented for non-polymer substances are likely to provide a guide, in many cases. However, it is expected that there could be potentially significant costs associated with implementing such risk management measures, as has been the case in ensuring that chemicals already subject to REACH are used safely.

Enforcement

Member States face enforcement costs, including staff and operating costs for enforcement, inspections, investigation and monitoring. A study on monitoring the impacts of REACH and innovation (COM, 2015) specifies that these can include 'one-off adaptation costs (costs of recruiting and/or retraining staff and purchase of equipment to adapt to the new regulation), information costs and administrative burdens (costs of gathering and collecting information needed to effectively monitor compliance), monitoring costs (costs of monitoring compliance with the legislation e.g. border checks collecting statistics, etc.), pure enforcement costs (costs of running inspections, investigations, processing sanctions, handling complaints etc.), and adjudication/litigation costs (costs of using the legal system or an alternative dispute resolution mechanism, to solve controversies generated by the legal rule)[129]'. The above quantitative assessment does not cover such enforcement costs. In particular, the REACH review reports that '*no relevant data have been provided by CAs in the 2015 Member States' reports. […]12 CAs indicated that it was impossible to provide an estimate of the annual budget dedicated to REACH enforcement since it is not separated from other activities of the National Enforcement Authorities. 15 Member States provided an estimate of the time dedicated to the enforcement of REACH. The data submitted is however rather heterogeneous (expressed in number of staff, FTEs, man-year etc.) and does not provide a clear picture of time spent on enforcement of REACH across the EU[130]'*.

ECHA, on the other hand, has no enforcement responsibilities, as an EU-level institution, apart from hosting the Forum for Exchange for information on Enforcement[131].

In any case, it is assumed that there would be a need for enforcement of future registration requirements for polymers. Any such system of enforcement for polymers registered under REACH would involve:

- Presumably no additional set-up costs for member state authorities, assuming that the same authorities would be responsible for enforcement as those for substances already included under REACH; but
- Additional costs to member state authorities due to the additional companies and substances (polymers) for which enforcement activities are required.

Insufficient data exist to be able to estimate these costs quantitatively.

Total costs of registrations and indirect costs from potential withdrawal of substances from the market

The results of the Monte Carlo analysis illustrate that the total costs of registration for industry follow a lognormal distribution, as shown in the figure below. The mean estimate of the total costs is €2,480 million with a 90% confidence range (P95 and P5) of €800 to €5,210 million (i.e. the analysis indicates a 95% chance that the total costs will be below €5,210 million).

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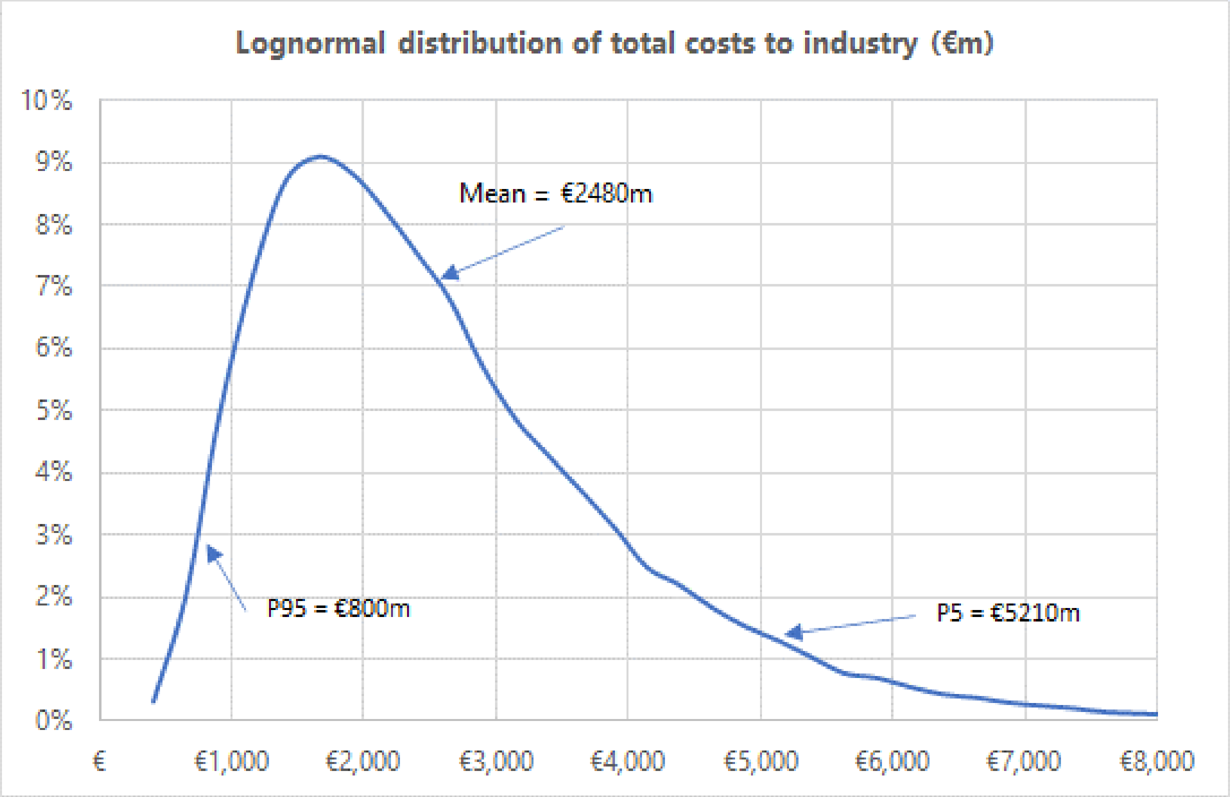
[129] COM, 2015, Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs

[130] COM, 2018, Commission General Report on the operation of REACH and review of certain element

[131] https://echa.europa.eu/regulations/enforcement

Figure 5.4 Probability distribution of total costs to industry of registration



Note: Figures calculated based on the cost model for this study, using CrystalBall™

However, the costs of registration to industry will vary significantly depending on the circumstances of the individual polymer being registered, both related to the costs of registration itself (performing any necessary tests, demonstrating read-across, registration fees, etc.) and also the affordability of registering, which relates to the volumes and margins realised through sales of the polymer. The results of the Monte Carlo analysis give:

- Mean costs per polymer registered of €109,000, with 90% confidence intervals of €76,000 to €142,000; and
- Mean costs per unique polymer registered of €231,000, with 90% confidence intervals of €113,000 to €391,000.

Costs in some cases would be higher still. This could lead to a decision by some companies to withdraw polymers from the market, if the costs of registration were to make the polymer no longer sufficiently profitable.

As for non-polymeric substances, the main indirect costs are likely to be generated by the withdrawal of a substance from the market due to economic reasons, e.g. the registration cost being too high. A study from COM, 2015 highlighted that '*near to one third of companies (including downstream users) have reported to be affected by a withdrawal of a substance from the EU market due to registration costs*[132]'. The same study concluded that the 2013 registration deadline was unlikely to have resulted in *significant increase in prices of chemical substances, as the main reaction from companies was to absorb costs rather than increase prices to recuperate costs*[133]'.

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[132] COM, 2015, Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs

[133] COM, 2015, Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs

The Commission's extended impact assessment for REACH (cited in COM, 2017) included estimates, based on the Commission's microeconomic model, that 1-2% of substances across all tonnage bands were likely to be withdrawn owing to REACH registration costs, across all of the scenarios it examined. While this did not specifically relate to polymers, in the absence of better or more recent information this figure is used here.

While the most expensive registration costs will not always be the least affordable (due to variability in the margins made and volumes sold across different polymers), it is assumed here – as an illustration – that the polymers with the most expensive costs of registration (top 1.5% of costs) would be withdrawn from the market.

Based on the costs per unique polymer registered, the Monte Carlo analysis suggests that 1.5% of unique polymer registrations would cost over around €460,000[134].

To illustrate the impact of these costs in terms of affordability, assuming a hypothetical average polymer sales price of €1,500/t and an EBIT of 15%[135]:

- Assuming sales of 1,000t polymer per year, the cost of €460,000 would represent around 40% of the EBIT earned over 5 years[136]; and
- Assuming sales of 20,000t polymer per year, the cost of €460,000 would represent around 2% of the EBIT earned over 5 years.

While sales quantities and margins vary significantly across the range of polymers on the market – as do the potential registration costs – these hypothetical calculations indicate that it is likely that (in some cases) the costs of registration will be prohibitive, particularly in the case of products sold in low volumes and/or those with low profit margins.

Other costs

Furthermore, some regulatory risk management processes will inevitably take place as a consequence of registration (e.g. CLH requirements and possible future restriction or authorisation for example). It was outside the scope of the current study to estimate potential costs and benefits associated with these other processes.

Finally, there are also other costs that have not been quantified here, such as the costs associated with the update/adaptation of IT tools. These are, however, expected to be much lower than the costs associated with the initial registration[137].

5.2.7 Analysis of potential alternative registration requirements for polymers

The table below summarises key data on the numbers of polymers that would be registered and the associated costs under each of the scenarios described in section 5.1.

This shows that, under the preferred scenario 1, the total costs of registration are at close to €2.5 billion, with those costs primarily falling upon industry. However, under other scenarios, the costs could be

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[134] This is based on an assumed lognormal distribution, with a mean value of approximately €218,000 and a standard deviation of around €86,000 as calculated using CrystalBall™.

[135] These are the authors' own *hypothetical average* values, but are within the ranges of values found in the literature and statistical publications. Clearly in practice there will be huge variability in both figures, with many polymers valued at much greater prices per tonne (and others less), and EBIT varying from a few % to 40% or more, depending on the sector, products concerned, wider market conditions and numerous other factors.

[136] Authors' own assumption for typical time period over which costs could be amortised in the sector, taking into account need to maintain profitability, estimated remaining product lifetimes, etc.

[137] By way of example, the costs over 5 years for IT tools related to REACH were quoted as €18 million in the 2018 evaluation of the REACH regulation (COM, 2018d).

significantly higher (e.g. up to 25 times higher), and hence the proportionality of registering polymers is highly dependent on only prioritising certain polymers for registration, and on ensuring that vertebrate tests in particular are only undertaken when there is clear need. The assumption is that the most expensive tests could be avoided in most cases.

The total costs to industry per unique polymer registered are the same under scenario 2 as for scenario 1 (around €230,000). However, scenario 2 would involve registering many more polymers (i.e. all those that do not meet the PLC criteria) and hence the total cost of that option is over three times higher. The analysis in this report suggests that the benefits of requiring registration for those additional polymers would be lower than the benefits for registering only PRR as defined in this report and indeed could be negligible in some cases.

The table also highlights that the process for identification of polymers that are truly unique is important. When polymers undergo registration, there would need to be an inquiry process for identifying which endpoints are relevant and hence what test data are needed. A process for determination of "sameness" should lead to grouping of polymers for registration and hence avoidance of additional testing and other assessments. Likewise, further grouping and demonstration that read-across of results between similar polymers is appropriate, while incurring some additional cost would lead to substantial savings compared to a situation where all polymers require specific information on all endpoints. Under the preferred scenario 1, while the total costs per polymer registered are substantial (mean value of €230,000), the costs per company, per registration would be substantially lower (mean of around €110,000).

Finally, as is made clear throughout this report, there are multiple uncertainties around many of the key data points used in this cost analysis. These uncertainties will be reduced as the details of future registration requirements are further developed, and as more data becomes available on the numbers, types and available information on properties is identified.

Table 5.8 Summary of registration costs under different scenarios

Parameter [Note 1]	**Scenario 1**	**Scenario 2**	**Scenario 3**	**Scenario 4**
Total number of polymers registered [Note 2]	33,000 (15,000 – 56,000)	110,000 (54,000 – 171,000)	110,000 (54,000 – 171,000)	220,000 (109,000 – 342,000)
Total number of unique polymers registered [Note 2]	11,000 (5,000 – 19,000)	36,000 (17,000 – 58,000)	36,000 (17,000 – 58,000)	71,000 (34,000 – 116,000)
Total costs to industry (€ m) [Note 3]	2,480 (800 – 5,210)	8,290 (2,870 – 16,770)	29,910 (6,730 – 66,740)	59,910 (13,560 – 134,420)
Total costs to Member States (€ m)	2 (1 - 4)	7 (3 - 11)	7 (3 - 11)	14 (7 - 23)
Total costs to ECHA (€ m) **Note that the costs to ECHA are not additive to the fees paid by registrants.**	39 (16 - 74)	132 (58 - 232)	131 (58 - 230)	263 (116 - 462)
Average costs to industry per unique polymer registered (€)	231,000 (113,000 – 391,000)	232,000 (114,000 – 391,000)	838,000 (241,000 – 1,610,000)	840,000 (244,000 – 1,610,000)
Average costs to industry per polymer registration dossier (€)	109,000 (76,000 – 142,000)	109,000 (76,000 – 142,000)	384,000 (163,000 – 577,000)	384,000 (164,000 – 577,000)

Notes: [1] Estimates presented are mean values resulting from Monte Carlo analysis using CrystalBall™. Figures in parentheses are percentile values (P95 and P5 respectively). [2] See Section 5.1.2 for a description of how these figures were derived, for Scenario 1. [3] As described previously, these are largely one-off costs associated with registration. There will also be ongoing costs associated with e.g. update of registration dossiers. It is not practicable to quantify these costs here, but they are expected to be significantly smaller than the costs of the initial registration.

5.2.8 Conclusion

The table below provides a summary of the estimated (quantified) costs to each type of stakeholder.

Table 5.9 Summary table of cost assessment (rounded to nearest 100)

Stakeholder	Type of costs	Mean	P95	P5
TOTAL COSTS				
Industry	Total costs of forming groups of pre-registrants	20,289,700	6,336,900	44,648,900
Industry	Total costs of revising SDS	11,000,000	4,444,600	20,477,500
Industry	Total costs of submission	51,967,800	21,236,900	95,945,400
Industry	Total costs to generate information	2,107,909,700	706,966,500	4,379,297,100
Industry	Total fees of registration	273,631,400	37,326,200	665,638,700
Industry	Total SIEF and consortia admin costs	15,237,300	5,439,200	30,655,100
	Costs of enhanced RMM, substance withdrawal		Not quantified	
	Total industry (quantified costs) [Note 1]	**2,480,035,800**	**781,750,300**	**5,236,662,600**
ECHA	Total costs of forming groups of pre-registrants	17,400	7,000	32,400
ECHA	Total costs for final dossier evaluation output	36,696,000	14,827,200	68,312,900
ECHA	Total costs for processed registration dossiers	2,771,500	1,102,800	5,216,100
	Costs of IT tools		Not quantified	
	Total ECHA (quantified costs)	**39,485,000**	**15,937,000**	**73,561,400**
Member States	Costs to Member States of substance evaluation	2,077,600	905,700	3,645,600
	Costs of enforcement		Not quantified	
	Total Member States (quantified costs)	**2,077,600**	**905,700**	**3,645,600**
AVERAGE COSTS				
Industry	Average costs per registration dossier (for industry, €)	109,000	76,200	141,600
Industry	Average costs per unique polymer (for industry, €)	231,500	113,300	390,700
ECHA	Average costs per registration dossier (for ECHA, €)	1,800	1,800	1,800
ECHA	Average costs of per unique polymer (for ECHA, €)	3,700	2,700	5,000
Member States	Average costs per registration dossier (for MS, €)	100	100	100
Member States	Average costs per unique polymer (for MS, €)	200	200	200

Notes: [1] As described previously, these are largely one-off costs associated with registration. There will also be ongoing costs associated with e.g. update of registration dossiers. It is not practicable to quantify these costs here, but they are expected to be significantly smaller than the costs of the initial registration. There are also various other costs that it was not practicable to quantify in the current study.

The predicted costs of registration for polymers are estimated to be between around €800 million (min, percentile 5%) and €5,200 million (max, percentile 95%), with a best estimate of €2,500 million (under scenario 1). However, there is significant uncertainty over the total number of polymers, the total number of PRRs as well as their distribution among tonnage bands and types (1, 2 and 3). This relates to scenario 1; the costs of other scenarios are higher as set out above.

The above are largely one-off costs associated with registration and evaluation. There will also be ongoing costs, which it is important to take into account when comparing costs against the benefits generated by registration (see below), particularly as the benefits will continue to be realised over several years after registration[138]. While it has not been possible to quantify these ongoing costs, they are concluded to be significantly smaller than the initial costs of registration, as explained in Section 5.2.3.

5.3 Task 4.2 Benefits from registration/evaluation of PRR

5.3.1 Overview of actions leading to benefits from registration/evaluation of PRR

A registration requirement for certain polymers will lead to better information on the physicochemical, toxicological and ecotoxicological properties of those polymers. It will also lead to wider availability of that information to society. This improved knowledge is a benefit of itself, although a non-quantifiable one.

However, the main quantifiable benefits associated with a requirement for registration of certain polymers would arise through the actions taken as a result, to protect human health and the environment. These actions include:

- **Improved risk management measures**: Information on the hazardous properties of polymers (including for classification) and on their uses and exposure will help companies to identify and implement improved risk management measures and to communicate the need for these throughout the supply chain. These include measures to reduce exposure of people in the workplace, as well as to reduce releases to the environment and to protect consumers.
- **Avoiding inappropriate uses**: This information will also help companies (registrants) to decide on situations where specific polymers cannot be used safely and to advise against such uses.
- **Regulatory risk management for the highest-risks**: As with REACH, a registration requirement will help identify those polymers where EU-wide action is necessary[139], such as:
  - EU-level controls for the use of some of the most hazardous substances in the workplace, such as occupational exposure limit values.
  - Restrictions on use of certain polymers, ensuring that exposure is reduced and that protection of health and the environment is increased.
  - Identification of polymers with the most hazardous properties – such as those that are PBT/vPvB and those that are CMRs – and actions taken to avoid their use where feasible (such as the authorisation process under REACH).

In the following sections, details are provided of the types of human health and environmental benefits that would be expected as a result of these actions. Some of these benefits are described qualitatively while an

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[138] A 'benefit realisation period' of 40 years is used in the following assessment of benefits.

[139] Such regulatory risk management measures can achieve substantial human health and environmental benefits, but they also have the potential to impose significant costs on industry and society as a whole. In-built into existing chemicals and other legislation (such as EU legislation on occupational safety and health, and the REACH restriction and authorisation processes) is a requirement to demonstrate – on a case by case basis – that the benefits outweigh the costs. It would be important for such a safeguard to also be applied to polymers.

attempt has been made to quantify certain types of benefits where a suitable methodology exists. The fact that certain health and environmental benefits cannot be quantified does not make them any less important.

There are also other types of benefits that have not been quantified, but which are described qualitatively, such as implications for innovation in the chemicals sector, and in ensuring a level playing field.

5.3.2 Main steps in the benefits assessment

This task's objective was to provide an assessment of the benefits of registration of polymers. As well as qualitatively assessing non-quantifiable benefits, this section includes a quantitative assessment in order to monetise, where possible, the benefits of registration.

It is assumed that the additional benefits from registration of polymers that are not PRR would be marginal, because the process of identifying PRR effectively screens out those polymers for which registration is unlikely to lead to any real benefit to health or the environment. It is therefore assumed, for scenarios 2, 3, and 4, that the level of benefits from registration would not be substantially greater than those under scenario 1. Therefore, this section provides an assessment of benefits for scenario 1 (only polymers meeting the criteria for PRR would be registered), which is assumed to be similar to the level of benefits from registering more polymers, as under scenario 2 (registration of all non-PLC, with waiving of testing), scenario 3 (registration of all non-PLC, without waiving of tests) and scenario 4 (registration of all polymers).

In this context, COM (2017) conducted an analysis of the costs and benefits to modify the requirements for the registration of low tonnage substances (1-10t/year) and the CSA/CSR Requirement for CMR substances in the framework of REACH. This indicated that the associated benefits from registration were related to a reduction in the impacts to human health and the environment from the following hazardous properties: mutagenicity (and via this route, genotoxic carcinogens)[140], dermal, inhalation/oral toxicity, aquatic toxicity and bio-persistence/bio-accumulation. Hence, the main benefits for these 1-10t substances were reduced incidence of diseases, disorders and impacts from hazardous properties and environmental pollution/ecological status[141].

The study on low tonnage substances (COM, 2017) concluded that there is a benefit to cost ratio of 34 to 1[142] for substances in the 1-10t range as a result of the provisions already in place under REACH for the 2018 registration deadline. It further concluded that, under the additional options explored to modify requirements for registration of 1-10t substances, the benefit to cost ratio would increase to between 100 and 1,390, under a medium scenario (without a requirement for a CSA).

In the context of registration requirements for polymers, examples of hazards for health and the environment include mutagenicity, dermal, inhalation/oral toxicity, aquatic toxicity and bio-persistence/bio-accumulation. The improved information throughout supply chains on such hazards, and requirements to implement risk management measures as a result, are therefore expected to lead to reduced levels of harm to health and the environment.

The main elements of the assessment in this chapter include:

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[140] Since no testing for carcinogenicity or reproductive toxicity is required in Annex VII of REACH, the study did not suggest identifying non-genotoxic carcinogens or reproductive toxins for any 1-10t substances. Since polymers with such properties might be identified in a registration system for polymers (e.g. at higher tonnage bands), improved risk management of non-genotoxic carcinogens or reproductive toxins could occur. This has not been quantified in the current study, meaning that the results tend to underestimate the benefits for these endpoints.

[141] https://op.europa.eu/en/publication-detail/-/publication/9380c012-055f-11e7-8a35-01aa75ed71a1

[142] Benefits of €14,016 and costs of €411 as per Table 15 of COM (2017).

- Quantified estimates, and monetary valuation, of the benefits that would arise as a result of registration, through avoided health and environmental damage, due to the improved information on hazards and risks. This is done for some endpoints only.
- A description of other benefits of a registration requirement that could not be quantified within the current assessment.

In order to conduct the benefits assessment, an approach similar to that taken in the COM (2017) study was applied, as agreed with the steering group at the start of the project. It involved the following steps:

- Estimate the nature of PRRs for registration i.e. which of the hazardous properties (e.g. mutagenicity, dermal, inhalation/oral toxicity, aquatic toxicity, bio-persistence/bio-accumulation) need to be considered for groups of substances (defined in Task 1) in order to assess the benefits of avoiding or reducing the occurrence of such properties and their impacts to human and environmental health.
- Hazardous properties were considered in terms of units of impact avoided i.e. the number of diseases/disorders avoided or the units of reduced environmental impact per substance by registration.
- Apply economic metrics to disease/disorder/unit of reduction in environmental impact to provide a monetary estimate.
- Estimate the number of diseases/disorders/environmental impacts which would be avoided.
- Calculate the total present value of benefits of registering PRRs (for those benefits that could be quantified.
- Complement this, where possible, with qualitative descriptions of the non-quantifiable benefits.

It is important to note that the benefits are assessed and estimated with uncertainty due to the reliance on several assumptions, which are discussed further below. It is also important to note that in the assessment the benefits do not accrue directly as a result of registration and that, due to latency effects, health and environmental benefits will likely have a delayed occurrence post-implementation[143]. Latency refers to the time between chemical exposure and when symptoms first become apparent (and hence when benefits can be realised). As concluded in the impact assessment for nanomaterials and applicable here, for longer latency diseases (e.g. chronic obstructive pulmonary diseases and cancers) attribution of benefits to reduced exposure to chemicals (and the associated legislation/policy) is more complex and requires a number of assumptions. For shorter latency diseases, effects can be felt almost immediately (e.g. skin diseases) or in the short term (e.g. asthma)[144].

5.3.3 Assumptions for the benefit assessment

The approach used to assess the benefits from registering PRRs follows the steps taken in the COM (2017) impact assessment study on low tonnage substances; such an approach has also been applied in previous assessments of the benefits of REACH, for substances more broadly.

All of the data and assumptions in the COM (2017) study were reviewed in detail, and where possible the calculations used were checked in terms of replicability, before application to polymers in the current study. The data points and underlying data sources were reviewed in order to conclude on whether they were reasonable and potentially applicable for polymers, noting that several of the estimates in the COM (2017)

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[143] Commission Staff Working Document (2017)– Impact Assessment accompanying regulation EC No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation and Authorisation and Restriction of Chemicals (REACH) as regards Annexes, I,II,III,VI,VII,VIII,IX,X,XI,XII to address nanoforms of substances.

[144] RPA (2016) Final report for the European Commission: Study on the Calculation of the Benefits of Chemicals Legislation on Human Health and the Environment. Available at: http://ec.europa.eu/environment/chemicals/reach/pdf/study_final_report.pdf

study were based on the authors' expert judgement. In cases where a more or less conservative approach than that applied in the COM (2017) study were concluded to be appropriate, the methodology was adjusted. In the following text, it is made clear where such deviations from the COM (2017) study have been applied.

ECHA provides guidance on assessing the benefits to health and the environment from managing the risks of a substance in its guidance on socioeconomic analysis for Authorisation and Restriction. However, this typically focuses on one substance or group of substances and a limited number of uses; while, as for low tonnage substances and other assessments of benefits of chemicals legislation as a whole, the current study is addressing ca. 11,000 polymers with a wide range of properties. Nonetheless, many of the principles in such a socioeconomic analysis are similar to (and are based upon) those for Impact Assessment of new policies, such as is covered in the present report.

There is far less information available on the potential benefits of controlling the exposure to polymers for health and the environment than there is for non-polymer substances. Therefore, as in the COM (2017) study, conservative conclusions on the risks of an 'average substance' have been used for the benefit assessment. The following table presents the main variables, assumptions and indicators for the benefit assessment, including key gaps.

In deriving quantified estimates of benefits, the assessment is based on the number of 'unique' polymers registered, of which there are estimated to be around 11,000 under scenario 1 (mean value, with significant uncertainty, as described in Section 5.1.2[145]). While there would be around three times as many registration dossiers submitted in total (mean value of 33,000), there would not be three times the benefits, because the additional registration dossiers are expected to cover largely the same uses of what is essentially the same polymer.

Table 5.10 Assumptions for the benefit assessment

Indicator	Estimate	Source
Disorders, diseases and impacts associated with each hazardous property	See table below. Further information and assumptions are provided in Appendix J.	COM (2017) impact assessment study on low tonnage substances.
Monetary values per unit of incidence of representative outcome	See table below. Further information is provided in Appendix J.	COM (2017), as above.
Cases/outcomes avoided per year	See table below. Further information is provided in Appendix J.	COM (2017), as above.
Numbers of workers exposed per PRR	Table J3 in Appendix J sets out the assumed numbers of workers exposed per polymer, using the same assumptions as in COM (2017) for workers exposed per substance. For example, under for substances without diffuse uses, the number of workers exposed per substance through the value chain is around 14,400. Note that the total number of workers exposed to all polymers cannot be calculated by multiplying the number exposed per polymer by the number of polymers. In practice, multiple different substances/polymers are used in any given workplace, on their own or within mixtures, for example. Workers will therefore be exposed to multiple different chemicals simultaneously.	COM (2017).

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[145] The value is estimated to be in the range 5,000 to 19,000 (based on the P95 and P5 percentile values).

Indicator	Estimate	Source
Calculated annual damage cost avoided by the identification of one substance with corresponding classification	Assumptions are based on calculations from the above two variables. Annual damage cost avoided by the identification of one substance with corresponding classification = monetary values per unit of incidence of representative outcome x cases/outcomes avoided per year.	Own calculations presented in Table 5.12.
Percentage of total unique PRRs with certain hazardous properties	This uses the percentage of maximum substances with hazardous properties not identified under the baseline in the low tonnage study out of the total number of substances registered in the same option. These percentages (see Table J7 in Appendix J) have been applied to the number of unique PRRs, in the absence of better data and with the following assumption: although Task 1.4 shows that the overall risk of polymers in general should be lower than those of normal substances, this is likely to be balanced by the fact that the registration process considered in this study excludes polymers that would be of limited concern. (PLCs and other polymers that do not meet the PRR criteria). Of around 200,000 polymers, only around 30,000 are assumed to require registration (around 15%), and these are selected for registration based on properties likely to give them a higher chance of being hazardous for health or the environment.	COM (2017), as above and own estimates for the number of PRRs.

The cost per case of disorder and disease associated with hazardous properties of mutagenicity, dermal irritation, inhalation/oral toxicity and carcinogenicity which have been used for this assessment are included in the table below. The costs per case have been taken from COM (2017). However, it should be noted that the disorders presented in the table below are not exhaustive and that, in the context of polymer registration, it is possible that disorders related to other hazardous properties may also be impacted by registration (e.g. reproductive toxicity) for which cost per case data was not available. In the case of CMRs, for example, the benefits will therefore be understated, because the data in the table below do not include all of the relevant endpoints that would be identified through the testing that would be needed for registration purposes[146]. As such, the costs presented in the subsequent analysis represent only some of the potential health and environmental benefits for a selection of the relevant endpoints and therefore represent an underestimate of the total. Further information on the assumptions made below can be found in the table below and in Appendix J.

Likewise, for PBT and vPvB substances, it is worthwhile noting the very wide ranges associated with the valuation of benefits achieved per kg of emission avoided. This reflects the fact that data on the relevant underlying properties does not generally allow a quantitative assessment of the human health or environmental impacts (e.g. using the 'impact pathway' approach) to be undertaken. There are also significant differences in potency amongst the substances concerned[147]. It is therefore not practicable, or meaningful, to further separate out the estimates (e.g. into PBT vs vPvB substances, or into different substance types), for the purposes of this benefits assessment. Indeed, it is worth noting that the starting point for assessments by ECHA's socio-economic analysis committee is that a unit of emission (e.g. kg) of any PBT or vPvB substance is considered to be the same in terms of the potential damage to human health and the environment (ECHA, 2016).

Note that there are significant uncertainties in assessing how accurate the scenarios and estimates described below are. However, to derive better estimates would require far better information on the extent of use of different polymers, and the properties of those polymers, than stakeholders were able to provide in the

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[146] In the case of CMRs, it was not possible to separate out the underlying data to provide estimates for the cases/outcomes per year associated with the different endpoint (carcinogenicity, mutagenicity and reproductive toxicity); only an assessment for CMRs as a group was possible.

[147] See for example ECHA (2016) for a further discussion, as well as the report on 1-10t substances (COM, 2017).

course of this study. It is believed that the approach used in the 1-10t study provides a reasonable basis for this task, despite the significant uncertainty ranges presented in the results.

Note that insufficient information from the literature or from stakeholders was available for the current study to derive more robust estimates of the number of people exposed per substance/polymer, or of other key parameters such as the number of adverse health outcomes arising as a result of exposure (and hence the potential to avoid those outcomes).

Table 5.11 Detailed assumptions for the benefit assessment

Hazardous property	Monetary value	Cases / outcomes avoided
Substances classified for skin/eye damage and irritation	Medical treatment cost = € 0 Productivity loss = € 390 WTP to avoid a single episode of mild acute dermatitis = € 277 Cost of a case of mild acute dermatitis = € 667	**Estimation of ill effects from acute exposure** RPA in-house chemical risk experts suggested that a reasonably conservative assumption for the estimation of the likelihood of exposure to ill effects to individuals working in manufacture would be that one in every 100 exposures is of a dose/duration sufficient to have an acute ill effect i.e. likelihood of 0.01. This is combined with the likelihood of a single exposure of 0.1, hence for manufacturers, the likelihood of an exposure event resulting in acute ill effects is 0.1 x 0.01 = 0.001 per day per individual or 0.24 per individual per year (one chance in 4 years) assuming 240 work days per year. RPA assumed that the substance dilutes as it passes down the supply chain, therefore the likelihood that an individual exposure of sufficient dose/duration to have an ill effect can be expected to be smaller for a downstream user than a manufacturer. Therefore, the probabilities applied to downstream users have been estimated with reference to volumes passing down the supply chain. Combining the probability of any exposure event occurring with the probability of an exposure event leading to acute ill effects provides the overall probability of an exposure which leads to acute ill effects per individual per day. RPA experts indicated that the estimated likelihood of an exposure that causes acute ill effects varies substantially between scenarios and uses, and that in virtually all cases, these estimates show very low probabilities. RPA applied those individual probabilities to the number of exposed individuals and the study assumed that the total number of cases of acute ill health associated with exposure to the substances considered with as yet unidentified acute hazardous properties would be 23, 63 and 126 for respectively low, medium and high scenarios. The estimated number of exposed individuals per substance was: 612 for the low scenario, 14,423 for the medium scenario and 186,046 for the high scenario. It should be noted that these numbers cannot be simply multiplied by the number of PRR, as many workplaces will use multiple chemicals/polymers, on their own and in mixtures, for example.
CMRs 1A/1B	COM (2017) assumed: Latency = 15 years Survival/treatment period (years) = 5 years Fatality rate at end of period = 47%	**Estimation of ill effects from repeated exposure** RPA in-house chemical risk experts suggested that a reasonably conservative assumption is that 40 exposures per year result in a 50% chance of a chronic health outcome for individuals exposed during manufacture. For the downstream users, the number of exposures required to have a 50% chance of

Hazardous property	Monetary value	Cases / outcomes avoided
	Annual cost per patient (€) = € 14,966 VSL (€) = € 4,000,000 VCM (€) = € 410,000 The authors calculated an aggregated NPV of €22,673,090 "for the prevention of one cancer exposure per year over a period of 40 years". (Understood to mean the avoidance of exposure that leads to one cancer case each year.) The above estimates for effects are based on those for non-polymer substances and there may be differences in disease types/incidence for polymers. However, there is no sufficient information at this stage to be able to provide any quantitative estimate. It is expected that a registration requirement for polymers would in part lead to better information on such aspects, enabling better estimates to be derived in the future. Hence, this is an area for further research in the future.	triggering a chronic ill health outcome has been changed in proportion to the relative volumes handled by downstream users compared with manufacturers. Combined data for the probability of n exposures per year per individual and the probabilities that n exposures per year will lead to a disease outcome provides the overall probability that a disease outcome will be triggered by n repeated exposures received per individual per year. Note that the study assumed that workers have a 10-year service life during which exposure occurs. The calculated total number of chronic cases over 40 years per substance were estimated as 29, 88 and 573 for low, medium and high scenarios. This gives the number of cases per year per substance of 0.7, 2.2 and 14.3 respectively. **Note on review of the NPV estimate of avoided cancer cases** The value from COM (2017) of €22,673,090 could not be replicated exactly using the assumptions quoted in that report, but it was possible to replicate the value approximately based on: Avoidance of 0.47 cancer cases each year in years 15-40, valued at €4,000,000 per case (applying the relevant discount factor each year and a discount rate of 4%); avoidance of 0.53 non-cancer cases each year in the same years, valued at €410,000 per case; and avoidance of 0.53 x €14,966 treatment costs for 5 years from year 15, again discounted in the same way. It is noted that there could of course be differences between polymers and non-polymer substances in terms of the types of cancers caused, for example. However, there is no information available to support a different estimate, so the values for non-polymeric substances have been used in the current study.
Substances classified for skin sensitisation	Medical treatment cost = € 2,100 Productivity loss = € 2,100 WTP to avoid a single episode of case of chronic dermatitis = € 1,055 Cost of a case of severe chronic dermatitis = € 5,255	See above 'estimation of ill effects from repeated exposure'. Number of cases per year per substance of 0.7, 2.2 and 14.3 for respectively the low, medium and high scenarios.
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	Medical treatment cost = € 1,370 Productivity loss = € 1,500 Cost of a 'poisoning event' = € 2,870	See above 'Estimation of ill effects from acute exposure' The study assumed that the total number of cases of acute ill health associated with exposure to the substances considered with as yet unidentified acute hazardous properties would be 23, 63 and 126 for respectively low, medium and high scenarios.

Hazardous property	Monetary value	Cases / outcomes avoided
Substances with long-term toxicity information	Medical treatment cost = € 4,500 Productivity loss = € 6,000 Kidney disease of short-term duration = € 10,500	See above 'estimation of ill effects from repeated exposure'. Number of cases per year per substance of 0.7, 2.2 and 14.3 for respectively the low, medium and high scenarios.
Substances that would have classification for STOT RE 1 or 2	Medical treatment cost per year = € 40,300 Productivity loss per year = € 6,000 Annual cost of a case of chronic kidney disease = € 43,300 Total cost of a case of chronic kidney disease assuming 10 years of treatment = € 380,400 Authors of the 1-10t study likely used UK data in the absence of other data available to them at the time of the study. A relevant article focusing on reimbursement for dialysis in different countries (Vanholder, 2012) [148] suggests that the values in other European countries are of a similar order and therefore, the assumption used was considered reasonable.	See above 'estimation of ill effects from repeated exposure'. Number of cases per year per substance of 0.7, 2.2 and 14.3 for respectively the low, medium and high scenarios.
Substances classified for acute aquatic toxicity	The study used the willingness to pay of UK households for improving the quality of water bodies to different Water Framework Directive Status levels, i.e. bad, poor, moderate, and good, in order to provide indicative values for water quality improvements. These values reflect improvement in six components of waterbody status: fish, other animals such as invertebrates, plant communities, the clarity of the water, condition of the river channel/flow of water and the safety of the water for recreational contact. The annual average per component value in England and Wales are below: • From 'bad' to 'poor': € 4,083 per km river per year per component. • From 'poor' to 'moderate': € 8,793 per km river per year per component.	The environmental benefits of identifying substances that are toxic to the aquatic environment are presented in € per km^2 waterbody improved, with the following ranges: • Low: 2 km2 'improved' per substance newly identified as having aquatic hazards; • Medium: 5 km2 'improved' per substance; and • High: 10 km2 'improved' per substance. Note that the benefit does not arise through additional area (km^2) being affected each year, but by continued benefit for the same area in each year (years 1 to 40). Therefore, the estimated benefit covers the removal of the substance in one km^2 for one year as well as the continued absence of the substance for the same area for the time period of 40 years.

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[148] Vanholder R, (2012) Reimbursement of Dialysis: A Comparison of Seven Countries, https://jasn.asnjournals.org/content/jnephrol/23/8/1291.full.pdf.

Hazardous property	Monetary value	Cases / outcomes avoided
	• From 'moderate' to 'good': € 14,243 per km river per year per component. The study assumed that three components will be affected, namely fish, other animals (such as invertebrates) and plant communities. It is assumed that the identification of acute aquatic toxic substances that do not currently have an associated 'Predicted No Effect Concentrations' (reflecting concentrations at which no (adverse) impact is observed) would result in the quality of water bodies improving from "bad" to "poor" at a value of €12,250 per km^2 river per year (i.e. three times the annual average per component value shown above, €4,083, for an improvement from 'bad' to 'poor'). The definition of PNECs would result in the setting of more stringent environmental risk management measures, with the effect of improving the quality of water bodies from "bad" to "moderate" at a value of €26,380 per km^2 river per year (i.e. three times the annual average per component value shown above, i.e. €8,793, for an additional improvement from 'poor' to 'moderate').	

<table>
<tr><th>Hazardous property</th><th>Monetary value</th><th>Cases / outcomes avoided</th></tr>
<tr>
<td>Substances classified for acute aquatic toxicity with enough information for PNECs</td>
<td>IVM conducted a study in 2015 for SEAC that gathered information on the past and current cost of PBT emission reduction or on reductions in the use or exposure to PBTs/vPvBs. That report states that the 'basic presumption of this study is that we can use information on the cost that society spends to avoid the environmental presence of and exposure to PBT substances can function as an (albeit imperfect) indicator/proxy for its willingness to pay to achieve this (IVM, 2015)'.
The study identifies a range of €1,000 - €50,000 per kg PBT substituted, remediated or emission reduced, as follows:

Low WTP = €1,000 per kg PBT substituted, remediated or emission reduced;
Medium WTP = €25,500 per kg PBT substituted, remediated or emission reduced; and
High WTP = €50,000 per kg PBT substituted, remediated or emission reduced.
</td>
<td>RPA experts estimated the total annual average production of an average 1-10t substance is 19,550 kg/year. This production was applied firstly for substances with no diffuse uses, assuming that 10% of the substance is released to the environment. For substances with one or more diffuse uses, it was assumed that 60% of the use (11,730kg) was used in non-diffuse applications, and that 40% (7,820kg) was used in diffuse applications, with 50% release to the environment. This was used to calculate the total estimated environmental release eliminated per PBT/vPvB substance.

Note that there was a specific focus in the COM (2017) on substances with diffuse uses, because part of the remit of that study was to consider an option of removing the reference in Annex III of REACH to "substances with dispersive or diffuse use(s)".
<table>
<tr><th></th><th></th><th>Quantity used (kg/year)</th><th>% released to the environment</th><th>Environmental release eliminated (kg/year)</th></tr>
<tr><td>Substance with no diffuse use</td><td></td><td>19,550</td><td>10%</td><td>1,955</td></tr>
<tr><td rowspan="2">Substance with one or more diffuse uses</td><td>Non-diffuse use</td><td>11,730</td><td>10%</td><td>1,173</td></tr>
<tr><td>Diffuse use</td><td>7,820</td><td>50%</td><td>3,910</td></tr>
<tr><td></td><td>Total</td><td></td><td></td><td>5,083</td></tr>
</table></td>
</tr>
</table>

Note: All data in the above table are taken directly from COM (2017).

Table 5.12 Assumptions per damage metric or representative outcome

Hazardous properties covered	Damage metrics/ representative outcomes	(A) Monetary value per unit incidence of representative outcome (in € unless stated otherwise)			(B) Cases/outcomes avoided per year per substance (number of cases, unless stated otherwise)			(C) Calculated annual damage cost avoided by the identification of <u>one substance</u> (PRR) with corresponding hazard (in €) (C) = (A) x (B)		
		Low	Medium	High	Low	Medium	High	Low	Medium	High
Substances classified for skin/eye damage and irritation	Cases of mild acute dermatitis	667	667	667	23.0	63.0	126.0	15,341	42,021	84,042
Substances classified for skin sensitisation	Cases of severe chronic dermatitis	5,255	5,255	5,255	0.7	2.2	14.3	3,679	11,561	75,147
CM(R)s 1A/1B	NPV cancer over 40 years	22,673,090	22,673,090	22,673,090	0.7	2.2	14.3	15,871,163	49,880,798	324,225,187
	Equivalent Annual Cost (EAC) cancer							801,867	2,520,152	16,380,988
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	Poisoning events	2,870	2,870	2,870	23.0	63.0	126.0	66,010	180,810	361,620
Substances with long-term toxicity information	Cases of kidney disease of short-term duration	10,500	10,500	10,500	0.7	2.2	14.3	7,350	23,100	150,150
Substances that would have classification for STOT RE 1 or 2	Cases of chronic kidney disease of longer term duration	380,400	380,400	380,400	0.7	2.2	14.3	266,280	836,880	5,439,720
Substances classified for acute aquatic toxicity	Improvement of WFD water body Improvement of water body status from 'bad' to 'poor' (as per the Water Framework Directive, WFD)	12,250 per km2	12,250 per km2	12,250 per km2	2.0 km2	5.0 km2	10.0 km2	24,500	61,250	122,500

Hazardous properties covered	Damage metrics/ representative outcomes	(A) Monetary value per unit incidence of representative outcome (in € unless stated otherwise)			(B) Cases/outcomes avoided per year per substance (number of cases, unless stated otherwise)			(C) Calculated annual damage cost avoided by the identification of one substance (PRR) with corresponding hazard (in €) (C) = (A) x (B)		
		Low	Medium	High	Low	Medium	High	Low	Medium	High
Substances classified for acute aquatic toxicity with enough information for PNECs	Improvement of WFD water body status from 'bad' to 'moderate'	26,380 per km2	26,380 per km2	26,380 per km2	2.0 km2	5.0 km2	10.0 km2	52,760	131,900	263,800
PBTs/vPvBs with no diffuse uses	Willingness to pay (WTP) to eliminate emissions of polymer PBTs	1,000 per kilo	25,500 per kilo	50,000 per kilo	1,955.0 kg	1,955.0 kg	1,955.0 kg	1,955,000	49,852,500	97,750,000
PBTs/vPvBs with one or more diffuse uses	WTP to eliminate emissions of polymer PBTs	1,000 per kilo	25,500 per kilo	50,000 per kilo	5,083.0 kg	5,083.0 kg	5,083.0 kg	5,083,000	129,616,500	254,150,000

Note: All data in the above table are taken directly from COM (2017).

The percentage of total unique PRRs with hazardous properties is estimated assuming that the same percentages of PRR will have each hazardous property as was assumed for substances registered at 1-10t in COM (2017), in the absence of better data. In turn, the data for the 1-10t substances were based on substances registered under REACH more broadly (i.e. in greater tonnage bands). Therefore, the assumption in this report – in the absence of any better data from industry, authorities or others – is that the small subset of polymers that would qualify as PRR would on average have comparable hazards to substances already registered under REACH. Importantly, this is not assumed to be the case for polymers *as a whole*; those polymers that do not qualify as PRR are assumed to have on average much lower hazards than both PRR and non-polymers substances that are already subject to REACH registration.

Therefore, although Task 1.4 shows that the health and environmental risks of polymers in general is expected to be lower than those of non-polymer substances, this is likely to be balanced by the fact that the registration process considered in this study excludes polymers that would be of limited concern (PLCs and other polymers that do not meet the PRR criteria). This assumption was agreed with the steering group for the project, in the absence of there being better data available for polymers.

The number of unique PRR with each hazardous property was calculated by multiplying the percentage of PRR with each hazardous property by the number of PRR estimated in the Monte Carlo analysis for the cost estimates.

Similarly, there are significant uncertainties in assessing how accurate the estimates described below are. In the absence of better data from the literature or from stakeholders, it is believed that the approach on the 1-10t study provides a reasonable basis for the estimates below.

Table 5.13 Assumptions on the number of unique PRRs with certain hazardous properties

Hazardous properties covered	Damage metrics/ representative outcomes	% of total unique PRRs with each type of hazardous property	Number of unique PRRs with hazardous properties (assumed number of unique PRR: 11,000 as in the cost assessment scenario 1)
Substances classified for skin/eye damage and irritation	Cases of mild acute dermatitis	22.1%	2,430
Substances classified for skin sensitisation	Cases of severe chronic dermatitis	12.0%	1,319
CM(R)s 1A/1B	NPV cancer over 40 years	2.4%	261
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	Poisoning events	27.3%	3,006
Substances with long-term toxicity information	Cases of kidney disease of short-term duration	7.4%	812
Substances that would have classification for STOT RE 1 or 2	Cases of chronic kidney disease of longer term duration	1.1%	118
Substances classified for acute aquatic toxicity	Improvement of water body status from 'bad' to 'poor' (as per the water framework directive, WFD)	10.7%	1,172

Hazardous properties covered	Damage metrics/ representative outcomes	% of total unique PRRs with each type of hazardous property	Number of unique PRRs with hazardous properties (assumed number of unique PRR: 11,000 as in the cost assessment scenario 1)
Substances classified for acute aquatic toxicity with enough information for PNECs	Improvement of water body status from 'bad' to 'moderate' (as per the water framework directive, WFD)	20.4%	2,248
PBTs/vPvBs non-diffuse	Willingness to pay (WTP) to eliminate emissions of polymer PBTs	0.3%	31
PBTs/vPvBs non-diffuse	WTP to eliminate emissions of polymer PBTs	0.1%	11

Notes: Percentage of total unique PRRs with hazardous properties assumes that the same percentages of PRR will have each hazardous property as was assumed for substances registered at 1-10t in COM (2017). Number of unique PRR with each hazardous property was calculated by multiplying the percentage of PRR with each hazardous property by the number of PRR estimated in the Monte Carlo analysis for the cost estimates. The data in the table take into account that some substances may be classified for more than one endpoint. For example, it includes substances with classification for both human health and environmental concerns, as well as taking into account the fact that some substances will be classified for several endpoints. The data are based on proportions of substances classified for different health and environmental effects under REACH. The data also take into account the fact that some polymers (PRR) that are registered will not have any identified classification (expected to be around 30% of the total), by analogy with non-polymer substances registered under REACH. The percentages of total PRR with different hazardous properties do not, therefore, sum to 100% and the numbers of PRR with the different properties does not sum to exactly 11,000.

5.3.4 Predicted health and environmental benefits through better information and enhanced risk management measures

Improved information leading to enhanced risk management measures

The registration of certain polymers is expected to increase the availability of information on PRRs, particularly regarding those substances where human health or environmental impacts were previously unknown, or impacts were considered uncertain. This was reiterated by various stakeholders during the study consultation and at the expert workshops. This increased knowledge on the hazards and risks of PRR should improve the implementation of risk management measures, and hence lead to improved protection of health and the environment.

As highlighted in COM (2012), generating new data on chemical properties (and demonstrating how chemicals (polymers) can be used safely through a chemical safety assessment) will result in the identification of previously unknown hazardous properties of some number of existing classified substances and unclassified substances (polymers). As such, generating new data and better information on substance properties leads to overall improvements regarding the information that is available on hazards, risk management measures and classifications (COM, 2012).

COM (2012) estimated that the application of the two more stringent registration options proposed in their study would result in 2,600-10,000 newly classified polymers. Furthermore, around 500-3,800 polymers with an existing classification would have additional classification endpoints. They estimated that these new classifications would result in the identification of previously unknown PBT, vPvB and CMR substances with related benefits regarding the reduced impacts to human health and the environment.

Despite the registration process being one of the largest sources of costs (according to the REACH review) and the actual costs being higher than those predicted in advance (it is estimated that costs for the first two registration deadlines amounted to €2.3-2.6 billion as opposed to initial estimates of €1.7 billion), it was noted that the information generated during registration has contributed to better knowledge about substances, increased transparency regarding missing information, as well as developing an awareness of the needs of stakeholders up and down the value chain. It was noted in the review that the REACH registration requirement leads to better and more recent physicochemical and (eco)toxicological information for substances, while at the same time avoiding animal testing and improving knowledge on use and exposure.

Requirements for registration, in turn, allow companies to make the most appropriate risk management decisions based on information that is up to date. For example, a survey conducted by CSES (2015) on REACH registration found that 53% of companies indicated that they had improved their approach to risk management in the workplace due to REACH requirements, with 39% having improved management and control of environmental emissions of substances. As such, legislative requirements can be drivers of risk management, encouraging measures to protect the environment and the health of employees and consumers. The chemical safety assessment required under REACH, and the inclusion of information from this in required risk management measures throughout the supply chain (e.g. through safety data sheets), is a key element in ensuring that chemicals are used safely across the EU[149].

Value of the evaluation process

The 2018 REACH review study also highlights that the evaluation processes lead to better information being available. The evaluation processes can confirm if any initial concerns about a substance need to be considered further. These benefits are in addition to the progressive restriction of substances of concern, which has obvious benefits in terms of increased level of human health and environmental protection to EU and global citizens.

Triggering regulatory risk management at the EU level

As set out in Section 5.3.1 above, better information can in some cases lead to the identification of significant hazards with certain substances (polymers). The processes and information generated under the REACH regulation have contributed to the realisation that certain substances are CMRs and PBT/vPvB substances. This is expected to be the case for polymers as well.

EU chemicals policy recognises that restrictions on use of chemicals may be needed when there is an unacceptable risk to human health or the environment, arising from manufacture, use or placing on the market and which needs to be addressed on an EU-wide basis. This is achieved through the restriction process under REACH.

Likewise, for chemicals that are of most concern – such as those that are CMRs and PBT/vPvB – there is a need for additional controls, and an expectation that they should be progressively replaced by suitable alternatives or technologies, where these economically and technically viable. The authorisation process under REACH is designed to achieve this.

A registration process for polymers is thus expected to lead to enhanced regulatory risk management (in addition to e.g. improved risk management measures in the workplace).

In the current assessment, it is assumed that such regulatory risk management would lead to reductions (or cessation) of the use of some of the most high-risk polymers at an EU level, through similar restriction and/or authorisation processes. This could include some or all uses of certain polymers being prohibited.

For non-polymer substances, this is one of the areas where significant health and environmental benefits have been achieved. For example, the recent review of REACH (COM, 2018d) highlights that 9 of the restrictions adopted under REACH in the review period (2010-2016) were estimated to produce health and environmental benefits of more than €380 million per year. Indeed, the underlying analysis (ECHA, 2016),

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[149] This report (CSES, 2015) does not, however, contain any quantitative estimate of the costs of risk management measures.

highlights that, when 4 additional restrictions from before that review period are included, the total human health and environmental benefits are valued at €700 million per year.

In the following analysis, some of the most significant benefits are estimated to be achieved through controls on PBT/vPvB substances (polymers) and those that are CMRs. It is assumed that these could be achieved through restricting or replacing certain uses, in a similar manner to the REACH authorisation and restriction processes.

Approach to valuation of health and environmental benefits

The approach described below, similar to the COM (2017) study, was used in order to value the main human health benefits of identifying more substances with hazardous properties by extending the REACH requirements to include polymers. As such, the proposed registration requirements for polymers are expected to be the first step in reducing the occurrence of diseases, disorders and environmental pollution impacts associated with those polymers through enhanced knowledge on polymers' properties and in turn, better risk management measures applied through the supply chain[150].

However, it should be noted that the extent of evidence on actual damage caused by polymers is less than that available for non-polymeric substances, as they are already subject to registration under REACH. Indeed, for non-polymer substances, there was already significantly more information available (and in the public domain) before the introduction of REACH than there is today for polymers. Nonetheless, consultation for the current study indicates that much information on the hazards and risks of polymers is already held within companies, but not necessarily made available in the public domain.

The benefit assessment described above was carried out for Scenario 1. Under Scenario 1, the polymers with most potential for health/environmental effects would be selected for registration and only relevant health/environmental/physicochemical endpoints would require provision of information and new testing. Other polymers, those not identified as PRRs, are assumed to have little to no benefits associated with a requirement for registration. It has not been possible to quantify the benefits of the additional registration requirements that would occur by registering polymers that are not PRR (as per scenarios 2, 3, and 4), and the incremental (additional) benefits are assumed here to be zero. The work on the previous tasks of this study (task 1 in particular) did not identify any significant health or environmental hazards/risks associated with polymers that do not meet the PRR criteria; though this is not to say that information may not become available in the future providing evidence of such hazards.

The estimates of annual health and environmental benefits under each of the options below (low, medium and high) depend on the number of substances newly identified with different hazard classifications through the requirement for registration, and the (health or environmental) damage cost avoided through introduction of appropriate risk management measures to address those hazards.

The quantitative estimates of benefits are calculated based on the following approach:

- The starting point is that an assumed 11,000 unique polymers would be subject to registration (see Table 5.8) based on the results of the Monte Carlo analysis.
- For each category of hazardous property, the number of unique PRR newly identified as having that given hazard property (through a registration requirement) is provided in Table 5.13. For example, for PRR classified for skin/eye damage and irritation, the assumed number of substances is 11,000 x 22.1% = 2,430.
- This number of PRR from the previous step is then multiplied by the estimate of the annual damage cost avoided by the (new) identification of one PRR with that given hazard (Table 5.12).

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[150] Including enhanced risk management measures during the manufacture and use of polymers (including those introduced indirectly as a result of other legislation), as well as regulatory risk management through processes such as authorisation and restriction.

For example, for PRR classified for skin/eye damage and irritation, the monetary value of the avoided cases of mild acute dermatitis (using the 'medium' value for cases avoided per year per substance/PRR of 63.0) is €42,021 and hence the total annual damage cost avoided is 2,430 x €42,021 = approximately €102 million per year.

- This is then repeated for each estimate of the number of PRR with each hazard property (Table 5.13) and the corresponding damage cost avoided per PRR (Table 5.12), giving an estimate of the total quantified benefits of €4,776 million.
- If instead the 'low' and 'high' estimates of the value of the annual damage cost avoided per PRR with the corresponding hazard are used (Table 5.12), the corresponding values for the annual damage cost avoided are €751 million (low) and €12,992 million (high).
- It should also be noted that there are other elements of uncertainty in these estimates, including the number of unique polymers that would be subject to registration. As set out in Table 5.8, there is also significant uncertainty in this value, with a range of 5,000 to 19,000 estimated around the best estimate (mean) of 11,000[151]. However, it is also important to note that the variability in this value will not necessarily affect the ratio of benefits to costs, as the estimates of costs of registration are also based on the number of polymers registered.

Quantified estimates of annual human health and environmental benefits

Based on the above, the figures below provide an indication of the range of benefits from registration of polymers, for those aspects that could be quantified. Note that there are a number of other benefits discussed elsewhere in this chapter that are important but which could not be quantified..

Table 5.14 Quantified estimates of annual benefits for each type of hazardous property

Hazardous properties covered	**Damage metrics/ representative outcomes**	**Monetary value of avoided impacts (benefits) for all PRR (€ million per year)**		
		Low	Medium	High
Substances classified for skin/eye damage and irritation	Cases of mild acute dermatitis	€37	€102	€ 204
Substances classified for skin sensitisation	Cases of severe chronic dermatitis	€5	€15	€99
CM(R)s 1A/1B	NPV cancer over 40 years	-	-	-
	Equivalent Annual Cost (EAC) cancer	€209	€658	€4,275
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	Poisoning events	€198	€544	€1,087
Substances with long-term toxicity information	Cases of kidney disease of short-term duration	€6	€19	€122
Substances that would have classification for STOT RE 1 or 2	Cases of chronic kidney disease of longer term duration	€31	€99	€642

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[151] Based on P95 and P5 values respectively.

Hazardous properties covered	**Damage metrics/ representative outcomes**	**Monetary value of avoided impacts (benefits) for all PRR (€ million per year)**		
		Low	Medium	High
Substances classified for acute aquatic toxicity	Improvement of WFD water body status from 'bad' to 'poor'	€29	€72	€144
Substances classified for acute aquatic toxicity with enough information for PNECs	Improvement of WFD water body status from 'bad' to 'moderate'	€119	€297	€593
PBTs/vPvBs non-diffuse	WTP to eliminate emissions of polymer PBTs	€61	€1,545	€3,030
PBTs/vPvBs non-diffuse	WTP to eliminate emissions of polymer PBTs	€56	€1,426	€2,796
Total quantified benefits (€ million per year)	**Based on mean PRR registered (11,000)**	**€751**	**€4,776**	**€12,992**
	Range based on low and high estimates of PRR registered	**€341 - €1,297**	**€2,171 - €8,249**	**€5,906 - €22,441**

Note: Data in this table are calculated based on the calculated annual damage cost per PRR from Table 5.12 (including low, medium and high estimates) multiplied by the number unique PRR with each of the hazardous properties in Table 5.13. This is based on the mean number of PRR from Scenario 1 (approximately 11,000). The total quantified have also been presented taking into account the range in the number of PRR that would be registered, taking into account the relevant percentile values (P95 = 5,000 PRR registered; P5 = 19,000 PRR registered). The individual values have not been presented for each hazard type using these ranges because the values are simply scaled linearly according to the number of PRR registered. These values only include benefits for which it has been possible to derive a quantitative estimate; there are other health and environmental impacts that would be avoided but for which it has not been possible to provide a quantitative estimate.

To provide further context to these estimates, it was explained above (section 5.1.3) that the estimate of 11,000 polymers requiring registration is highly dependent on the extent of grouping of polymers that would take place, and on the establishment of appropriate criteria for the identification of PRR. Three alternative scenarios were considered for costs associated with the registration requirements:

- Scenario 2: Registration of all polymers not meeting the PLC criteria (i.e. not just those identified as PRR in this study) with the same degree of testing (and waiving of testing) as in scenario 1.
- Scenario 3: Registration of all polymers that do not meet the PLC criteria like scenario 2 but without the same waiving of tests.
- Scenario 4: Registration of all polymers, also including those that meet the PLC criteria. Again, the waiving of tests would not apply.

These would all involve substantially more polymers being registered than under the main scenario (1) and/or substantially more extensive data requirements; the associated costs of registration would therefore be much higher. However, there would not be correspondingly higher benefits. Indeed, it is assumed in this study that there would be very limited (zero) additional benefits from registering polymers that do not meet the PRR criteria (i.e. those included under scenarios 2, 3 and 4).

As well as being highly dependent on the number of polymers, the results in Table 5.14 are also highly dependent on the valuation of benefits associated with each hazard endpoint. Under the 'medium' scenario, for example, the benefits associated with avoidance of the releases of PBT and vPvB substances represent around 60% of the total benefits. However, the underlying range for benefits avoided is very wide, and under the 'low' scenario, avoidance of such releases only represents 16% of the total €750 million benefits[152]. If only the 'low' estimate of values for PBT/vPvB substances were taken and the medium estimates taken for the remaining endpoints, the total benefits under the medium scenario would be €1,920m with only 6% of that derived from PBT/vPvB substances.

Estimation of total present value benefits

The previous section presented quantitative estimates for those benefits that could be quantified, based on the total estimated damage costs avoided per year. However, the risk reduction measures and policies would continue to achieve benefits to health and the environment over several years.

In common with previous assessments of the health and environmental benefits of changes to REACH (such as COM(2017)), the damage costs avoided are presented below over a 40 year assessment period (impact realisation period[153]), based on the net present value assuming a discount rate of 4%. The approach adopted was as follows[154]:

- The base year for the assessment was assumed to be 2022, with benefits occurring over the period 2025 to 2064 taken into account in the analysis.
- Non-cancer human health benefits were assumed to begin in 2025 and occur over the period to 2064[155].
- Cancer-related human health benefits were calculated based on the present value of damage cost avoided over the 40 year period, taking into account the latency of effects and fatality rates from cancer[156].
- Environmental benefits were assumed to occur with a lag due to the time taken for the benefits to be established, and were assumed to occur over the period from 2029 to 2064[157]. This lag time is consistent with it taking longer for environmental benefits to be realised, particularly those linked to reduced impacts of chemicals that are persistent in the environment.

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[152] As with the assessment for 1-10t substances (COM, 2017), the quantified benefits for PBT/vPvB substances were calculated based on data from IVM (2015) which quotes a value of between €1,000 and €50,000 per kg of emission avoided, in the context of cost-effectiveness of risk management. It was assumed (COM, 2017),this represents the range of willingness to pay (WTP) to avoid emissions of PBT/vPvB substances, and a value of €25,000 was taken as the central estimate in that study. The range is based on the conclusion that, broadly, measures costing less than €1,000 per kg PBT use or emission reduction will usually not be rejected for reasons of disproportionate costs, while measures costing over €50,000 per kg are likely to be rejected. This is referred to as a 'grey zone' by the authors, within which the cost of a measure can either be 'acceptable' or 'too high'. Within this 'grey zone' the outcome of the decision making may depend on substance-specific and situation-specific conditions and on other considerations than cost-effectiveness (e.g. affordability and competitiveness). There are therefore considerable uncertainties associated with this figure.

[153] A 40 year impact realisation period was used in the COM (2017) study and is considered to be appropriate here. This allows all benefits to be assessed over the same time period, even though there is a lag between exposure and effects in some cases. It also reflects the fact that many of the endpoints relate to severe, chronic illness (or long-term environmental impacts) and that measures to reduce such impacts will continue to have benefits over time in terms of avoided damage costs.

[154] All of these assumptions are consistent with those in COM (2017), except that the years have been increased by three to account for the difference in the date of the analysis (2017 versus 2020 for the present study). The calculation methods were checked against the underlying data and results in the COM (2017) study, to ensure that these could be replicated.

[155] As such, a cumulative discount factor was derived by estimating the sum of the discount factors for each year from 2025 to 2064. The discount factor (DF) for each year is based on the formula $DF = 1 / (1 + r)^n$ where r is the discount rate (4%) and n is the number of years from the base year. For example the discount factor in 2025 (n=3) is 0.889 and the discount factor in 2064 (n = 42) is 0.193. The cumulative discount factor is calculated as 17.41.

[156] Calculated based on the NPV of €22,673,090 for the avoidance of exposure that leads to one cancer case each year (Table 5.11). This was estimated in COM (2017), calculated assuming a latency of 15 years, survival/treatment period of 5 years, fatality rate at the end of the period of 47%, annual treatment cost per patient of € 14,966, VSL of € 4,000,000 and VCM of € 410,000. Note that the present value of the annual cancer cost avoided, over the period of 40 years, is approximately 19.8 times the annual value.

[157] These were calculated in a similar way to the non-cancer health benefits, with the exception that the first year that benefits are realised is assumed to be 2029 (DF = 0.760). Combining the discount factors up to 2064 gives a cumulative discount factor of 14.18.

The types of damage avoided were divided into the above three categories (non-cancer health benefits, cancer health benefits and environmental benefits) as the calculation of present value benefits is slightly different for each of these three groups.

The table below summarises the total quantified benefits over the assessment period. It firstly includes the quantified annual benefits for each of the above three categories of benefit, based on a summation of data in Table 5.14. The total present value benefits are then presented based on the approach described above. The mean value for the number of unique polymers registered (11,000) is used as the central estimate, with the range (5,000 to 19.000 also presented). The total benefits are also presented based on the low, medium and high values for the damage costs avoided per polymer (Table 5.12).

The discussion earlier in this chapter on the approach and uncertainties associated with the underlying estimates should also be taken into account here.

Table 5.15 Quantified estimates of total present value benefits over 40 years for each type of hazardous property

Type of damage cost avoided	**Total present value of avoided impacts (benefits) for all PRR (in € million)** [1]		
	Low	Medium	High
Summation of annual damage cost avoided [2]			
Total annual environmental damage costs avoided	264 (120 to 456)	3340 (1,518 to 5,768)	6,562 (2,983 to 11,335)
Total annual cancer cost avoided	209 (95 to 361)	658 (299 to 1,136)	4275 (1,943 to 7,385)
Total annual non-cancer human health damage costs avoided	278 (126 to 480)	778 (354 to 1,344)	2,154 (979 to 3.721)
Total damage costs avoided over 40 years (not discounted)			
Total environmental damage costs avoided over 2029-2064 (not discounted)	10,553 (47,97 to 18,229)	133,580 (60,718 to 230,729)	262,500 (119,318 to 453,409)
Total cancers avoided over 40 years (not discounted)	8,371 (3,805 to 14,460)	26,310 (11,959 to 45,445)	171,018 (77,735 to 295,394)
Total non-cancer human health damage costs avoided over 2025-2064 (not discounted)	11,118 (5,054 to 19,204)	31,135 (14,152 to 53,779)	86,167 (39,167 to 148,834)
Total present value damage costs avoided			
Total PV environmental damage costs avoided over 2029-2064 [3]	**3,742** **(1,701 to 6,464)**	47,366 (21,530 to 81,814)	93,080 (42,309 to 160,774)
Total PV cancers avoided over 40 years [4]	4,142 (1883 to 7155)	**13,019** **(5,918 to 22,487)**	84,623 (38,465 to 14,6167)

Type of damage cost avoided	**Total present value of avoided impacts (benefits) for all PRR (in € million) [1]**		
	Low	Medium	High
Total PV non-cancer human health damage costs avoided over 2025-2064 [5]	4,839 (2,200 to 8,359)	**13,552** **(6,160 to 23,408)**	37,505 (17,048 to 64,782)
Total quantified damage cost avoided	12,724 (5,784 to 21,977)	73,937 (33,608 to 127,710)	215,208 (97,822 to 371,723)
Best estimate of damage costs avoided [6]		**30,313** **(13,779 to 52,359)**	

Notes
[1] Main figures are based on the mean estimate of numbers of unique polymers registered of 11,000. Figures in parentheses represent percentile values P95 (5,000 polymers) and P5 (19,000 polymers).
[2] These values are based on the summation of the relevant categories of damage cost avoided from Table 5.14. Environmental damage costs avoided encompasses damage linked to substances classified for acute aquatic toxicity (improved water body status), as well as elimination of emissions of PBT/vPvB substances. Non-cancer human health damage costs include those related to substances classified for skin/eye damage and irritation and those classified for skin sensitisation (avoidance of acute and chronic dermatitis); those linked to oral/dermal/inhalation toxicity (poisoning events) and kidney disease. These are set out in Table 5.12, Table 5.13 and Table 5.14.
[3] Calculated using a base year for the analysis of 2022 (assumed year when a registration requirement is introduced) and benefits realised over the period 2029-2064, with a lag assumed between implementation of the registration requirement, introduction of risk management measures and realisation of benefits in the environment. This is consistent with the approach in COM (2017) though with all years increased by 3. A discount rate of 4% was used. The cumulative discount factor applied was therefore 14.18 (i.e. annual values from Table 5.14 are multiplied by this factor to give total PV benefits).
[4] Present value of annual benefits in Table 5.14 over 40 years and using a discount rate of 4%. Calculated based on an NPV of €22,673,090 for the avoidance of exposure that leads to one cancer case each year. The present value of the annual cancer cost avoided, over a period of 40 years, is therefore approximately 19.8 times the annual value. For example, under the medium scenario, there are an assumed 2.2 cases avoided per year (Table 5.12), and 261 polymers (Table 5.13), giving the total of €13,019 million above.
[5] Calculated in the same way as for environmental benefits but with damage costs assumed to be avoided from 2025 to 2064. The corresponding cumulative discount factor is 17.41. The benefits are only assumed to start in 2025 due to the assumed time taken from introduction of a registration requirement in legislation to the implementation of measures to reduce exposure.
[6] Summation of figures in bold in the above table, reflecting 'low' estimate for environmental benefits and 'medium' estimates for human health benefits.

The table also presents a 'best estimate' of the damage costs avoided. This has been calculated based on the 'medium' estimates for the value per substance of damage costs avoided for human health endpoints and the 'low' estimate for environmental benefits. The estimates of environmental benefits in the 'medium' scenario are dominated by damage costs avoided through reduced emissions of PBT/vPvB substances. In order to ensure that the benefits are not overstated, the lower end of the range has been taken[158].

5.3.5 Non-quantifiable benefits of polymer registration

In addition to those benefits that have been quantified, added value can occur from polymer registration due to enhanced pressure on industry to innovate and the increased requirements to regularly generate the most up to date information. This is of particular benefit regarding substances where human health and environmental concerns were previously unknown. It is not practicable to economically assess the indirect

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[158] The COM (2017) study used a value of €25,000 per kg of PBT/vPvB substance emissions avoided as the medium estimate, with a low value of €1,000 per kg and a high value of €50,000 per kg. Following review with the Commission, it was agreed that sensitivity testing using the lower end of the range was appropriate, given the extent to which these costs can affect the overall results. Note that a value of €1,000 per kg appears to be consistent with some of the restrictions that have already been introduced under REACH for PBT/vPvB substances, which were estimated to have incurred costs of approximately: €500 per kg for decaBDE, €850 per kg for PFOA and €400 per kg for siloxanes (calculated based on Table 3 in ECHA (2016))..

impact of increased innovation and information sharing which may be brought about by polymer registration, because of the great diversity in polymers, functions in products and end markets (amongst other factors). Nevertheless, these elements are discussed qualitatively below.

In addition, it is possible that disorders related to other hazardous properties (than those assessed in the previous section on quantified benefits) may also be impacted by registration (e.g. reproductive toxicity). Qualitative evidence has also been presented on those human health and environmental impacts where it has not been possible to develop value metrics for the purposes of this study.

Innovation in the chemicals sector

Increased knowledge is likely to stimulate innovation processes within companies searching for new and better applications in terms of safety and performance. As discussed in the Chemicals Innovation Action Agenda developed by Wood and the Lowell Center for Sustainable Production for the European Commission (2019), improving the knowledge base is a key element in closing knowledge gaps regarding hazard properties, risks and available alternatives[159]. Registration of certain polymers has the potential to better demonstrate the applications in which they can be used safely and beneficially. For example, in a survey conducted by CSES (2015) it was found that 23% of respondents launched new products as a result of the knowledge brought about through complying with REACH registration. The same could be expected in the context of polymer registration. Furthermore, in some applications where hazardous properties and risk are identified, increased availability of information related to the impacts associated with certain polymers will spur on innovation in companies under increased regulatory and market pressure.

Improved knowledge of the hazards and risks of chemicals leads to increased awareness of the need to manage those risks. Registration of chemicals contributes to that improved knowledge. Where it cannot be demonstrated that substances can be used safely, there is a need for further regulatory action. The figure below highlights the significant increase in patented inventions free of hazardous phthalates as knowledge of the hazards of these phthalate substances grew. While not the only driver, the analysis and data required by substance registration can contribute to this type of effect.

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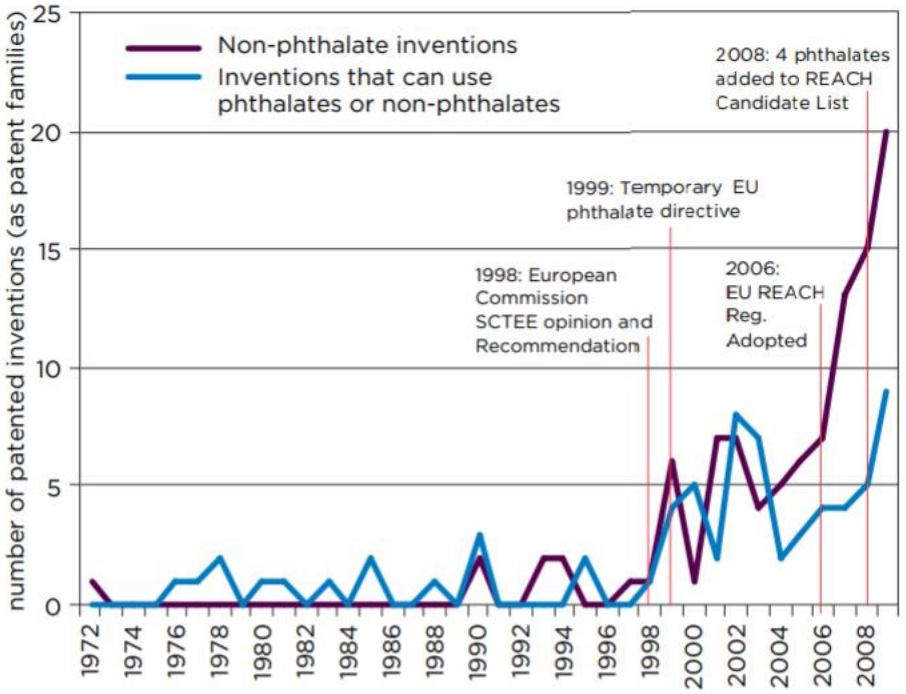
[159] Wood and the Lowell Center for Sustainable Production (2019) Final report to the Commissions: Chemicals Innovation Action Agenda. Available at: https://op.europa.eu/en/publication-detail/-/publication/2d7fc4d1-96f6-11e9-9369-01aa75ed71a1/language-en/format-PDF/source-109000193

Figure 5.5 Spike in patented inventions free of hazardous phthalates post REACH (CIEL 2013)



Exponential growth in the number of patented inventions for phthalate alternatives beginning in 1999, coinciding with the adoption of stricter rules (as captured by the number of patent families for "non-phthalate" and "phthalate free" inventions).

Ensuring a level playing field

The regulatory treatment of certain polymers would also bring various technologies onto a more 'level playing field'. For example, many polymers, particularly those with a lower molecular weight, are very similar to substances that already require registration under REACH and which have a comparable level of hazard and risk. For example, the addition of one monomer unit to a molecule may currently lead to a substance being exempted from the REACH registration requirements whereas the molecule with one fewer monomer units would require registration; often the difference in hazard properties would not differ much between the two substances.

There is therefore a non-level-playing-field between those substances that require registration at present, and those that do not because of the cut-off criteria regarding polymers under REACH, despite there often being comparable levels of hazard and risk close to that cut-off in particular. Registration (and subsequent Evaluation) would therefore help to manage the risks for those similar chemicals/polymers in a way that is already occurring for those which currently meet the criteria for registration under REACH. This primarily applies to "Type 1 PRRs".

5.4 Conclusions

5.4.1 Comparison of benefits and costs of registration of polymers

The data gaps reported in earlier sections make it difficult to draw direct, statistically robust comparisons between the costs and benefits from registering PRRs. Importantly, various costs and benefits could not be estimated quantitatively in terms of overall impacts.

In terms of costs and benefits for which quantified estimates have been derived, the previous sections highlight estimates that:

- For costs, mean values range from €2.5 billion (scenario 1) to €60 billion (scenario 4), with the latter encompassing registration of all polymers (not just PRR), and limited waiving of testing and the associated costs. Scenario 1 is the preferred scenario in this report but there is significant uncertainty around even the costs under scenario 1, with a range (between 5% and 95% probability) of €0.8 to €5.2 billion around the mean value of €2.5 billion.
- In terms of benefits, the total present value of damage costs avoided is estimated at €30 billion over 40 years, based on an assumed 11,000 unique polymers registered. Taking into account the uncertainties in the number of polymers that would be registered, the range of benefits is estimated at €14 to €52 billion. The estimate is also highly dependent on the exposed population and the value of damage costs avoided per substance; if the lower and higher values for these benefits are taken into account the range is much larger (€6 billion to €390 billion). All of these estimates relate to benefits under scenario 1.

Considering mean values for costs and the best estimate for benefits, the ratio of quantified benefits to costs through registration requirements for PRRs would be 12 (based on benefits due to the damage costs avoided from improved information on hazardous properties and risk management measures taken as a result).

Table 5.16 Ratio benefit to cost for various scenarios (quantified impacts only)

	Scenario 1 (mean)	Scenario 2 (mean)	Scenario 3 (mean)	Scenario 4 (mean)
Total industry (€m)	2,480 (800 – 5,210)	8,290 (2,870 – 16,770)	29,910 (6,730 – 66,740)	59,910 (13,560 – 134,420)
Total Member States (€m)	2 (1 - 4)	7 (3 - 11)	7 (3 - 11)	14 (7 - 23)
Total ECHA (€m)	39 (16 - 74)	132 (58 - 232)	131 (58 - 230)	263 (116 - 462)
Total costs of registration (excl. ECHA) (€m)	2,482 (801 - 5,214)	8,297 (2,873 - 16,781)	29,917 (6,733 – 66,751)	59,924 (13,567 – 134,443)
Total quantified present value benefits (€m)	30,313 (13,779 - 52,359)	30,313 (13,779 - 52,359)	30,313 (13,779 - 52,359)	30,313 (13,779 - 52,359)
Ratio (quantified) benefit/cost	12.2 (10.0 - 17.2)	3.7 (3.1 - 4.8)	1.0 (0.8 - 2.0)	0.5 (0.4 - 1.0)

Note that this table only includes quantified costs and benefits. There are important costs and benefits which could not be quantified which will affect the balance between costs and benefits. There are also numerous uncertainties as described in this report. For costs, the values presented are the mean average values and the ranges presented in parentheses represent the P95 and P5 percentile values of the outcome of the Monte Carlo analysis. For benefits, the ranges represent the estimates assuming the lower and upper bound of numbers of polymers registered (see Table 5.15). Note that in calculating the benefit/cost ratio, the lower estimates of benefits have been compared to the lower estimates of costs (and so on) as both depend on the assumed number of polymers that would be registered.

There are important costs that it was not possible to quantify at EU level. These include, for example, the costs of enhanced risk management measures to reduce risks for newly identified hazards (though note that some of those measures would be taken as a result of other legislation, not a registration requirement). Other costs that have not been quantified include the ongoing costs associated with keeping registration dossiers up to date (these costs are considered to be substantially smaller than the original registration costs), costs of enforcement activities; indirect costs from potential withdrawal of substances from the market; and costs of update/adaptation of IT tools.

Likewise there were also important benefits that it was not possible to quantify within the scope of this study, including the exclusion of certain health and environmental endpoints and effects, due to lack of appropriate methodologies at present. Note that it is assumed that these hazards/risks would still be identified through the registration process, even if it is not possible to quantify the benefits[160]. This does not imply that there is a corresponding additional cost, because the costs are already identified in the registration costs.

While these various costs and benefits that could not be quantified are important, it should be noted that the approach adopted in the current study is consistent (in terms of the costs and benefits that are quantified) with previous similar assessments for REACH.

There are also various uncertainties associated with these estimates including:

- For the costs, it is important to note that the estimates do not include costs of implementing risk management measures to address any concerns identified with managing the risks of those chemicals (e.g. measures in the workplace and/or to prevent release to the environment). These costs could be significant as noted in section 162.
- For the benefits, the estimates include only those that could be quantified. There would be other benefits – both in terms of reduced health/environmental impact (for avoided hazards/risks that are not covered in the assessment), as well as other benefits such as encouraging innovation in the chemicals industry and ensuring a level playing field. Even within the estimates presented above, there are very wide ranges of values.

Key conclusions in relation to the above include:

- The ratio of *quantified* benefits to costs is calculated to be greater than 1 for scenario 1, even taking into account the uncertainty ranges in estimated costs and benefits, and based on an approach to estimation of environmental benefits that is more conservative than previous assessments[161]. . As in every cost-benefit assessment of future measures, the quantified elements rely on assumptions and are an approximation. There are various important costs and benefits that could not be quantified. Taking into account the various non-quantified benefits and costs (see above), and that the majority of the costs of registration were quantified[162], these results suggest that there would be merit in introducing a registration requirement for a subset of polymers i.e. those identified as PRR in this study. However, it should be noted that the influence of these non-quantified benefits and costs upon the benefit to cost ratio was not estimated.
- The costs (and hence the benefit to cost ratios) are highly dependent on the ability to apply grouping approaches to polymers, and to ensuring a process of waiving of test data where it would clearly not be relevant to a polymer (e.g. given physicochemical properties) and of ensuring that approaches to read-across data from one polymer to another are well used.
- The selection of polymers for registration (PRR) in this study is expected to capture many or most of those polymers with potential for adverse effects on health or the environment. Some of these polymers will already be well-managed in their uses (in terms of health/environmental effects), while others may require additional risk management measures as a result of the new

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[160] This is because the range of health and environmental hazard endpoints considered is much wider than those that it was possible to quantify in the current study.

[161] Specifically taking the lower end of the range of environmental benefits, whereas previous assessments e.g. COM (2017) used the medium estimates, which would have given a much higher estimate of the overall benefits in this study.

[162] As set out in the REACH review (COM, 2018d), the main costs associated with REACH are understood to be in compiling registration dossiers and the associated fees that are payable. Both of these have been quantified in the present analysis. However, the current analysis (as with previous similar assessments for REACH) does not include a quantification of risk management measures introduced in the supply chain as a result of the registration requirement. The costs are therefore considered to represent a lower bound of the actual costs, although some of these risk management measures would be taken as a result of other legislation. Likewise, the estimates do not include costs of updating registration dossiers, but these are expected to be significantly lower than the costs of the initial registration process.

information generated through registration. As described above, based on current knowledge, there would be little merit in requiring registration for other (non-PRR) polymers. As such the benefits of requiring registration for a wider set of polymers may well be outweighed by the corresponding costs, as highlighted by the benefit-to-cost ratios above.

5.4.2 Critical uncertainties and assumptions

Critical uncertainties and assumptions affecting the results of this analysis – and which should be taken into account in further development of any policy to require registration of polymers – include:

Table 5.17 Critical uncertainties and assumptions for the cost and benefit assessment

Type of uncertainty	Implications for costs	Implications for benefits
The numbers of polymers on the market in the EU is not well known, and is also dependent on the definitions and grouping of polymers. Various estimates exist and these have been taken into account in the Monte Carlo simulation for estimation of the costs of registration.	A higher or lower number of polymers on the market in the EU would, in turn, result in a respectively higher or lower number of polymers that qualify as meeting the PRR criteria and number of registration dossiers, which would increase or decrease the level of registration costs.	A higher or lower number of polymers would, in turn, result in a respectively higher or lower number of PRRs with hazardous properties, which would lead to higher or lower annual damage cost avoided by the identification of one substance with those hazardous properties.
The numbers of polymers that would actually qualify as meeting the PRR criteria is unknown, as are the proportions that would qualify under each of the three PRR types. The estimates used here are based on limited data coupled with the expert judgement of the project team as well as inputs from various stakeholders consulted throughout the work.	A higher or lower number of polymers that qualify as meeting the PRR criteria would result in a respectively higher or lower number of registration dossiers, thereby increasing or decreasing the level of registration costs.	A higher or lower number of PRRs with hazardous properties, would lead to respectively higher or lower annual damage cost avoided by the identification of one substance with those hazardous properties.
The proportions of polymers within different tonnage bands is unknown and has a significant influence on the costs. The estimates used here are based on the proportions of substance registrations in each tonnage band for non-polymers.	Several costs items can increase or decrease with the tonnage band, e.g. costs of testing required, registration fees, submission costs, SIEF administrative costs, etc.	Assuming testing requirements are differentiated by tonnage band, additional testing if more polymers are within higher tonnage bands could reveal better information on hazards/risks, and allow improvement in measures to protect health and the environment. The opposite would be true if fewer polymers are within higher tonnage bands.
There is a relative lack of information in the public domain on the hazards and risks of polymers compared to other substances, and despite efforts to obtain such data in the current study, through extensive consultation and literature review, no definitive data was identified. In this report it is assumed (in the absence of better data) that, on average, polymers taken as a whole are in general of lower hazard and risk than non-polymer substances, but that those polymers that would qualify as PRR (assumed to be around 15% of the total) would on average have comparable hazard to non-polymer substances.	This does not directly affect the estimated costs.	If this assumption is incorrect, the ratio of benefits to costs could be significantly different e.g. if PRR are on average less hazardous than other substances, the ratio of benefits to costs would decrease. Likewise, if PRR are on average more hazardous than other substances, the ratio of benefits to costs would increase.

Type of uncertainty	Implications for costs	Implications for benefits
It is uncertain how many polymers meeting the PRR criteria already have datasets on relevant hazards and risks, due to a lack of available data.	More existing datasets on hazards and risks would reduce the costs of generating information and/or testing PRRs, thereby reducing the overall costs to register PRRs.	PRRs that already have datasets on relevant hazards and risks may already be well managed in their uses through appropriate risk management measures. This may reduce the potential for further health and environmental benefits to be realised. However, based on the information provided during the stakeholder consultation, it was concluded that it would only be a small proportion of PRRs that would have a complete dataset.
The number of registrations that would be required is highly dependent on the extent of grouping of polymers that would occur.	The number of registrations would have a major influence on estimated costs. Effective grouping is therefore essential to ensuring that the costs are proportionate to the benefits.	The extent of grouping is assumed to not substantially affect the requirement for (and costs of) risk management implemented as a result of registration.
The extent of additional testing that would be required to fulfil the registration requirements is another critical factor.	The extent to which test requirements could be waived where appropriate and the extent to which read-across amongst polymers is permitted will both significantly influence the ratio of benefits to costs.	The extent to which test requirements could be waived where appropriate and the extent to which read-across amongst polymers is permitted will both significantly influence the ratio of benefits to costs.
The cases and outcomes arising for each hazard endpoint, for each substance, are subject to significant uncertainty, reflecting the methodological challenges involved in estimating impacts of reduced exposure to chemicals. Likewise, the monetary values of avoiding those cases are methodologically challenging to estimate.	This does not directly affect the costs of registration.	Different assumptions for the number and types of cases/outcomes avoided per year per substance would influence the total benefits from registering PRRs.
The exposed population, i.e. number of workers exposed to PRR	This information would inform a potential quantification of the risk management measures.	A revision of the exposed population of workers to PRRs could lead to either higher or lower quantified benefits, depending on whether the population actually exposed is greater or smaller than that assumed in this report.

It may be possible to reduce some of these uncertainties in advance of introducing any requirement for registration of certain polymers. However, other data gaps and uncertainties may only be resolved once the data generated/submitted through registration becomes available.

Bibliography

AISE (2019). Development of criteria to identify and group polymers subject to registration under REACH. AISE Response, International Association for Soaps, Detergents and Maintenance Products, 1st July 2019.

AISE and EFRA Europe (2019). Cross-sectorial input on the proposed biodegradability derogation 3b) in the Annex XV restriction report for intentionally added microplastics – 16th May 2019. Drafter by AISE and IFRA Europe experts on microplastics biodegradability. AISE and EFRA Europe.

Ashford P (2018). The conundrum facing the European Union as it assesses potential options on polymers. Anthesis-Caleb.

Australian Government (2017). Implementing reforms to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Consultation Paper 5. Australian Government, June 2017. https://www.nicnas.gov.au/__data/assets/pdf_file/0004/50098/NICNAS-Reforms-CP5.pdf (accessed 26th February 2019).

Australian Government (2018a). Industrial Chemicals (General) Rules 2018. Exposure Draft. https://www.nicnas.gov.au/__data/assets/pdf_file/0011/65684/Industrial-Chemicals-General-Rules-2018-Exposure-Draft.pdf (accessed 2nd January 2019).

Australian Government (2018b). Consultation for: Categorisation Guidelines (Draft). Consultation finishes 31 May 2018. National Industrial Chemicals Notification and Assessment Scheme (NICNAS). https://www.nicnas.gov.au/__data/assets/pdf_file/0016/71521/Categorisation-Guidelines-DRAFT-March-9-2018-for-website.pdf (accessed 2nd January 2019).

Boethling R S and Nabholz J V (1997). Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, Hamilton, John D. and Sutcliffe, Roger (eds.), (1997) Van Nostrand Reinhold.

Bos JD and Meinardi M H M (2000). The 500 Dalton rule for the skin penetration of chemical compounds and drugs. Experimental Dermatology, **9**, 165–169.

Brandsch R (2017). Probabilistic migration modelling focused on functional barrier efficiency and low migration concepts in support of risk assessment. Food Additives Contaminants, **A 34**, 1743-1766.

Castellani F, Esposito A, Stanzione V and Altieri R (2016). Measuring the biodegradability of plastic polymers in olive-mill waste compost with an experimental apparatus. Advances in Materials Science and Engineering, Volume 2016, Article ID 6909283, 7 pages. Hindawi Publishing Corporation.

CEFIC LRI (2017). LRI ECO46: Improving the environmental (aquatic) hazard and risk assessment of cationic polymers. CEFIC-LRI Programme, European Chemical Industry Council. http://cefic-lri.org/request-for-proposals/lri-eco46-improving-the-environmental-aquatic-hazard-and-risk-assessment-of-cationic-polymers/ (accessed 29th October 2018).

CESIO (2017). CESIO Recommendations for the harmonized classification and labelling of surfactants. Brussels, March 2017. https://www.cesio.eu/images/content/CESIO_CL_Recommendations_Brochure_Updated.pdf (accessed on 9th September 2019).

CESIO (2019). Presentation by CESIO REACH and Polymers Task Force, 29th August 2019. CESIO Surfactants Europe.

COM (2003). Commission staff working paper "Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), establishing a

European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}", Extended Impact Assessment, {COM(2003)644 final}. https://ec.europa.eu/environment/chemicals/reach/pdf/background/eia_se_2003_1171.pdf.

COM (2007). Reference document on Best Available Techniques in the production of polymers. European Commission. August 2007. http://eippcb.jrc.ec.europa.eu/reference/BREF/pol_bref_0807.pdf (accessed 7th November 2018).

COM (2012). Review of REACH with regard to the registration requirements on polymers. Final Report. Part A: Polymers. 070307/2011/602175/SER/D3. Prepared for European Commission, 2012. Available at http://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/annexe1_study10.pdf

COM (2015). Technical assistance related to the review of REACH with regard to the registration requirements on polymer. Final Report. European Commission, 2015. Available at: https://ec.europa.eu/environment/chemicals/reach/pdf/FINAL%20REPORT%20POLYMER%20SI671025.pdf.

COM (2016). Cumulative Cost Assessment for the EU Chemical Industry, final report for the European Commission by Technopolis group. https://ec.europa.eu/docsroom/documents/17784/attachments/1/translations/en/renditions/pdf.

COM (2017). Impact Assessment of potential options, in particular possible amendments of REACH annexes, to modify requirements for registration of low tonnage substances (1-10t/year) and the CSA/CSR requirement for CMR substances in the framework of REACH. Final Report for the European Commission by Risk & Policy Analysts. Available at: https://op.europa.eu/en/publication-detail/-/publication/9380c012-055f-11e7-8a35-01aa75ed71a1.

COM (2018a). European Strategy for plastics in a circular economy. European Commission. http://ec.europa.eu/environment/circular-economy/pdf/plastics-strategy-brochure.pdf (accessed 30th July 2019).

COM (2018b). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. A European Strategy for Plastics in a Circular Economy. European Commission.

COM (2018c). Report from the Commission to the European Parliament and the Council on the impact of the use of oxo-degradable plastic, including oxo-degradable plastic carrier bags, on the environment. European Commission.

COM (2018d). Commission General Report on the operation of REACH and review of certain elements – Conclusions and Actions, COM(2018) 116 final.

COM (2018e). Third study on collecting most recent information for a certain number of substances with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC, methodological note. Available at: https://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=8224&furtherPubs=yes.

Cosmetic Ingredient Review Expert Panel (2002). Final Report on the Safety Assessment of Acrylates Copolymer and 33 Related Cosmetic Ingredients. International Journal of Toxicology, **21**(Suppl. 3), 1-50.

Cosmetic Ingredient Review Expert Panel (2011). Final Safety Assessment: Crosslinked alkyl acrylates used in cosmetics. Cosmetic Ingredient Review, Washing DC.

CSES (2015). Study monitoring the impacts of REACH on competitiveness, innovation and SMEs. http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations/en/renditions/native.

Cousins I T, Ng C A, Wang Z and Scheringer M (2019). Why is high persistence alone a major cause of concern? Environmental Science Processes and Impacts, 21, 781-792.

Danish Environmental Protection Agency (2013). Survey of PFOS, PFOA and other perfluoroalkyl and polyfluoroalkyl substances. Part of the LOUS-review. Environmental Project No. 1475, 2013. Danish Ministry of the Environment, The Danish Environmental Protection Agency. https://www2.mst.dk/Udgiv/publications/2013/04/978-87-93026-03-2.pdf (accessed 29th October 2019).

De Rosemond S J C and Liber K (2004). Wastewater treatment polymers identified as the toxic component of a diamond mine effluent. Environmental Toxicology and Chemistry, 23. 2234–2242.

ECETOC (2019). The ECETOC Conceptual Framework for Polymer Risk Assessment (CF4Polymers). Technical Report No. 133-1. European Centre for Ecotoxicology and Toxicology of Chemicals.

ECHA (2008). Guidance on information requirements and chemical safety assessment. Chapter R.6: QSAR and grouping of chemicals. European Chemicals Agency, May 2008.

ECHA (2012). Guidance for monomers and polymers. European Chemicals Agency, Version 2.0, April 2012.

ECHA (2016). Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC, 9 June 2016.

ECHA (2017a). Guidance on the application of the CLP criteria. Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures. Version 5.0, European Chemicals Agency, July 2017.

ECHA (2017b). Guidance for the identification and naming of substances under REACH and CLP. Version 2.1, European Chemicals Agency, May 2017.

ECHA (2017c). A study to gather insights on the drivers, barriers, costs and benefits for updating REACH registration and CLP notification dossiers, final report by Amec Foster Wheeler for the European Chemicals Agency. https://echa.europa.eu/documents/10162/22931011/study_drivers_and_obstacles_reach_clp_updates_en.pdf/

ECHA (2019a). Plastic additives initiative supplementary information on scope and methods 15.02.2019. European Chemicals Agency. https://echa.europa.eu/plastic-additives-initiative (accessed 30th July 2019).

ECHA (2019b). Annex XV restriction report. Proposal for a restriction: intentionally added microplastics. European Chemicals Agency, 22nd August 2019. https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/22921/term (accessed 24th September 2019).

EFSA (2016). Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials. EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids. EFSA Journal, **14,** 4357.

EFSA (2017). Note of guidance for the preparation of an application for the safety assessment of a substance to be used in plastic food contact materials. EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF). EFSA Journal 2008, **6**, 21r, 41pp. Adopted 31 July 2008, updated 23 March 2017.

Endes C, Camarero‐Espinosa S, Mueller S, Foster E J, Petri‐Fink A, Rothen‐Rutishauser B, Weder C and Clift M J D (2016). A critical review of the current knowledge regarding the biological impact of nanocellulose. Journal of Nanobiotechnology, **14**, 78.

Environment Canada and Health Canada (2014). Approach under the Canadian Environmental Protection Act, 1999 to address polymers on the Domestic Substances List that were identified as priorities during categorization. http://www.ec.gc.ca/ese-ees/42550DBF-1500-42ED-9891-4CB5255C8E22/Polymer%20Approach_EN.pdf (accessed 30th July 2019).

ERC (2019). Epoxy Resin Polymer Grouping. Identification and Testing Scheme. Confidential Presentation, July 2019. Epoxy Resin Committee, PlasticsEurope.

ERM (2018). Amino Resin Database and Study of Potential Polymer Hazards. Confidential Final Report. ERM GmbH, prepared for Formacare and Solvent Resin Manufactures (SRM) Sector Groups of CEFIC.

ESA (2019). ESA Response to Consultation. ESA_19.0381. European Seed Association.

Federal Register (1995). Premanufacture Notification Exemptions; Revisions of Exemptions for Polymers; Final Rule. Federal Register, Vol. 60, No. 60, pp16316-16336.

Fendinger N J (2000). Polydimethylsiloxane (PDMS): Environmental Fate and Effects. Organosilicon Chemistry IV. Edited by Norbert Auner and Johann Weis. WILEY-VCH Verlag GmbH, 2000.

Formacare (2019). Personal communication.

Gelbke H-P, Banton M, Block C, Dawkins G, Eisert R, Leibold E, Pemberton M, Puijk I M, Sakoda A and Yasukawa A (2019). Risk assessment for migration of styrene oligomers into food from polystyrene food containers. Food and Chemical Toxicology, **124**, 151-167.

Goodrich M S, Dulak L H, Friedman M A and Lech J (1991). Acute and long-term toxicity of water-soluble cationic polymers to rainbow trout (*Oncorhynchus mykiss*) and the modification of toxicity by humic acid. Environmental Toxicology and Chemistry, 10, 509-515.

Government of Canada (2005). Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers. Government of Canada, EPS M-688, 2005. http://publications.gc.ca/site/eng/280464/publication.html (accessed 2nd January 2019).

Government of Canada (2018). Second phase of polymer rapid screening. Results of the screening assessment. Government of Canada.

Groh K J, Backhaus T, Carney-Almroth B, Geueke B, Inostroza P A, Lennquist A, Leslie H A, Maffini M, Slunge D, Trasande L, Warhurst A M and Muncke J (2019). Overview of known plastic packaging-associated chemicals and their hazards. Science of the Total Environment, 651, 3253-3268.

Groh K J, Geueke B and Muncke J, 2017. Food contact materials and gut health: Implications for toxicity assessment and relevance of high molecular weight migrants. Food Chemistry and Toxicology, **109**, 1-18.

Haider T P, Vöçlker C, Kramm J, Landfester K, and Wurm F R (2019). Plastics of the future? The impact of biodegradable polymers on the environment and on society. Angew. Chem. Int. Ed., 58, 50–62.

Henry B J, Carlin J P, Hammerschmidt J A, Buck R C, Buxton L W, Fiedler H, Seed J and Hernandez O, 2018. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integrated Environmental Assessment and Management, 2018, 316–334

HERA (2003). Human and environmental risk assessment on ingredients of European household cleaning products. Alcohol ethoxysulphates (AES). Edition 1, January 2003. https://www.heraproject.com/RiskAssessment.cfm (accessed 29th October 2018).

HERA (2004). Human and environmental risk assessment on ingredients of European household cleaning products. Alcohol ethoxysulphates (AES). Environmental Risk Assessment. June 2004. https://www.heraproject.com/RiskAssessment.cfm (accessed 29th October 2018).

HERA (2009). Human and environmental risk assessment on ingredients of European household cleaning products. Alcohol ethoxylates. Version 2.0, September 2009. https://www.heraproject.com/RiskAssessment.cfm (accessed 15th October 2018).

HERA (2014a). Human and environmental risk assessment on ingredients of European household cleaning products. Polycarboxylates used in detergents (Part I). Polyacrylic acid homopolymers and their sodium salts (CAS 9003-04-7). Version 3.0, January 2014. https://www.heraproject.com/RiskAssessment.cfm (accessed 4th November 2018).

HERA (2014b). Human and environmental risk assessment on ingredients of European household cleaning products. Polycarboxylates used in detergents (Part II). Polyacrylic/maleic acid copolymers and their sodium salts (CAS 52255-49-9). Version 3.0, January 2014. https://www.heraproject.com/RiskAssessment.cfm (accessed 4th November 2018).

Holm M, Dahlman-Höglund A and Torén K (2011). Respiratory health effects and exposure to superabsorbent polymer and paper dust – an epidemiological study. BMC Public Health, 11, 557. http://www.biomedcentral.com/1471-2458/11/557 (accessed 25th February 2019).

IVM Institute for Environmental Studies (2015). Benchmark development for the proportionality assessment of PBT and vPvB substances - a report for the Dutch Ministry of Infrastructure and the Environment; http://echa.europa.eu/documents/10162/13647/R15_11_pbt_benchmark_report_en.pdf.

JRC (2010). Applicability of generally recognised diffusion models for the estimation of specific migration in support of EU Directive 2002/72/EC. C Simoneau (Ed.). JRC Scientific and Technical Report EUR 24514 EN 2010, Joint Research Centre, European Commission.

JRC (2015). Practical guidelines on the application of migration modelling for the estimation of specific migration. In support of Regulation (EU) No 10/2011 on plastic food contact materials. Eddo J. Hoekstra (Ed.), Rainer Brandsch, Claude Dequatre, Peter Mercea, Maria-Rosaria Milana, Angela Störmer, Xenia Trier, Olivier Vitrac, Annette Schäfer and Catherine Simoneau. JRC Technical Report, Joint Research Centre, European Commission.

Eddo J. Hoekstra (Ed.), Rainer Brandsch, Claude Dequatre, Peter Mercea, Maria-Rosaria Milana, Angela Störmer, Xenia Trier, Olivier Vitrac, Annette Schäfer and Catherine Simoneau"

Kuboi T and Fujii K (1984). Toxic ity of cationic polymer flocculants to higher plants. Soil Science and Plant Nutrition, 30, 311-320.

Li J, Yu F, Chen U and Oupický D (2015). Polymeric drugs: Advances in the development of pharmacologically active polymers. Journal of Controlled Release, 219, 369–382.

Lithner D, Larsson Å and Dave G (2011). Environmental and health hazard ranking and assessment of plastic polymers based on chemical composition. Science of the Total Environment, 409, 3309-3324.

MAK (2001). Acrylic acid polymer, neutralized, cross-linked. Occupational Toxicants, Vol. 15 (2001). The MAK-collection for occupational health and safety: Annual thresholds and classifications for the workplace. Wiley-VCH Verlag GmbH & Co. KGaA. https://onlinelibrary.wiley.com/doi/abs/10.1002/3527600418.mb900301nete0015 (accessed 25th February 2019).

NICNAS (2018). Nonylphenol ethoxylates and their sulfate and phosphate esters: Environment tier II assessment. National Industrial Chemicals Notification and Assessment Scheme, Australian Government. https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-ii-environment-assessments/environment-tier-ii-assessment-for-nonylphenol-ethoxylates-and-their-sulfate-and-phosphate-esters#Preface (accessed 4th November 2018).

OECD (1992). OECD 203: Fish, acute toxicity test. OECD Guideline for the testing of chemicals. Adopted 17.07.92, Organisation for Economic Co-operation and Development. https://www.oecd-ilibrary.org/environment/test-no-203-fish-acute-toxicity-test_9789264069961-en (accessed 14th November 2018).

OECD (2004). OECD 202: Daphnia sp., acute immobilisation test. OECD Guidelines for the testing of chemicals. Adopted 13.04.2004, Organisation for Economic Co-operation and Development. https://www.oecd-ilibrary.org/environment/test-no-202-daphnia-sp-acute-immobilisation-test_9789264069947-en (accessed 14th November 2018).

OECD (2009). Data analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern. Organisation for Economic Co-operation and Development, ENV/JM/MONO(2009)1, 27th January 2009.

OECD (2011). OECD 201: Freshwater alga and cyanobacteria, growth inhibition test. OECD Guidelines for the testing of chemicals. Adopted 23.03.2006, Annex 5 corrected 80.07.2011, Organisation for Economic Co-operation and Development. https://www.oecd-ilibrary.org/environment/test-no-201-alga-growth-inhibition-test_9789264069923-en (accessed 14th November 2018).

OECD (2014). Guidance on grouping of chemicals. Series on Testing and Assessment No. 194, Second Edition, ENV/JM/MONO(2014)4, 14.04.2014, Organisation for Economic Co-operation and Development. http://www.oecd.org/publications/guidance-on-grouping-of-chemicals-second-edition-9789264274679-en.htm (accessed 3rd December 2018).

Oldring P K T, O'Mahony C, Dixon J, Vints, M, Mehegan, J, Dequatre, C and Castle L (2017). Development of a new modelling tool (FACET) to assess exposure to chemical migrants from food packaging. Food Additives and Contaminants - Part A Chemistry, Analysis, Control, Exposure and Risk Assessment, 31, 444–465.

OSPAR (2014). OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF) as amended OSPAR Recommendations 2010/3 & 2014/17. https://www.ospar.org/documents?d=33027 (accessed 29th July 2019).

OSPAR (2015). OSPAR Guidelines for Completing the Harmonised Offshore Chemical Notification Format (HOCNF), (OSPAR Agreement: 2012/05. Update 2015. https://www.ospar.org/documents?d=33043 (accessed 29th July 2019).

PlasticsEurope (2018). Plastics – the facts 2018. PlasticsEurope.

PlasticsEurope (2019a). Data compilation for the toxicological assessment of cyclic oligomers of polyamide-6,6. Personal Communication.

PlasticsEurope (2019b). Support for the development of criteria to identify a group polymers subject to registration for Registration under REACH through data on polymer groups collected at sector level. Personal Communication.

RPA (2003). Revised business impact assessment for the consultation document, Working Paper 4, Assessment of the Business Impacts of New Regulations in the Chemicals Sector – Phase 2, report by Risk & Policy Analysts for the European Commission, Enterprise Directorate-General.

Rowland C D, Burton Jr G A and Morrison S M (2000). Implication of polymer toxicity in a municipal wastewater effluent. Environmental Toxicology and Chemistry, 19, 2136–2139.

USEPA (1997). Polymer exemption guidance manual. United States Environmental Protection Agency, EPA 744-B-97-001, June 1997. https://www.epa.gov/sites/production/files/2015-03/documents/polyguid.pdf (accessed 21st November 2018).

USEPA (2010). 40 CFR Part 723. Premanufacture Notification Exemption for Polymers; Amendment of Polymer Exemption Rule to Exclude Certain Perfluorinated Polymers. United States Environmental Protection Agency. Federal Register, Vol. 75, No. 17, January 27, 2010, p4295-4305.

USEPA (2012). Methodology document for the Ecological Structure-Activity Relationship Model (ECOSAR) Class Program. Estimating toxicity of industrial chemicals to aquatic organisms using the ECOSAR (Ecological Structure Activity Relationship) Class Program. MS-Windows Version 1.11. Contributors: K Mayo-Bean, K Moran, B Meylan and P Ranslow. United States Environmental Protection Agency, Syracuse Research Corporation and Consortium for Environmental Risk Management, May 2012. https://www.epa.gov/sites/production/files/2015-09/documents/ecosartechfinal.pdf (accessed 14th November 2018).

USEPA (2013). Interpretive Assistance Document for Assessment of Polymers. Sustainable Futures Summary Assessment. United States Environmental Protection Agency, updated June 2013. https://www.epa.gov/sites/production/files/2015-05/documents/06-iad_polymers_june2013.pdf (accessed 31st October 2018).

USEPA (2018). Overview: Office of Pollution Prevention and Toxics Laws and Programs. United States Environmental Protection Agency.

Vanholder R, (2012) Reimbursement of Dialysis: A Comparison of Seven Countries, https://jasn.asnjournals.org/content/jnephrol/23/8/1291.full.pdf.

Yang N J and Hinner M J (2015). Getting across the cell membrane: An overview for small molecules, peptides, and proteins. Methods in Molecular Biology, 1266, 29–53.

Zohuriaan-Mehr M J and Kabiri K (2008). Sperabsorbent polymer materials: A review. Iranian Polymer Journal, 17, 451-477.

Appendix A
Survey questionnaire

PRRs under REACH
Online Survey

Polymers of concern under REACH

Online survey

Scientific and technical support for the development of criteria to identify and group polymers of concern for Registration/ Evaluation under REACH and their impact assessment

Introduction

While REACH aims to ensure a high level of protection of human health and the environment through provisions for chemicals concerning their Registration, Evaluation, Authorisation or Restriction, the regulation does currently not specify any requirements for Registration or Evaluation of polymers. Article 138(2) of REACH asks the Commission to review this.

Two previous studies were completed in 2012 and 2015 for the European Commission on the issue; additionally, at international level the OECD completed its own review in 2009 intended to define criteria and approaches for polymers of low concern (PLC). The three previous studies have highlighted the challenges in identifying 'polymers of concern', largely due to scarcity of public data. While the previous reports provide a good foundation for the identification of PLC polymers and a mechanism for implementation within EU policy, the other end of the spectrum is not well described.

Wood, together with Peter Fisk Associates, have been contracted by the European Commission (DG ENV unit B2) to:

- **Propose criteria for the identification of polymers of concern (PoCs), including possibility of grouping PoCs, based on physico-chemical properties and/or indication of hazard;**
- **Estimate the potential risks to human health and the environment posed by polymers of concern in comparison with other substances;**
- **Test and validate assumptions in a workshop;**
- **Provide a detailed cost-benefit analysis of the registration requirements that can be used by the European Commission in a subsequent impact assessment.**

The study will present conclusions and serve as evidence to the European Commission for a possible future impact assessment. Therefore, the collection of data and information constitutes a critical part of the study. Our project team will consult a wide range of stakeholders in order to obtain evidence-based information. We would appreciate your participation and cooperation to ensure a high-quality study.

Overview of the questionnaire

This questionnaire covers:

- **Information about you.**
- **Questions on defining polymers of concern, registration requirements, naming and grouping of polymers and costs and benefits.**
- **Final question**

Please complete all of the sections/ questions that you are able to. Where you are not able to answer any of the questions – either for lack of data or because it is not relevant to your organisation – there is no need to provide a response. Where answers are uncertain, an estimate is more useful than no information at all. Where annual data is provided, please state the year, source and where relevant, please state the currency used in your answers.

If you would prefer to discuss the questionnaire over the phone rather than draft a written response do not hesitate to contact us. We would also welcome any additional supporting documentation you are able to provide.

Any question?

Please submit your response by 08 April 2019. If you have any question, please get in touch with Kastalie Bougas (kastalie.bougas@woodplc.com) and Gillian Federici (gillian.federici@pfagroup.eu).

Polymers of concern under REACH

Part A. About you

We recognise that some of the information you will provide might be commercially sensitive. We are committed to treat such data in an appropriate manner:

- We will make anonymous all information relevant to specific organisations in our reporting.

- We will not pass on information provided to any other party without your expressed permission.

- We will present uncertainty ranges in reported data in order to avoid disclosing market-sensitive information where fewer than three organisations have provided quantitative information.

- Where possible, we will aggregate any absolute figures provided to ensure individual organisations are not identifiable.

* 1. Please provide the following information:

Name and surname ☐

Organisation ☐

Country ☐

Email Address ☐

* 2. Please indicate the type of organisation you represent:

○ Member State Competent Authority

○ EU institution or agency

○ Other public sector (e g international organisation)

○ Business operator

○ Non Governmental Organisation

○ Other (academia think tank consultancy etc)

If you answered 'other' please specify

☐

3. If business operator: what is the size of your business?

○ Micro firm (0-9 employees)

○ Small firm (10-49 employees)

○ Medium firm (50-249 employees)

○ Large firm (over 250 employees)

If you are a large company, how many employees, are there in your organisation? A rough estimate is enough

4. If business operator: please indicate the average turnover (in EUR) of the organisation you are considering for this questionnaire – a rough estimate is enough.

Polymers of concern under REACH

Part B. General questions & scope

This study should not duplicate requirements for substances which are already included in REACH for registration. The table below highlights key substances for this project (polymer, monomer, unreacted monomer, additive, impurity, etc.) and indicates whether those are in the scope of this study.

Term	In scope of study
Monomer	No
Polymer	Yes
Additives / stabilisers in the manufacturing process	Yes
Additives / stabilisers, not necessary for preserving the stability of the polymer	No
Impurities	Yes
Unreacted monomers	No
Mixture / article	No
Imported polymers	No for monomers. Yes for additives, stabilisers added during the manufacturing process.
Microplastics	Yes. There will not be an approach specific to microplastics, i.e. no specific considerations will be developed in relation to particle size when developing the requirements for PoCs. Therefore, polymers produced in microparticle size will be in the scope but microplastics generated through the breakdown in the environment of larger plastics are outside the scope of the report.

Polymers of concern under REACH

B1. Defining polymers of concern

5. According to REACH article 138(2), the Commission is considering ways to extend registration to certain types of polymers, to ensure that polymers are treated in the same way as other substances and taking account of the protection of human health and the environment. Do you think this is the right thing to do?

○ Yes

○ No

○ I don't know

Why?

6. The estimation of the risks posed by polymers of concern in comparison with other chemicals is currently limited in its extent owing to the lack of useable data. The analysis carried out so far by the project team suggests that, in terms of numbers and types of classification and labelling, polymers of concern may present similar hazards as other chemicals but there are large uncertainties associated with the available data. Do you agree with this?

○ To a large extent

○ To some extent

○ To no extent

○ I don't know

Why?

7. The following hazards have been identified so far for at least some polymers. Are you aware of any other hazards or risks known to be associated with polymers? These should relate to the polymer itself rather than additives or unreacted monomers.

Table: Hazards of polymers related to the polymer itself rather than additive or unreacted monomer.

Examples of types of polymers with known or suspected hazards	Comment
Polymers with relevant hazard classifications under the Classification and Labelling (CLP) Regulation	Classification should relate to the polymer itself rather than additives or unreacted monomer.
Cationic polymers	May be associated with hazards to the environment if water soluble or water dispersible.
Anionic polymers	May be associated with hazards to the environment if water soluble or water dispersible.
Amphoteric polymers	May be associated with hazards to the environment if water soluble or water dispersible.
Nonionic polymers with surface-active properties	May be associated with hazards to the environment if water soluble or water dispersible.
Polymers containing low molecular weight oligomers	Hazards may be associated with oligomers with molecular weights <1000 Da and in particular <500 Da.
Polymers with reactive functional groups	
Others	For example, some types of degradable polymers may lead to formation of substances more hazardous than the polymer.

○ Yes

○ No

If yes please explain

8. Are you aware of any publications that address the health/environmental hazards or risks from polymers and/or the exposure to those hazards or risks?

Case examples of particular polymers would be particularly valuable, e.g. case examples associated with polymers leading to protective measures in the workplace?

Can you provide any link, references or example cases for those below? These should relate to the polymer itself rather than additives or unreacted monomers.

You can upload documents in the next question, using the upload button.

9. Please upload here any document relevant to the previous question.

Choose File   No file chosen

10. Are there any difficulties with the identification of the suggested hazards (e.g. determination of molecular weight distributions etc., applicability to inorganic polymers)?

○ Yes

○ No

○ I don't know

If yes, which are the main difficulties, according to you, in identifying these hazards for polymers?

11. Please upload here any document relevant to the previous question.

Choose File   No file chosen

12. Can you provide normal and/or extended safety data sheets for any polymers you have identified that are considered to be hazardous, whether the classification and labelling on the SDS is based on a) experimental data on the whole polymer and/or b) the classification and labelling of its constituent using the mixture method?

These should relate to the polymer itself rather than additives or unreacted monomers, and will help us identify polymer hazards and gather information on polymer properties etc.

Note that we will treat any confidential and sensitive company-specific data in confidence. As noted in the introduction of this survey, any information provided will be anonymised and presented with uncertainty ranges. Data provided from individual organisations will not be identifiable.

○ Yes

○ No

Comment

13. If you answered yes to the previous question, are you able to indicate whether the classification and labelling on the SDS sheet is based on:

○ Experimental data on the whole substance

○ The classification and labelling of its constituents using the mixture method

○ Both the previous two

○ I don't know

○ Other

14. Please upload here any document relevant to the previous question.

Choose File No file chosen

15. Concerning the bioavailability / systemic availability of polymers, is there a molecular weight cut-off **or any other physical principle** that is different to the molecular weight cut-off for the bioavailability / systemic availability for non-polymers, as identified in the literature?

○ Yes

○ No

○ I don't know

If yes which?

16. By which methods would you measure the molecular weight distribution of a polymer? Please provide any link or references to publications which address the topic.

Polymers of concern under REACH

B2. Registration requirements

17. With the objective to register and evaluate polymers of concern under REACH, are there hazards specific to polymers which are not covered in the registration requirements for substances under REACH Annexes VII to X?

○ Yes

○ No

○ I don't know

If yes, which?

18. If you answered yes to the previous question, are you aware of experimental guidelines that can be used to assess these properties?

○ Yes

○ No

○ I don't know

If yes, which?

19. Are there properties covered in REACH Annexes VII to X which are of no relevance to polymers?

○ Yes

○ No

○ I don't know

If yes, which?

20. In consortia for registration, what Confidential Business Information (CBI) issues would be faced that are specific to polymers and different from non-polymeric substances?

21. Will current exposure modelling methods used for non-polymeric substances be usable for polymers?

○ Yes

○ No

○ I don't know

Please explain your answer

B3. On naming and grouping polymers

22. Is there an existing nomenclature system to describe and name polymers accurately and concisely?

○ Yes

○ No

○ I don't know

If yes which?

23. Are you aware of any literature (e.g. report, study, academic paper, press release, etc.) about **how to describe and name polymers accurately and concisely**?

○ Yes

○ No

If so can you provide links or references?

24. Are you aware of any literature (e.g. report, study, academic paper, press release, etc.) about **how to assess polymer sameness that would support with collaboration for registration**?

○ Yes

○ No

If so can you provide links or references?

25. What are the ways to group polymers in respect to hazardous properties? Is this possible based on compositional chemistry, physical form, use patterns etc.?

26. The project team is currently considering the following grouping method for polymers of concern. Are you aware of any other grouping methods that could be used for registration purposes?

Basis for grouping	**Possible approaches**	
Similarity of hazards	Common low molecular weight oligomers and/or impurities. This may be related to the similarity of the product on process chemistry.	
	Common reactive functional group(s).	
	Ionicity, for example	Cationic polymers with common cationic group(s)
		Polymers with common group(s) that can, or can be expected to, become cationic in a natural environment
		Anionic polymers with common anionic group(s)
		Polymers with common group(s) that can, or can be expected to, become cationic in a natural environment
		Amphoteric polymers with common cationic and anionic group(s)
		Polymers with common group(s) that can, or can be expected to, become cationic and anionic in a natural environment
		Nonionic polymers with surface active properties with common nonionic groups
Similarity of use	In some cases, polymers with similar uses may be similar in terms of properties.	

○ Yes

○ No

If yes, which?

27. Do you think an inquiry type or pre-registration type system [1] would be a suitable initial step towards polymer registration? Note: Companies planning to register a non-polymeric substance have a duty to inquire with ECHA whether a registration has already been submitted for that substance.

More on inquiry: [1] https://echa.europa.eu/regulations/reach/registration/data-sharing/inquiry

○ Yes

○ No

○ I don't know

Please explain your answer

28. Would the inquiry process need to be modified for polymers?

○ Yes

○ No

○ I don't know

Please explain your answer

Polymers of concern under REACH

B4. Costs and benefits

The issue of costs and benefits are key elements in the elaboration of registration requirements for polymers of concern.

There is no comprehensive monetisation and/or quantification of costs and benefits of registration under REACH. However, there are different sources of data that can be used to estimate the costs of registration under REACH from previous Commission’s studies or ECHA general reports. For benefits, there are fewer data sources available, which reflect the difficulty of estimating benefits.

Quantification is subject to some shortcomings and knowledge gaps. This consultation provides an important opportunity to fill the existing gaps. Based on the preliminary results, we identified the following information gaps that we would like to fill in order to more accurately estimate costs and benefits: the number and/or tonnage of hazardous polymers on the EU market, the predicted number of polymers of concern with specific hazardous properties, the number of polymers of concern with different levels of information by hazard property, etc.

The section below shows the available evidence identified so far, including specific figures that will allow us to quantify/monetise/qualify the costs and benefits from registration of polymers of concern - subject to refinement based on the results of the consultation.

29. Are you aware of estimates of the total number and/or tonnage of **all polymers** on the EU market (if yes, please specify the unit, the year of reference, whether produced in the EU and/or imported to the EU)?

○ Yes

○ No

If yes, which?

30. Are you aware of estimates of the number and/or tonnage of **hazardous polymers** (according to CLP) on the EU market (produced in the EU and/or imported to the EU) or elsewhere?

○ Yes

○ No

If yes, which?

31. Are you aware of estimates of the number and/or tonnage of **polymers within the following groups** on the EU market (produced in the EU and/or imported to the EU) or elsewhere?

- Cationic polymers (water soluble or dispersible).
- Anionic polymers (water soluble or dispersible).
- Amphoteric polymer (water soluble or dispersible).
- Nonionic polymers with surface-active properties.
- Polymers containing low molecular weight (<1000 Da) oligomers or impurities.
- Polymers with hazardous reactive functional groups.
- Polymer with a high exposure potential (environment or consumers).

○ Yes

○ No

If yes, which?

32. If not, how best should this be done (i.e. providing estimates of the number and/or tonnage of hazardous polymers – as total or by group presented above – according to CLP on the EU market)?

33. Based on the current registration system for other (non-polymer) chemical substances under REACH, to what extent do you think the costs of registering polymers of concern would be proportionate given the benefits that would be achieved?

○ The costs are likely to be proportionate to the benefits **to a large extent**

○ The costs are likely to be proportionate to the benefits **to some extent**

○ The costs are **not** likely to be proportionate to the benefits

○ I don't know

Please explain your answer

34. Are you aware of any information on the following elements:

The predicted number of polymers of concern by specific hazard classes according to CLP on the EU market

The number of polymers of concern with different levels of information by hazard property on the EU market

With test information on all REACH annex V endpoints
With test information on skin and eye corrosion irritation and acute oral toxicity only
Without test information

Other available data you are aware of and of relevance to this exercise (on the EU market)

35. Do you have any suggestions to make the registration of polymers of concern efficient, i.e. minimising costs while increasing the benefits related to their registration?

○ Yes

○ No

Please explain your answer

36. Are the OECD Test Guidelines on endpoints for non-polymeric substances applicable to polymers?

○ Yes

○ No

○ I don't know

Please explain your answer

37. The link below shows costs available in the literature. Could you please indicate whether you think these are good estimates for each of the cost categories?

See available cost assumptions

○ The attached costs figures are very good estimates

○ The attached costs figures are good estimates

○ The attached costs figuresare not got estimates

If you are aware of a better estimate, could you please provide this information / a link / a reference below

38. Are you aware of any information covering the costs of testing and information gathering under REACH annexes VIII, IX and X?

○ Yes

○ No

If yes, which?

39. If you are a Member State Competent Authority: how many effective working days per year are spent on the following activities under REACH?

Enforcing registration requirements

Examining testing proposals submitted by registrants

Running compliance check of the dossiers submitted by registrants

Evaluating substances

40. Do you have any information on the following **benefits that could be expected from the registration of polymers of concern**?

Impact avoided i e diseases/disorders avoided per substance registration

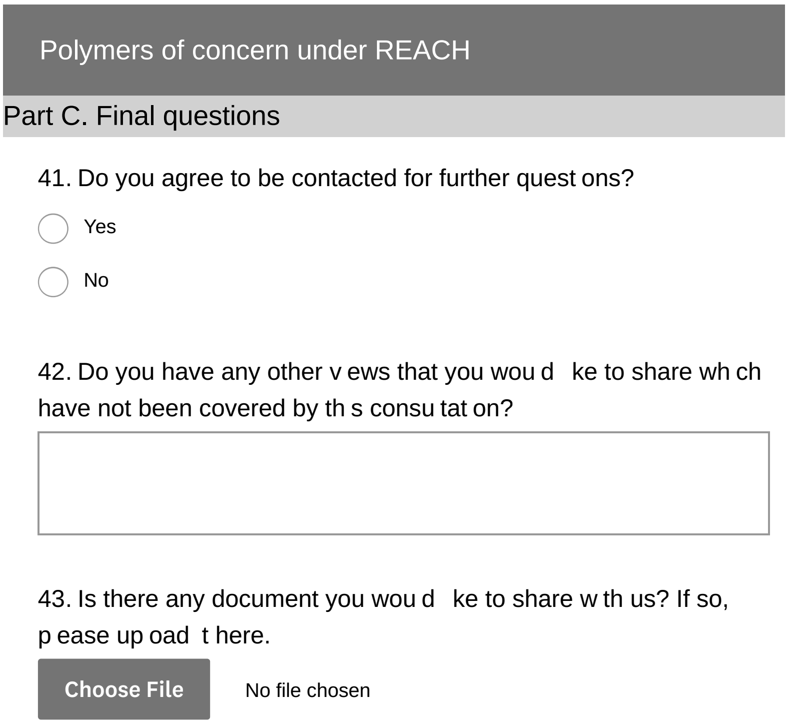
Impact avoided i e reduced environmental impact per substance registration

Increased availability of information on polymers of concern

Innovation processes within companies searching for new and better solutions

Level playing field with non polymeric substances

Other benefits


Polymers of concern under REACH

Part C. Final questions

41. Do you agree to be contacted for further questions?

○ Yes

○ No

42. Do you have any other views that you would like to share which have not been covered by this consultation?

☐

43. Is there any document you would like to share with us? If so, please upload it here.

Polymers of concern under REACH

Thank you!

Thank you very much for taking the survey. If you have any question or additional comment, please get in touch with Kastalie Bougas (Kastalie.bougas@woodplc.com) and Gillian Federici (gillian.federici@woodplc.com).

Appendix B
Workshop report

Workshop report

European Commission, ENV B.2 – Sustainable Chemicals

Scientific and technical support for the development of criteria to identify and group polymers requiring Registration/ Evaluation under REACH and their impact assessment

Workshop Report

Views expressed in this workshop report are from participants attending the workshop on 'polymers requiring registration under REACH' (21-22 May 2019) and do not represent the opinions from the European Commission nor the project team. The content and conclusions of the final study report will take into account the workshop conclusions and further stakeholder consultation. These conclusions may therefore vary from those presented at the workshop.

This Workshop Report has been prepared by Amec Foster Wheeler Environment & Infrastructure GmbH which is now part of John Wood Group plc (known as Wood) and is hereinafter referenced by our brand name Wood

Report for

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Document revisions

No.	Details	Date
1	Workshop Report	12/06/2019
2	Revised Workshop Report	15/07/2019

Contents

1. Introduction

1.1 Workshop background

This document provides a summary of the content and outcomes of the stakeholder workshop held in Brussels on 21 and 22 May 2019 for the study on support for the development of criteria to identify and group Polymers Requiring Registration under REACH and their impact assessment. The study is being led by Wood and PFA, as contractors to the European Commission. This report is provided for internal use by the Commission.

Polymers are currently exempt from the provisions on registration of Title II of the REACH regulation (Article 2(9)). However, Article 138(2) of REACH placed an obligation for a further review of polymers and comparison of the risks compared to other substances. Two previous studies for the European Commission were completed on the issue, in 2012[1] and 2015[2]. Additionally, at international level, the OECD[3] completed its own review in 2009 intended to define criteria and approaches for polymers of low concern (PLC).

The three previous studies have highlighted the challenges in identifying which polymers may require registration under REACH, largely due to data scarcity and lack of methodology regarding criteria for registration. While the previous reports provide a good foundation for the identification of polymers of "low concern" (PLC) and a mechanism for implementation within EU policy, the other end of the spectrum is not well documented (i.e. amongst those polymers that are potentially not of 'low concern', which may be appropriate for registration). The 2012 report makes clear that the cost burden between medium (<10 t) and high tier (>1000 t) REACH registration requirements is significant and therefore there is an imperative need to better understand and manage any requirements for registration of polymers in a cost-effective way that limits the burden on industry, but which provides a high level of protection for human health and the environment.

The study terms of reference refer to "polymers of concern" (PoC) being those that may be suitable for registration. However, this terminology may cause confusion. Therefore, the term '**polymers requiring registration' (PRR)** is used in the rest of this document to indicate the polymers that could be candidates for registration under REACH.

Based on previous work to date and current understanding of how polymers are managed under EU legislation, the overall study has the following objectives:

- **Task 1** – Propose criteria for the identification of PRR, including the possibility of grouping PRR, based on physicochemical properties and/or indication of hazard.
- **Task 2** – Assess appropriate registration requirements for PRR under REACH;
- **Task 3** – Test and validate assumptions in a workshop; and
- **Task 4** – Provide a detailed cost-benefit analysis of the registration requirements that could be used by the Commission in a subsequent impact assessment.

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[1] European Commission (2012), Review of reach with regard to the registration requirements on polymers, http://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study10.pdf

[2] European Commission (2015) Technical assistance related to the review of REACH with regard to the registration requirements on polymers. Final report. http://ec.europa.eu/environment/chemicals/reach/pdf/FINAL%20REPORT%20POLYMER%20SI671025.pdf

[3] OECD (2009), Data analysis of the identification of correlations between polymer Characteristics and potential for health or ecotoxicological concern

The project also includes several consultation activities, including an online survey, an advisory group (with ca. 20 experts from European institutions, industry, international organisations, non-governmental organisations, etc.) as well as interviews and meetings with stakeholders.

It should be noted that substances already covered currently by REACH are not in the scope of this study. **Table 1 below describes substances which are to be included in the study and those which are out of scope (e.g. already covered by REACH).**

Table 1 Substances covered by the scope of the study and those which are not to be included

Substance	Coverage under REACH	Included in the study?
Monomer	Covered under REACH article 6(3).	No
Polymer	Exempted from REACH registration.	Yes
Additives / stabilisers in the manufacturing process	These stabilisers are considered to be part of the substance (article 3(1)) and do not have to be registered separately.	Yes
Additives / stabilisers, not necessary for preserving the stability of the polymer	When a polymeric material contains such substances, it should be considered as a mixture or an article. For such substances normal registration requirements apply.	No
Impurities	These impurities are considered to be part of the substance and do not have to be registered separately.	Yes
Unreacted monomers	Both the reacted monomers and unreacted monomer should be covered in the same registration dossier for that monomer substance.	No
Mixture / article	When a polymeric material contains such substances it should be considered as a mixture or an article, as the case may be. For such substances normal registration requirements apply.	No
Imported polymers		Yes for polymers No for monomers Yes for additives, stabilisers added during the manufacturing process.
Microplastics		There will not be an approach specific to microplastics, i.e. no specific considerations will be developed in relation to particle size when developing the requirements for PRR. Therefore, polymers produced in microparticle size will be in the scope but microplastics generated through the breakdown in the environment of larger plastics are outside the scope of the report.

1.2 Purpose of the workshop

The workshop on PRR is part of Task 3 of the study and is an integral part of the overall consultation process. The objective of the workshop was to gather expert stakeholder inputs on how to develop criteria to identify and group polymers potentially requiring Registration under REACH; to discuss what the proposed Registration requirements may comprise; and to get a better idea of costs and benefits of doing so.

The discussion was focussed on four key topics: developing criteria to identify and group polymers for Registration/Evaluation under REACH; Registration requirements and testing strategies; approaches to name/group polymers; and costs and benefits data. These topics were discussed in break out groups facilitated by the project team. The workshop brought together representatives from the European Commission, Member State officials, industry and NGOs. The agenda for the workshop is included in Appendix A.

Desired outcomes from this workshop were:

- To review and refine the proposed criteria for the identification of PRR
- To review potential Registration requirements for PRR, including testing strategies
- To consider the potential for grouping approaches, including the approach to be followed for substance identification of polymers;
- To contribute ideas about systems for handling information, sharing data on PRR, including Confidential Business Information.
- To confirm or gather new evidence in terms of costs and benefits from registering PRR.

Thought starter

A Thought Starter was circulated to all participants ahead of the workshop as a means of encouraging discussion. The Thought Starter provided:

- An overview of preliminary findings of the study;
- A list of discussion points to be covered during the workshop;
- A detailed appendix A on possible criteria for the identification of Polymers Requiring Registration;
- A detailed appendix B on costs data obtained so far;
- A list of abbreviations used in the project so far.

1.3 Workshop participants

Approximately 59 stakeholders attended the workshop. Stakeholders were admitted to the workshop based on type (i.e. authority, industry, NGO, trade association) to ensure a good representation of different perspectives on the day. A full list of the participants is included in Appendix B.

An indicative breakdown of the stakeholders who attended is included below in Table 1.1.

Table 1.2 Breakdown of workshop participants by stakeholder type

Breakdown of participants by stakeholder type	**%**
Industry	37%
Authorities	18%
Project team	10%
Trade Association	17%
NGO	10%
European Commission	8%
Total	N=59

1.4 Description of breakout session themes

As a means of focussing the workshop discussion over the two-day workshop, a number of topics were developed which were organised as follows:

- Development of criteria to identify and group polymers for Registration/Evaluation under REACH
- Development of Registration requirements and testing strategies
- Approaches to name and group polymers requiring Registration
- Costs and benefits data

2. Key points emerging from the workshop

2.1 Morning plenary session (Day one)

Four presentations were made during the morning plenary session on Day One. These presentations can be found as Appendix C to this report. In summary, these were:

Welcome address and policy background by Katrin Schutte, European Commission, DG Environment

In this presentation, an overview of the project background and the relevant legal framework was presented. A short summary of the previous studies done on this topic was also presented and their key findings summarised. This presentation concluded by highlighting to participants that the aim of the study is to develop criteria to identify polymers requiring Registration (PRR), noting that the exact Registration provisions are still to be decided and could well differ from other substances.

A presentation from Wood/PFA

Wood then presented a description of the project context and overview of project, a summary of the Thought Starter document provided to participants prior to the workshop and a description of the project scope. This presentation highlighted that there is a need for Registration of polymers (hazards/risks, scale, level playing field) and the desired outcomes and structure of the workshop were explained to participants. This presentation also specified those substances covered in the scope of the study.

A presentation from PFA on criteria to identify polymers for Registration

PFA presented possible criteria to identify PRR, specifying that all findings were preliminary and thus subject to potential change. The development of criteria for the identification of PRR was based on the following:

- information in previous studies e.g. EC (2015)
- existing regulatory schemes
- the hazard profile of polymers screened so far
- information from the consultation

This presentation described the types of polymers with hazards that makes them candidate PRRs (which are presented in Table 2.1 below). The criteria that were suggested in Appendix A of the Thought Starter were also explained to participants during this presentation.

Table 2.1 Examples of polymers with known/suspected hazards from the presentation

Polymers with known/suspected hazards	Comment
Polymers with relevant hazard classifications under the Classification and Labelling (CLP) Regulation.	Classification should relate to the polymer itself rather than additives or unreacted monomer.
Cationic polymers.	May be associated with hazards to the environment if water soluble or water dispersible.
Anionic polymers.	May be associated with hazards to the environment if water soluble or water dispersible.
Amphoteric polymers.	May be associated with hazards to the environment if water soluble or water dispersible.
Nonionic polymers with surface-active properties.	May be associated with hazards to the environment if water soluble or water dispersible.
Polymers containing low molecular weight oligomers.	Hazards may be associated with oligomers with molecular weights <1000 Da and in particular <500 Da.
Polymers with reactive functional groups.	For example polymers that are alkylating agents or which are electrophilic in nature
Others	For example, some types of degradable polymers may lead to formation of substances more hazardous than the polymer. Exposure (wide-dispersive use) as a catch-all criterion?

A presentation on Registration requirements (including testing strategies) from PFA

This presentation explained the potential testing strategies and Registration requirements as well as a worked examples of possible polymers requiring registration, additional needs and commentary on grouping.

Panel presentations and discussions (Day One)

Four panel presentations were given by speakers selected ahead of the workshop. The slides accompanying these presentations can be found in Appendix C of this report.

ECETOC Polymers Task Force: Assessing the human health and environmental safety of polymers (Mark Pemberton – MP)

- MP presented on the objectives of setting up the ECETOC task force on polymers, the approach to their study (i.e. steps of the CF4Polymers approach) and their timeline[4].
- Noted that they believe exposure assessment should be done before hazard assessment to avoid wasting resources – but the rest of the panel was divided on this.
- The need for further data collection and assessment was emphasised and the following recommendations were made for the Commission and the project team:
    - Understand the importance of clear definitions for all key terms

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[4] http://www.ecetoc.org/wp-content/uploads/2019/05/ECETOC-TR133-1CF4Polymers.pdf

    - A major roadblock in drawing sound conclusions is the lack of public availability of polymer identity information and lack of public availability of hazard data
    - Confidential Business Information is also a challenge to Grouping and industry SIEF activities

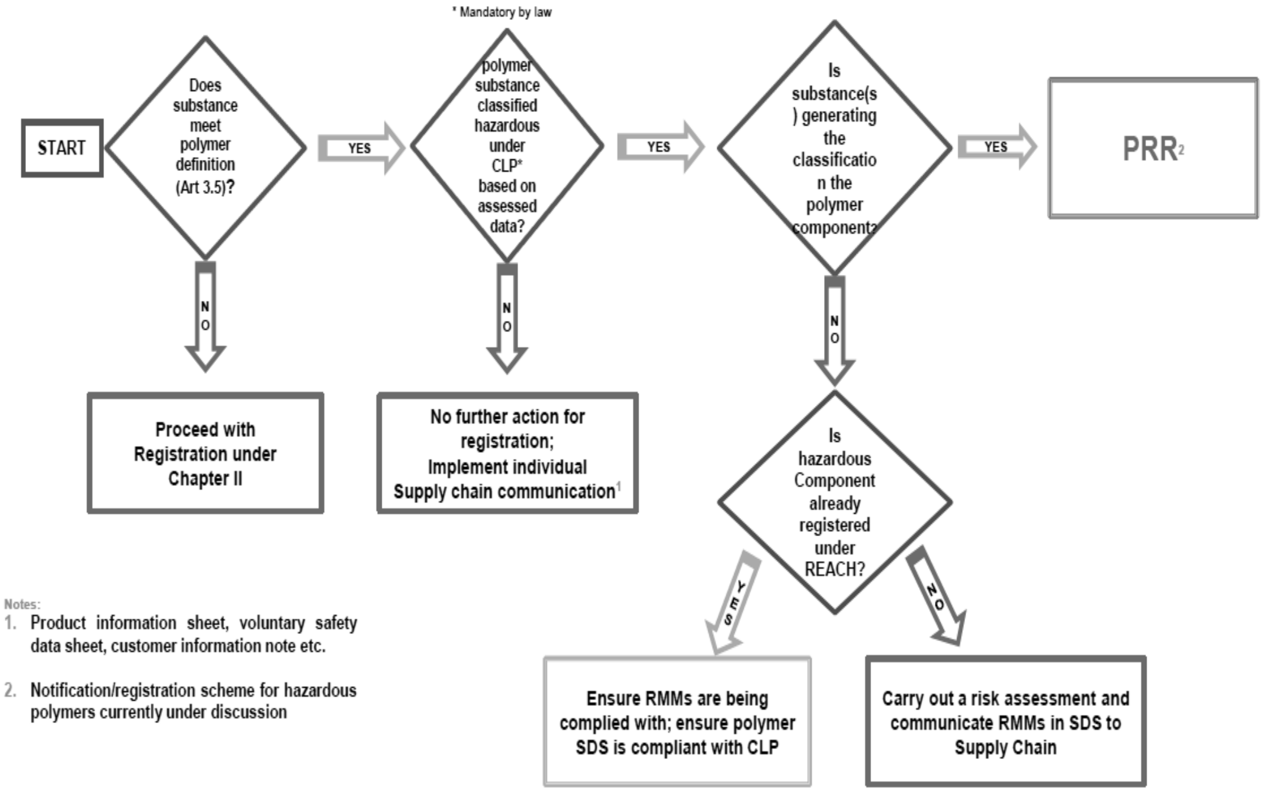
ECHA: Information on polymers to date and recommendations for the study team (Mike Rasenberg – MR)

- MR presented a number of issues identified for potential PRR and solutions. These included:
    - Consequences of polymers currently not covered by REACH are: no systematic information on polymers on the market, their uses and life-cycles. Consequently insufficient data for classification and labelling and for risk management.
    - Monomer data cannot be used to assess polymers.
    - The possibility of too many Registrations. ECHA's proposal is to begin the approach by examining major monomers as a first step.
    - The possibility of too much testing being required
    - Many polymers are probably not dangerous.
    - Noted that stability seems to be a relevant parameter
- Overall MR stated that there is very little data available, so a potential approach may be to simply take pragmatic cut-offs
- MR suggested considering a possible initial notification requirement for all polymers. Following that notification, a tiered decision tree could then be used to dictate potential further data needs.
- Two possible options for a legislative approach were also identified:
    - A tiered, decision-tree type approach, executed and documented by registrants;
    - Mandate for authorities to request generation of data

Plastics Europe: Assessment of Polymers Requiring Registration

- The polymer lifecycle was described and a proposed draft flow chart was presented for assessment of polymers under REACH. The draft flowchart presented had three endpoints. For those substances that do not end up classifying as a PRR, one endpoint is to ensure RMMs are being complied with and to ensure polymer SDSs are compliant with CLP. The other endpoint was to carry out a risk assessment and communicate RMMs in SDS to Supply Chain. The example flow chart is presented in Figure 1 below.
- The importance of clear definitions of key terms was also reiterated
- Various cases were highlighted where compounded polymers have been notified to the C&L inventory (e.g. PVC + DEHP, with DEHP driving classification) and other cases where hazards of the monomer triggered the notification.

Figure 2.1 Proposed flow chart for Polymers assessment under REACH from Plastics Europe.



Perspectives from the New Substances Assessment and Control Bureau of Health Canada (No slides) (Graham White)

The presentation based on the Canadian experience highlighted the following:

- Significant numbers/proportions of new substances that are being registered, in their experience, are polymers. They currently assess 20,000 substances, around half (10,000) of which are polymers. The 20,000 notifications around 7,000 unique substances. Of the 10,000 polymers, around half (5000) are of low concern, referred to as RRR (reduced regulatory requirement[5]) substances, as no action will be taken on them. Of the 10,000 polymers, only 4,000 are unique.
- They are working on 4 polymers that were initially considered as RRR but which degrade to long-chain fluorinated compounds and which are hence no longer considered of low concern.
- It was noted that conducting rodent (and other mammalian) studies by default is of little value, and generally does not yield new knowledge. Currently, polymers not meeting the PLC criteria have tests done for algal toxicity and acute oral toxicity (rat).
- The main concern of Health Canada seems to lie with polymers with a molecular weight of <1000Da
- In Canada, they also address issues regarding residual monomers, as well as reactive diluents

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[5] Considerations for RRR polymers include > 10,000 MW, as well as reactive functional groups.

A COM representative commented that a key distinction is that the New Substances Assessment and Control Bureau of Health Canada is not responsible for worker safety (whereas REACH needs to cover that).

2.2 Breakout sessions (Day One)

These sections present summaries of the breakout group discussions and reflections on these topics from the plenary. For Day One, each topic was discussed by two different breakout groups, hosted by a facilitator and rapporteur. The notes from the two groups have been merged.

Developing criteria to identify and group polymers for Registration/Evaluation under REACH

Questions/discussion points

For each criterion:

- Is the suggested criterion appropriate?
- Is there any possible issue with implementation?
- Is there any evidence available to support that criterion?
- Overall, are there any other areas that should be considered in relation to PRR criteria?

Cationic/anionic/amphoteric polymers or nonionic polymers with surface active properties

- Should cationic/anionic/amphoteric polymers or nonionic polymers with surface active properties polymers be considered PRR?
- Are the criteria suggested appropriate?
- Are there other factors that should be considered, e.g. limiting to cationic/anionic/amphoteric polymers with surface-active properties?
- Are the exceptions appropriate and should others be considered?

High exposure potential

- Is it appropriate to consider polymers with a high exposure potential to be PRR?
- If so how can this be defined?

Low molecular weight polymers

- Should low molecular weight polymers and polymers containing low molecular weight oligomers be considered as PRR?
- If so, what are appropriate molecular weight cut-offs?
- Are there other factors that should be taken into account?
- Should nano-plastics be considered regardless of molecular weight?

Reactive functional groups

- Should polymers containing reactive functional groups be considered as PRR.

- Are the suggested RFG groups suitable in identifying potential candidate PRR? How can we capture others?
- Should exceptions be identified and if so which?

CLP classification

- Should polymers classified as hazardous under CLP be considered as PRR?
- If so, are all hazard classifications relevant?

Exemptions

- Is a specific exclusion for certain polyesters appropriate?

The table below summarises the key points that were raised during this breakout session:

Question/discussion point	Issues raised
Polymers classified under CLP	• Classification under CLP should be on the basis of the polymer, however participants noted that it will not always be known whether the toxicological data relates to the monomer or to the polymer. While CLP classification helps to identify PRR, it should not be a criterion in itself due to the diversity of notified classifications to the C&L inventory. It was also highlighted that to use this as a criterion, there would be a need to understand the source of toxicity for all polymers from the CLP inventory. This is achievable in principle but could be a burden, especially to those companies with a large product range. PFA highlighted that if you know classification is due to the monomer (or other non-polymer components), then you know this criterion is not met. Therefore, you must examine other criteria. There is a lack of awareness (and institutional memory) on whether (self) classification was on basis of polymer, residual monomer or other constituents. • It was also noted that there are different groups and chemistries behind each CAS number and the Hera report[6] was mentioned as an important source of information as it discusses how data groups and polymers relate to CAS numbers. • It was estimated that the vast majority of classified polymers placed on the market have been treated as mixtures and that monomer specification is known for products within each sector.. In practice, it is usually possible to analyse monomer content, which is typically done for product specification / sales purposes. • One option that was suggested was that there could be "notification" stage in the first place and then more substantive "Registration" if further information is needed. It was confirmed by the Commission that there is no expectation for all polymers to be registered and that there could be some basic first notification for authorities to identify groups and determine whether further information is needed. • The possibility of free-riders regarding the possible notification stage was highlighted in the discussion; If this is a case of self-declaration, then this could be a problem. • The group also noted that there is diversity on 'notified classifications' to the C&L inventory, where people have taken different approaches. • Many 'hazardous polymers' are also thought to have been classified based on the mixture rule (additives, monomer). • It was concluded that polymer classifications done under CLP would be a good criterion, but notifications to the C&L inventory since 2010 are not a good criterion (as mostly done on monomers)

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[6] https://www.heraproject.com/files/HERA_P-AA_final_v3_23012014.pdf

Low MW polymers and oligomers:	• It was noted by some industry participants that it is the large number of polymers in existence which is the issue, rather than their molecular weight. It was reiterated that low molecular weight does not equate to being hazardous, it indicates that something could cross a biological membrane. It was flagged that PE have done a lot of work regarding this but the approaches used by PE are not hazard based. It was suggested that using MW as a criterion may be useful, but you will also need basic toxicological information thereafter. • Some participants suggested that a criterion addressing risk is needed, such as what they have in the Food Contact Materials (FCM) legislation. • It was noted that the ECETOC report suggests a cut-off value (which is different from the one used by the project team), based on scientific evidence. • Chemsec highlighted that 500Da and 1000Da MW cut-offs were developed some time ago, and some articles suggest that even larger molecules could be bioavailable. In some rare cases of direct exposure to very high concentrations at >1000Da, biological membranes could be crossed. However, as most polymers are not aligned correctly to do so, this would require a high concentration. • Industry (polystyrene sector group) has done tests on oligomers for EFSA under FCM legislation – and would not want to repeat these. These wouldn't necessarily be Klimisch compliant and used animal testing, which should not be repeated. It was suggested to ask EFSA for more information. • The use of a flow chart that would allow you to go through the criteria to identify which polymers are PRR was suggested. • MW changes throughout the lifecycle of a polymer and makes it difficult to isolate the polymer that requires testing. A such, there is a need to consider that some polymers are 'transient' i.e. potentially giving rise to infinite number of Registrations down one supply chain. • In general, it was agreed that one may end up with too many PRRs if the MW cutoff is used alone. Nonetheless it was agreed to be an important consideration. It was also agreed in this session that the C&L inventory was deemed of limited use for identification of PRR and its use as a criterion for their selection would generate a lot of work for little gain. •
Cationic, anionic and amphoteric polymers:	• For the criteria related to the potentially cationic polymers, it was suggested that it may be better to work with pKB values. • Experience from Canada suggests that for cationic polymers, protonation generally occurs only on a few sites and they rarely become highly protonated. There is not much evidence for toxicity of these substances. There was a general agreement that it should be considered to remove the criterion C2 related to potentially cationic polymers. This may also be relevant to potentially amphoteric polymers. • Similar arguments over definitions and exposures were also raised for the other criteria related to ionicity. • There was a suggestion to also consider biodegradability in relation to anionic polymers. • Experience from Canada suggests that the hazards from amphoteric and nonionic polymers is often related to low molecular weight polymers only. This will need to be checked, particularly in relation to those with surface active properties. • There was a feeling within the group that the Functional Group Equivalent Weight cut-off of 5000 Da may be too high. This will need to be looked at. This may also be relevant to anionic and amphoteric polymers.
Catch-alls (incl. exposure)	• It was explained that this criterion is about exposure not about widespread use such as polyethylene products. The "catch-all" term should be changed for "safety net" instead.

	Exposure should be understood in relation to the portion of a substance that is physically and biologically available, • Industry highlighted that, to use this criterion, very clear definitions would be needed about exposure. It was also noted that identifying a scenario where there is potential for adverse human effects can only be done via supply chain assessment. • It was also noted that accounting for exposure only is not workable. Instead, high exposure and high bioavailability could be considered – it was already clarified that this relates to 'internal' exposure. Generally, the risk assessment approach was noted as positive but doing this just based on exposure does not make sense, i.e. if you have a very high exposure of a low risk polymer. • Incorporating elements of usage in any of the criteria was questioned as the uses may not be fully known and may change in the future. On the other hand, reasonably expected uses are generally known.
Surface active properties	• In general, it was noted that surface active properties are reactive and could be expected to react with proteins, causing adverse effects. Therefore, they are a potentially useful criterion.
Reactive functional groups	• Similar to surface active properties, reactive functional groups can react with proteins and therefore can be a useful criterion. However it was also raised that many RFG might be unavailable after polymerisation.
Exemptions	• Regarding exemptions for certain polyesters, it was noted that the rationale would need to be specified (e.g. as identified under TSCA).
Discussions regarding sharing of data potentially needed for this project	• Industry highlighted that while data is needed to progress in a proportionate way, a level of confidence must be provided that the data will be used in a CBI appropriate way. A secure mechanism will be required for this (i.e. by setting up a third party), which is unlikely to be developed within the timescales of the project. It was also noted that even if single companies put data forward, it would not be representative of the entire sector and there examples where sector groups could characterize their hazard landscape. • Industry participants emphasised that the criteria and substance identity need to be considered in an iterative process. A two-step process was proposed based first on broad groupings and then secondly by conducting a detailed assessment against more specific criteria that are applicable to each grouping. • The grouping stage would possibly include subgroupings based on chemistry/biochemistry. It was suggested that the information available on these groupings would be submitted (possibly to ECHA) and this would then be used to decide on whether the polymers would need to be registered or not. • No additional criteria were suggested by the workshop participants. • There was agreement that biodegradability, bioavailability and water solubility need to be taken into account in the criteria.

Development of Registration requirements and testing strategies for polymers

Questions/discussion points

Discuss Registration requirements and testing strategies for:

- Physico-chemical properties
- Environmental fate and ecotoxicology
- Human health

For each strategy, discuss the following questions:

- Do participants accept the principle of trying to be as consistent as possible with REACH as it functions at present?
- Do the processes presented in this Thought Starter help potential registrants understand what a Registration process might be?
- Will it be achievable to share data on constituents?

The table below summarises the key points that were raised during this breakout session

Question/discussion point	Issues raised
Human health	• Avoiding unnecessary mammalian testing was seen as a key priority by all. • Polymers are typically tested within companies for sensitisation. • Identification of hazard may be based on bioavailability, reactivity, monomer properties as 'alerts' for polymer properties (but the tests which industry carry out as part of their own hazard identification approaches are typically modified from the standard tests). QSARs can also be used to predict chemical reactivity. (If something reacts with chemicals it will react with proteins.) Industry often uses functional groups to determine testing requirements. • It was noted that there is a relatively large volume of data within industry on oral toxicity (compared to other routes) because the oral toxicity tests are less expensive. • It was noted that the possible cutoffs for low MW oligomers may be lower for dermal than for oral toxicity. • It was noted that most currently available data is from FCM legislation, older data on veterinary tests or from PPP legislation. • Participants noted that there is a need for inhalation toxicity testing where polymers can be inhaled. • Industry also noted that most polymers are produced with a pre-determined physical effect / property. The polymer use is associated with a particular quality – that determines the hazard. The hazard does not occur randomly. It is possible that there is a lot that could be learned from use patterns. • Physical availability was known to be important based on PFA's own experience. It was also noted by participants that, under REACH, the largest molecules registered were e.g. 1000Da. But then what is the difference between substances registered under REACH and the polymers? Toxicity will be dependent on migration of hazardous constituents from the polymer. Properties of the polymer will be required in determining whether the tests will be of value. • PE /ECETOC highlighted they would provide more information on how low MW components are retained / trapped within matrices and on how migration stops when polymer becomes more rigid. • Generally, participants stressed the need for understanding the route of exposure in determining what type of study is done, more so than for non-polymer substances. Industry noted that oral route tests are often done because it's cheapest and can be read across.

Environmental fate and ecotoxicology	• Participants were asked whether there is any reason to diverge from the pre-REACH approach i.e. whereby the need for testing (or not) has been linked most strongly to solubility. No clear reasons were identified why testing should not be done in certain cases. • It was noted that the testing requirements would need to be adapted for high MW components and things that might get degraded in waste. • It was noted that most tests have been acute studies so far (e.g. in Daphnia) and linked to physical impairment. The TR132 report was mentioned; this presents testing of particulate and poorly water soluble materials, and what considerations should be taken into account.[7] • Polymers may have more extreme properties, so it should be clarified to what extent existing models work or whether qualitative, exposure-based arguments should be used. It was suggested that a qualitative approach may also be useful in this instance. Models e.g. EUSES are unlikely to be useable (slow partitioning means equilibrium is never reached) though they can be 'forced' to allow certain aspects of polymer exposure to be assessed. • Industry stated that the read across assessment framework has been a hindrance for them, because of the high burden of proof e.g. due to demonstrating a hypothesised mode of action (other than narcosis or physical effects). For read-across to have any applicability, it was stated that there would need to be flexibility on how it is applied. • There is a difference between poorly soluble and not soluble and there may need to be a quantitative cut-off for this. • Regarding analytical techniques, there will not be a "cookbook" approach that is workable so a generic guidance document won't be possible.
Physicochemical	• Differential Scanning Calorimetry (DSC)[8] can be used to examine melting temperature (Tm), boiling temperature (Tb) and thermal stability – which could be mentioned in the report. Differential scanning techniques enable understanding of a large range of properties. This has the potential to save a lot of time and effort. • For most polymers, within the temperature range of biological systems, only glass transition temperature (Tg) is relevant, and most other physicochemical properties are not relevant. • It was also noted that gel permeation chromatography (GPC)[9] should be included (as relevant to substance identification). • Industry suggested that absorption coefficients for particulates may also be relevant (related to environmental fate). • The following physicochemical properties were suggested to be important as these are the properties that define polymers.

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[7] ECETOC (2018) TR 132 – An evaluation of the challenges and limitations associated with aquatic toxicity and bioaccumulation studies for sparingly soluble and manufactured particulate substances. Available at: http://www.ecetoc.org/publication/tr-132-an-evaluation-of-the-challenges-and-limitations-associated-with-aquatic-toxicity-and-bioaccumulation-studies-for-sparingly-soluble-and-manufactured-particulate-substances/

[8] Differential scanning calorimetry, or DSC, is a thermoanalytical technique in which the difference in the amount of heat required to increase the temperature of a sample and reference is measured as a function of temperature

[9] Gel permeation chromatography (GPC) is a type of size exclusion chromatography (SEC), that separates analytes on the basis of size, often used for the analysis of polymers.

	- Average MW - Number average MW - Dispersivity - Glass transition temperature • Properties such as vapor pressure were thought to have limited relevance for polymers.
Other	• A staged, iterative approach following the ECETOC outline was recommended by industry. • A proposal was made to stage the Registration by carrying out an initial grouping (proposed by industry), then collecting and submitting the information to ECHA, followed by a prioritisation and selection of the substances or groups for Registration. This was also mentioned in the previous break-out group on criteria. • Registration stages may be better linked to groups, rather than by tonnage as is currently done in REACH. • Modifications of testing requirements, based on the column 2 REACH Annex adaptations may not be applicable to a number of polymers. • It needs to be defined what the substance to be tested is – i.e. only the final polymer or also oligomers?

2.3 Morning plenary session (Day two)

Feedback session on outcomes from Day One

The project team presented a compilation of key feedback on the topics covered during Day 1, including results from the breakout groups. The main points raised by the participants during the Q and A session on feedback from Day One are outlined below.

Points raised by the group during this session included:

- Different groups and chemistries are behind each CAS number.
- If there is a third party through which data could be supplied, this could protect CBI.
- There is a clear lack of data. Industry indicated a readiness to provide further data, but it needs time.
- It was agreed that an additional request for information beyond the previous consultation would be sent to each industry sector as a formal request.

The Hera report on polycarboxylates[10] was highlighted as an important source of information as it includes a discussion on how it may be possible to group data on polymers related to CAS numbers. It was noted that this may be a useful starting point to identify what is not covered in this document and then ask more directly. It was also noted by industry that the format of the data they currently have may not be useful for

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[10] https://www.heraproject.com/files/HERA_P-AA_final_v3_23012014.pdf

grouping. A lot of work would need to be done to clean and analyse this data for the purposes of this project.

Molecular weight:

It was noted from the Canadian experience that when polymers with a high molecular weight (MW) do degrade, they do not disappear from the environment and can remain for the long term.

It was clarified that MW changes throughout the supply chain, rather than the life cycle (which was written on the slides). Industry reiterated that MW is part of the issue when building a hazard profile but should not be considered a hazard on its own.

Generally, it was noted that the criteria presented as part of the Thought Starter should be re-visited based on inputs from the day before, and further refined. The possibility of a decision tree for each grouping criteria was raised. The relevance regarding reactive functional groups and surface active properties was reiterated in this discussion, and chemical reactivity was discussed as being a potentially important proxy for biological reactivity.

On testing requirements:

Industry participants emphasised that there need to be very clear instructions on what needs to be tested. The difficulty of testing was also brought up regarding those polymers which may contain multiple oligomers as this would be hugely expensive to test each of them separately. It was also noted that, in some cases, it may be very difficult to produce sufficient amounts of certain polymer species which would be required for testing to be carried out. Furthermore, from previous experience of some participants, separating oligomers was identified as being very troublesome and expensive.

Plenary presentation on grouping (PFA)

PFA highlighted to participants that naming and grouping of polymers requiring Registration will be key for data sharing, in order to avoid duplication and unnecessary testing. Some possible approaches were set out in the slides. These were:

1) **Grouping of polymers to decide if the polymers meet any criteria of a PRR.** This type of grouping could be at a reasonably general level and possible options are:
    - Similarity of hazards.
    - Similarity of use.
    - Similar relevant physicochemical properties, including physical availability and bioavailability.
2) **Grouping of polymers in relation to any subsequent Registration requirements.** This is closely related to polymer sameness and is considered further later.

2.4 Breakout sessions (Day Two)

This section presented summaries of the breakout group discussions and reflections on these topics from the plenary. For Day Two, each topic was discussed by three different breakout groups, hosted by a facilitator and rapporteur. The notes from the three groups have been merged. The breakout sessions on Day Two covered sameness and grouping and also costs and benefits.

Approaches to name and group polymers requiring Registration

Questions/discussion points

- Sameness and grouping could be relevant to Registration processes and to read across/sharing of data. What is the best way (or ways) to approach grouping for Registration purposes?
- Are there other applications of grouping to be considered, e.g. exposure considerations?
- Will it be possible to establish 'sameness' analytically?
- What validation exists for analytical methods?
- What deviations from specified contents are considered to be reasonable?
- How can sharing of data between polymers which contain similar relevant constituents be facilitated?
- Is the minimal dataset sufficient for the first stage of the Registration process? Will registrants find it achievable?
- Can the CBI topics be agreed?

The table below summarises the key points that were raised during this breakout session.

Question/discussion point	Issues raised
Terminology	• It was emphasised that sameness and grouping should not be considered as synonyms.
Are there other applications of grouping to be considered e.g. exposure considerations?	• Participants noted that the starting point for grouping should be chemistry rather than exposure considerations. Rather than a REACH format, there could first be a notification stage followed by discussions (within industry) on how to group for submission. A plan regarding testing and SIEF Formation could take place at a later stage. • There were mixed views on how to group. For example, certain participants stressed that when criteria have been determined, chemistry can be used to group (e.g. solubility) but that current sector groups are not always based on chemistry. It was noted also that in Canada, sameness is examined based on expert judgment. • Other participants stressed that a starting point for grouping could be sector groups, which could be used to develop the SIEF. Some sector groups have criteria already (i.e. Plastics Europe). • One company suggested to group based on classification. • It was suggested that other regimes should be looked at. However, in the US, Canada, Australia, Japan, they look at new substances individually. A consortium approach is an added complexity, that they don't have to deal with.
Will it be possible to establish 'sameness' analytically?	• Some participants highlighted that this is not possible, due to potential for having to disclose product and manufacturing information. It was noted that analysis could reveal a large amount of CBI information (i.e. reveal information about monomers) and may therefore, not be practical.

	• Participants also noted that current sector groups are determined based on the fact that companies sell into the same market, rather than on sharing of analytical data. This could be an important means of grouping as customers will consider the product description/specification of what they buy to be the same for different suppliers. • In industry, not all groups are organised by chemistry. For example, within resins, some groups may be chemistry based but the sector group related to CEPE coatings covers a range of chemistries. • Industry has never considered grouping substances with the idea of chemical sameness in mind. Rather, polymers have been grouped for their use. • It was stressed that in order to work in practice, the grouping approach must be comprehensive but not duplicative. All substances must have a group, but criteria must be narrow enough to avoid the possibility of double grouping. • Authorities must be involved at some point. It may not be possible to rely on the data which already exists. Instead, dialogue between the Commission and ECHA is needed regarding suitable grouping and hazard profiles. • Overall, it is achievable to group polymers based on PRR status, and to establish principles of joint Registration. However, there are significant challenges.
Can CBI topics be agreed upon?	• One approach to avoid breaching CBI was so define families of polymers. • Another was for each sector group to use a third party (in a similar way to the Technical Platform on resins). A third party could be defined, deliver the information and decide which family the polymer is being added to. • It was noted that CAS number, monomers, stabilisers and additives can all be CBI. In practice, companies decide in sector groups based on whether they are selling to the same markets. Could what they market to their customer be included in the minimal list of information ? • The approach to UVCBs could be applied. For example, this could be based on ranges. However, there could be a tendency to make the ranges as wide as possible which would require more read-across and vice versa.
Is the minimal dataset sufficient for the first stage of the Registration process? Will registrants find it achievable?	• The general perception is that the list of data presented in the Thought Starter is too much for some participants. • Under REACH, the driver for sameness of strange mixtures was whether the substance fits the same hazard profile as the substances included in the joint dossier. • If you end up with very wide groups, you will need more read-across and vice versa. • Manufacturing description, composition information can also cause CBI problems. • One approach would be after screening out non-PRR based criteria, basic information would be notified for companies to come together. At this stage, relevant hazards would need to be determined (e.g. skin sensitisation). Some suggested that the authorities would need to specify what hazards are relevant.

Understanding the costs and benefits of registering polymers

Questions/discussion points

- Are there any other sources of data available on the costs from Registration under REACH?
- Do you have any qualitative or quantitative information on the costs that could be expected from the Registration of PRR?
- Are you aware of estimates of the number and/or tonnage of polymers that may meet the possible criteria for PRR, on the EU market (produced in the EU and/or imported to the EU) or elsewhere? If not, how best should this be done?
- Do you have any suggestions to make the Registration of polymers of concern efficient, i.e. minimising costs while increasing the benefits related to their Registration?
- Do you have any information on the following benefits that could be expected from the Registration of polymers of concern? Examples include:
    - Impact avoided, in terms of diseases/disorders avoided per substance Registration
    - Impact avoided, in terms of reduced environmental impact per substance Registration
    - Increased availability of information on polymers of concern
    - Innovation processes within companies searching for new and better solutions
    - Level playing field with non-polymeric substances

The table below summarises the key points that were raised during this breakout session.

Question/discussion point	Issues raised
General comments from participants on costs and benefits:	• It was noted that there is currently a very broad range of polymers on the EU market and estimating this number would depend on how the market is divided. • Suggestions were made to look at the CLP inventory as a means of identifying the number of polymers listed there. It was noted that this is something that has already been done in this project and drawbacks were identified from this. Based on the polymers considered in Canada it may be possible to estimate how many are “of concern”. • It was estimated that up to 10,000 polymer substances would need Registration, based on Canadian experience. • It was suggested by industry that there may be 2000-5000 groups of polymers which include PRR candidates, and that without grouping there would be many more. • Others suggested that there might be 50-200 sector groups, which may not all be polymers.
Current testing costs:	• It was generally noted that Annex IX and X data need to be added to the figures that were presented in the Thought Starter. Some industry participants noted that they may be able to provide costs data based on Annex VII Registration. • Low MW polymers are basically the same as substances – so the approach and costs the same.

	• Cost estimates provided by the participants include: - The costs for testing polymers may be up to 75% higher than for other substances - Completion and submission of Annex X dossier: €1M - Full REACH Registration for polymers: €1.5M - If sector groups were to nominate the polymers to be registered, there may be 50-200 groups with €350k testing costs per group
Additional types of costs specified by participants to be considered:	• Administrative costs • Third party data review • Gap analysis • Legal costs • Consortium management • Selection of PRR • Interaction with downstream users • The costs of developing guidance documents by the Commission should also be considered • Costs to determine if you are covered • Noted that under the DSD, only a few new polymers were developed due to the cost of notification – this situation could reoccur
Data sources available:	• Individual companies are commissioning studies and ECETOC highlighted the possibility of providing data on lab costs for all REACH datasets. • It may also be possible to provide polymer characterisation tests at low levels of detail. It was also noted that Korean data exists on polymer Registration costs (which are estimated at €600k).
Benefits:	• In general, benefits were difficult to identify since data are not widely available. • Increased regulation could help steer innovation toward polymers of low concern. • Debate was raised regarding the creation of a 'level playing field' vs non-polymers. • It was also argued that while benefits of increased innovation in this sector may occur, the potential costs that registration would have on the supply chain would need to be assessed. No other benefits were identified at the workshop.

3. Workshop closing remarks

The breakout group sessions were useful to the study team in building greater understanding of the approach to be developed for Tasks 1 and 2 of the project and how to build on the preliminary findings that were outlined in the Thought Starter document. The breakout session on costs and benefits also provided clarity on the extent of data available for the conducting Task 4, the cost-benefit analysis.

The workshop discussions also provided an insight into the important factors at play in developing criteria and Registration requirements and the opinions of different stakeholders. Sources of additional information to improve the work were also highlighted.

A few specific reflections on some of the key discussions:

- Certain approaches proposed in the Thought Starter may not be appropriate for the development of criteria to identify and group polymers for Registration/Evaluation under REACH for the purposes of this study (e.g. CLP classification). However, surface active properties and reactive functional groups are clearly relevant and will be further developed for this purpose. The need for a secure third-party mechanism where data could be shared was identified as a priority to overcome CBI issues. The possibility of a decision tree for each grouping criterion was raised as a potential approach.
- Various options to establish a PRR system were raised, including tonnage, hazard severity and building a risk profile. The approach to Registration needs to be phased and considerable amounts of new guidance will be required regarding intrinsic properties, and exposure of humans and the environment. Regarding testing, the need for understanding the route of exposure in determining what type of study is done was emphasised and it was noted that oral route tests are often done by industry due to the fact that they are less expensive and can then be read across to other routes.
- Regarding the approach to grouping polymers, sector groups are determined based on the fact that companies sell the product to the same market and are therefore not based on sharing analytical data (and this could be used as a basis for grouping). A possible two-step process was discussed based firstly on broad groupings and then secondly by conducting a detailed assessment against more specific criteria that are applicable to each grouping.
- Regarding data for the costs and benefits analysis, it was highlighted that data does exist which may be useful for this, which needs to be formally requested from the companies. In general, the participants reiterated that the costs for polymer substances would be significantly more than those outlined in the Thought Starter.
- The Commission indicated that they now have a clearer idea of what can be done. It is clear that some information won't be immediately available.[11]

Next steps

Industry representatives suggested that a way forward would benefit from collection of information on polymers as groups within the different polymer sectors and sharing of such compiled information with the

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[11] In terms of further information provision by industry, some will be used for the purposes of the current study and other information which comes later can be used in the Commission's Impact Assessment (i.e. if not available in time for the current study). It may be possible to set up a subgroup under CARACAL to look at Registration of polymers, and then develop an impact assessment based on a specific proposal to amend REACH. This would also link with the timescales for the ECETOC study and could lead to development of the IA after 2020.

Commission and the project team. Given that the accessibility of more data to the consultant could significantly improve the study's conclusions, after the workshop, it was agreed that a letter would be developed by PFA and Wood which outlined the exact data requirements which were needed, requesting information from sector groups.

The notes from the workshop, summarised in this report, will be used by the study team in preparing the final report for this study, due for completion in September 2019.

Appendix A: Workshop Agenda

Date: Tuesday 21- Wednesday 22 May 2019

Meeting at:
European Commission (DG ENV)
Avenue de Beaulieu 5,
1160 Auderghem,
Belgium

Subject / purpose:

Two-day workshop for the study to provide '*scientific and technical support for the development of criteria to identify and group polymers for Registration/Evaluation under REACH and their impact assessment*'

Day 1 – 21 May 2019

Timing	Session	Lead
10:00	Registration and coffee	
10:30	Welcome and introduction by the European Commission	DG ENV
11:00	Context – Overview of project, thought starter, scope, desired outcomes and structure of the workshop	Project team (Wood)
11:30	Coffee	
11:45	Panel presentations (10 min each) and discussions • Need for Registration of polymers (hazards/risks, scale, level playing field) by project team • ECETOC (overview of work, findings so far) • Canadian authorities (experience with Registration of polymers) • Possible others Q&A	
13:00	Lunch	
14:00	Criteria to identify polymers for Registration (plenary)	Project team (PFA)
14:30	Registration requirements (including testing strategies) (plenary)	Project team (PFA)
14:45	Coffee	
15:00	Break-out sessions on criteria and Registration requirements	All
16:45	Presentation of day 2	Project team (Wood)
17:00	Closure	

Day 2 – 22 May 2019

Timing	Session	Lead
09:30	Plenary session and plan for day 2 Feedback on the first day (incl. break-out sessions)	Project team (Wood/PFA rapporteurs)
10:15	Sameness and grouping (including CBI) (plenary)	Project team (PFA)
10:30	Coffee	
10:45	Break-out sessions on sameness and grouping	All
12:30	Lunch	
13:30	Costs of Registration of PRR	Project team (Wood)
13:45	Benefits from Registrations of PRR	Project team (Wood)
14:00	Break-out sessions on costs and benefits	All
15:15	Coffee	
15:30	Plenary session and Q&A Feedback from the second day (incl. from break-out sessions on sameness, grouping, costs, benefits)	Project team (Wood/PFA)
16:15	Concluding remarks and next steps, by the European Commission with the support of project team	DG ENV
16:30	Closure	

Appendix B: List of participants

First Name	Last Name	Organization
Toni	Alasuvanto	ECHA
Paul	Ashford	Resins Technical Platform
Philippe	Azam	Solvay
Sami	Belkhiria	Dow Europe
Marcel	Bosma	SABIC
Michel	Cassart	PlasticsEurope
Marie	Dahlberg Persson	Norwegian Environment Agency
Olivier	de Matos	ECETOC
Sophie	Dikoundou Njooh	EFCC (European Federation for Construction Chemicals)
Christopher	Dobe	Syngenta Crop Protection on behalf of European Crop Protection Association
Dunja	Drmac	EURATEX
Lina	Dunauskiene	Environmental Protection Agency, Lithuania
Gitta	Egbers	BASF Polyurethanes GmbH
Jürgen	Emig	Borealis Polyolefine
Gesine	Fickel	Celanese
Lara	Fornabaio	ClientEarth
Nicolas	Fuentes Colomer	Cefic
Catherine	GAGNIER	ARKEMA FRANCE
Oscar	González Sánchez	Ministry for the Ecological Transition
Rune	Hjorth	DK EPA
Chris	Howick	INOVYN/Plastics Europe
Martin	Klatt	EPDLA (European Polymer Dispersion and Latex Association), Brussels
Jonatan	Kleimark	ChemSec

Didier	Leroy	CEPE
Laszlo	Majoros	European Chemicals Agency
Salvatore	Minardi	Versalis SpA
Mike	Neal	Committee of PET Manufacturers in Europe (CPME)
Marie-Amélie	Paul	DuPont
Friederike	Paven	Covestro Deutschland AG
Mark	Pemberton	Systox
Laia	Perez Simbor	ETRMA - European Tyre & Rubber Manufacturers Association
Oliver	Peters	Federal Institue for Occupational Safety and Health - Federal Office for Chemicals (BAuA, Germany)
Véronique	Poulsen	L'Oréal
Madhuri	Prabhakar	Plastic Soup Foundation
Mike	Rasenberg	ECHA
Josephine	Reinaud	EXXONMOBIL CHEMICALS
Gordon	Sanders	ECETOC
Holger	Schmidt, Dr.	LANXESS Deutschland GmbH
Julie	Schneider	CHEM Trust
Giulia	Sebastio	A.I.S.E.
Jay	Shi	Procter & Gamble
Gilly	Stoddart	PETA International Science Consortium
Marko	Susnik	SMEunited
Johannes	Tolls	Henkel AG & Co KGaA
Katinka	van der Linden	Chemours
Michiel	van Kuppevelt	RIVM (Dutch National Institute for Public Health and the Environment)
Graham	White	New Substances Assessment and Control Bureau - Health Canada
Marc	Willemse	Chugoku Paints B.V.
Katrin	Schutte	European Commission (DG ENV)

Sylvain	Bintein	European Commission
Peter	Baricic	European Commission
Mateo	Gallego	European Commission
Bernhard	Berger	European Commission

Appendix C
Review of the COM (2015) study

Introduction

A previous study (COM, 2015) developed possible criteria for identifying polymers of low concern in relation to the REACH Regulation. These were based on a review of polymer registration schemes and requirements worldwide. The proposed criteria developed in COM (2015) are outlined briefly below. It should be noted that the study did not clearly differentiate the contribution of residual monomer to the whole product polymer.

A polymer of low concern was based on the OECD Polymer Working group definition (OECD, 2009).

- Polymers of low concern are those deemed to have insignificant environmental and human health impacts. Therefore, these polymers should have reduced regulatory requirements.

The criteria given in Table C1 were suggested in COM (2015) for identifying polymers of low concern.

Table C1 Criteria proposed in COM (2015) for identifying polymers of low concern

Area	Criteria
Discrimination using hazard information available in REACH and CLP dossiers[163]	
Hazard information (H)	H 1 - for candidate polymers for which information on hazard classification under the EU CLP Regulation[164] is available: the candidate polymer should not be classified as any of the following classes. • Acute toxicity (Acute Tox. 1 to Acute Tox. 4); • Germ cell mutagenicity (Muta. 1A, Muta. 1B and Muta. 2); • Carcinogenicity (Carc. 1A, Carc. 1B and Carc. 2); • Reproductive toxicity (Repr. 1A, Repr. 1B, Repr. 2, Lact.); • Aspiration hazard (Asp. Tox. 1); • Respiratory/skin sensitisation (Resp. Sens. 1 and Skin Sens. 1); • Specific target organ toxicity – single exposure (STOT SE1 to SE3); • Specific target organ toxicity – repeated exposure (STOT RE 1 and STOT RE 2); • Hazardous to the aquatic environment (Aquatic Acute 1, Aquatic Chronic 1 to 4); • Hazardous for the ozone layer (Ozone); • Furthermore, the polymer should not be identified as PBT or vPvB[165]; and • If no information is available on hazard classification, then the criterion H 1 does not apply.

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[163] In the 2015 study, in respect of hazard classification, absence of classification is implied. Under CLP suppliers have obligations regarding polymers.

[164] The Classification, Labelling and Packaging (CLP) Regulation – Regulation (EC) No 1272/2008.

[165] Persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB).

Area	Criteria
	H2 - One or more monomers or other substances in the candidate polymer should not be classified or thought likely to be classified, on the basis of its REACH Registration dossier, as any of the following classes: • Acute toxicity (Acute Tox. 1 to Acute Tox. 4); • Germ cell mutagenicity (Muta. 1A, Muta. 1B and Muta. 2); • Carcinogenicity (Carc. 1A, Carc. 1B and Carc. 2); • Reproductive toxicity (Repr. 1A, Repr. 1B, Repr. 2, Lact.); • Aspiration hazard (Asp. Tox. 1); • Respiratory/skin sensitisation (Resp. Sens. 1 and Skin Sens. 1); • Specific target organ toxicity – single exposure (STOT SE 1 to SE 3); • Specific target organ toxicity – repeated exposure (STOT RE 1 and STOT RE 2); • Hazardous to the aquatic environment (Aquatic Acute 1, Aquatic Chronic 1 to 4); • Hazardous for the ozone layer (Ozone); • Furthermore, the monomers or substances contained should not be identified as PBT or vPvB; and • If no monomers or other substances[166] in the polymer are classified under the CLP or registered under REACH, then the H 2 criterion does not apply.
Eligibility criteria	
Elemental limitations (EL)	EL 1 – the candidate polymer must not contain less than two of the following elements: C, H, N, O, Si and S.
	EL 2 – the candidate polymer must not contain elements, other than the following, covalently bound to carbon: F, Cl, Br and I. It must not contain perfluoroalkyl moieties consisting of a $-CF_3$ or longer chain length.
	EL 3 – the candidate polymer must not contain counter-ions other than the following: Cl^-, Br^-, I^-, Na^+, Mg^{2+}, Al^{3+}, K^+ and Ca^{2+}.
	EL 4 – the candidate polymer must not contain more than 0.2% w/w of the following elements: Li, B, P, Ti, Mn, Fe, Ni, Cu, Zn, Sn and Zr. Any other element is not allowed.
Cationicity (C)	C 1 – the candidate polymer must not be a cationic polymer. Exceptions are: • Solid polymers, not dispersible or soluble in water, not dispersible in air (i.e. not sprayed or processed into powders) and only intended to be used in the solid phase; and

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[166] In the 2015 report the word substance is used but it is not entirely clear what this refers to. Here, we have assumed that it relates to a constituent of the polymer itself rather than an additive substance such as a plasticiser, colourant etc. that may be subsequently added to a polymer mixture.

Area	Criteria
	- Polymers with a low cationic density, i.e. a polymer whose cationic group has a combined equivalent weight greater than 5,000 Da.
	C 2 – the candidate polymer must not be expected to become a cationic polymer, i.e. it must not contain groups reasonably anticipated to become cationic (e.g. amines and isocyanates) and/or be cationic in a natural aquatic environment (4 < pH <9). Exceptions are: - Solid polymers, not dispersible or soluble in water, not dispersible in air (i.e. not sprayed or processed into powders) and only intended to be used in the solid phase; and - Polymers with a low cationic density, i.e. a polymer whose cationic group as a combined equivalent weight greater than 5,000 Da.
Degradability (D)	D 1 – the candidate polymer must not be designed to substantially degrade, decompose or depolymerise, i.e. it must not be designed to convert into small, simpler substances through oxidation, hydrolysis, attach by solvents, heat, light or microbial action, or through other processes.
	D 2 – the candidate polymer must not be reasonably anticipated to substantially degrade, decompose or depolymerise after manufacture or use, even though it is not intended to do so.
Water absorption (WA)	WA 1 - The candidate polymer must not be a water-absorbing polymer (i.e. a polymer capable of absorbing its own weight in water) with molecular weight (MW) ≥ 10 000 Da.
Criteria on average molecular weight and oligomer content	
Molecular weight and oligomer content (MW/OC)	MW/OC 1 – polymers with 1000 < MW<10 000 Da must contain <10% oligomer content of molecular weight below 500 Da and <25% oligomer content of molecular weight below 1000 Da. There are also restrictions on the nature and content of reactive functional groups (see RFG 1 below).
	MW/OC 2 – polymers with MW ≥10 000 Da must contain <2% oligomer content of molecular weight below 500 Da and <5% oligomer content of molecular weight below 1000 Da. There are no restrictions on the nature and content of reactive functional groups.
Criteria on reactive functional groups	
Reactive functional groups (RFG)	RFG 1 – for a polymer with 1000 < MW < 10 000 complying with criterion MW/OC 1, the following restrictions regarding the content of reactive functional groups apply: - No restrictions on low-concern functional groups;

Area	Criteria
	• If the polymer contains only moderate-concern groups, these groups should have a functional group equivalent weight (FGEW) above 1000 Da each and a combined FGEW over 1000 Da; and • If the polymer contains high-concern and moderate-concern groups (or high-concern groups only), the combined FGEW of these groups should be over 5,000 Da. Furthermore, each high-concern group should have a FGEW over 5,000 Da and each moderate-concern group should have a FGEW over 1000 Da. The categories of RFGs are defined as follows. For moderate- and high-concern groups, the main toxicity concerns are indicated in brackets. • Low-concern groups: carboxylic acid groups; aliphatic hydroxyl groups; "ordinary" unconjugated olefinic groups; butenedioic acid groups; conjugated olefinic groups present in naturally-occurring fats, oils and carboxylic acids; blocked isocyanates; thiols; unconjugated nitrile groups; halogens (except reactive halogen containing groups such as benzylic or allylic halides); • Moderate-concern groups: conjugated olefinic groups not contained in naturally occurring fats (genotoxicity), oils and carboxylic acid; alkoxysilanes with alkoxy groups >C2 (lung toxicity, ecotoxicity); and • High-concern groups: pendant acrylates and methacrylates (genotoxicity, skin irritation); aziridines (genotoxicity, skin irritation); carbodiimides (genotoxicity, skin irritation); halosilanes (lung toxicity, ecotoxicity); hydrosilanes (lung toxicity, ecotoxicity); hydrazines (genotoxicity, skin irritation, ecotoxicity); alpha or beta lactones (genotoxicity, ecotoxicity); vinyl sulfones or analogous compounds (genotoxicity, ecotoxicity); acid halides (genotoxicity, skin irritation); acid anhydrides (lung toxicity); aldehydes (genotoxicity, ecotoxicity); hemiacetals (genotoxicity, ecotoxicity); methylolamides (genotoxicity, ecotoxicity); methylolamines (genotoxicity, ecotoxicity); methylolureas (genotoxicity, ecotoxicity); methoxy- and ethoxysilanes (lung toxicity, ecotoxicity); allyl ethers (genotoxicity, cytotoxicity); cyanates, iso(thio)cyanate (genotoxicity, skin irritation); epoxides (genotoxicity, skin irritation); imines (genotoxicity); unsubstituted positions ortho or para to phenolic hydroxyl (genotoxicity); any other RFG not in low or moderate concern groups.
Exceptions	
Polyesters	Polyesters – if the candidate polymer is a polyester from an approved list, it is considered a polymer of low concern regardless of the number average molecular weight or oligomer content. [Note that a proposed list of approved polyester reactants was given in Table 7 in COM (2015); the list is not reproduced here. During the consultation it was pointed out that certain important reactants have been omitted from Table 7 in COM (2015) whereas the same reactants are included in similar criteria from schemes in other jurisdictions (e.g. USA, Canada, Australia). The reason for this omission is not clear and is considered further in the development of criteria for PRR.]

The approach proposed in COM (2015) takes the hazard classification of the polymer as a starting point. If the polymer itself is classified in any of the hazard classes in criterion H1 it is excluded from being a polymer of low concern (and hence is a potential hazard concern). If the polymer itself meets criterion H1 (or if there is no information on the classification) then the classification and labelling of the monomers and other substances present in the polymer is considered. If the monomers and other substances are not classified, then the polymer is considered as a polymer of low concern (limited hazard). If any of the monomers or other substances present in the polymer are classified in any of the hazard classes in criterion H2 (or if there is no information on their classification) then the other criteria on eligibility, molecular weight and reactive functional groups etc. were considered.

It should be noted that CLP gives the possibility to use an additivity method to set the classification of substances and mixtures and that method is also applicable to polymers.

The rationale for the criteria proposed in COM (2015) and a comparison with other approaches world-wide is given in the next Section.

Rationale for the criteria proposed in COM (2015) and comparison with other approaches world-wide

A brief summary of the justification for each of the criteria proposed in COM (2015) for identification of polymers of low concern is given below, along with a comparison with other approaches, and a brief discussion of potential issues and limitations. The other approaches considered were the following:

- United States – Toxic Substances Control Act (TSCA);
- Canada – Canadian Environmental Protection Act (CEPA);
- Australia – National Industrial Chemicals Notification and Assessment Scheme (NICNAS);
- Japan – Chemical Substances Control Law (CSCL);
- Japan – Industrial Safety and Health Law (ISHL);
- Korea – Act on the Registration and Evaluation of Chemicals (K-REACH);
- Korea – Toxic Chemicals Control Act (TCCA);
- Taiwan – Taiwan Toxic Chemical Substances Control Act (TCSCA);
- China – REACH (MEP Order No. 7);
- Philippines – Pre-Manufacture and Pre-Importation Notification (PMPIN); and
- New Zealand – Hazardous Substances and New Organisms (HSNO) Act.

Polymers are exempt from the following schemes and so they were not considered further:

- Malaysia – Environmentally Hazardous Substances Notification and Registration (EHSNR) Scheme; and
- Turkey – Regulation on the Inventory and Control of Chemicals (CICR).

The approach proposed in COM (2015) is broadly based on approaches taken in Australia, Canada, China and the United States.

Definition of a polymer

Rationale

The definition of a polymer in COM (2015) is taken from the REACH Regulation. This is consistent with the OECD definition of a polymer.

Comparison with other approaches

The definition of a polymer is generally consistent with the OECD definition. The Japan CSCL and ISHL has, in addition, another clause in the definition of a polymer related to the number average molecular weight (≥1000 Da).

There does not appear to be a definition of a polymer in the Taiwan TCSCA.

Issues/limitations

The definition of a polymer is set out in the REACH Regulation and its application is further elaborated in the relevant ECHA guidance (ECHA, 2012). This guidance focuses on organic polymers but, as noted in Appendix A, there are, for example, inorganic polymers that could prove problematic in checking that they meet this definition[167].

Hazard information

Rationale

The rationale for this criterion in COM (2015) is that it is important to rule out polymers labelled as hazardous from being polymers of low concern, before any other criteria are considered. The hazard classes considered for H 1 and H 2 are those considered most serious for health and the environment.

Polymers that are not classified in any of the hazard classes in H 1 and whose monomers and other substances present are not classified in any of the hazard classes in H 2 are considered as polymers of low concern. This is adapted from the approach for a reduced test package under the former Dangerous Substances Directive (67/548/EEC).

Comparison with other approaches

Hazard classifications are not considered directly as part of the approaches in the United States, Canada, Japan, China and the Philippines.

In Australia the polymer is eligible to be considered as a polymer of low concern if it is not classified as hazardous according to GHS. Similarly, in New Zealand the registration requirements apply to hazardous polymers.

In the Taiwan TCSCA, polymers of low concern must not be classified according to GHS as carcinogenic, reprotoxic or hazardous to the environment.

In Korea K-REACH, polymers with >2% by weight of monomers that are hazardous chemical substances are excluded from the polymers of low concern category.

.Issues/limitations

Several of the approaches do not directly take into account the classification of the polymer. Classifications according to GHS are considered in four of the schemes but it is not always clear if this applies to the polymer itself or if it also takes into account the classification of any monomers and other substances present.

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[167] In this case ECHA (2012) gives the following guidance: Whenever it is not scientifically possible to establish either of the following:
i) whether the substance falls under the definition of polymer
ii) the chemical structure of the monomer units (or any other unit) as well as their concentration in the substance,
then the substance can be regarded as a UVCB substance. In this case the registration for the substance as a UVCB can be submitted.

The criterion in H 1 in COM (2015) for hazard information relates to hazard classification under the CLP Regulation. If the polymer has a hazard classification, then it is potentially a polymer requiring registration. If no information is available on hazard classification, then according to COM (2015) the criterion H 1 does not apply, i.e. it is not of low concern. In this respect it may be important to further distinguish between polymers that are not classified as hazardous against all of the relevant endpoints and those that are not classified as hazardous against only some of the endpoints (i.e. there is no information on some of the hazard categories)[168]. The latter could potentially still possess (as yet unknown/untested) hazard properties. Therefore, in any proposed scheme for a polymer requiring registration, a lack of a relevant hazard classification should not automatically exclude the polymer from further consideration against the criteria for a polymer requiring registration.

The proposal in COM (2015) does not consider irritancy or corrosivity as part of the relevant hazard classes. Based on an analysis of safety data sheets and information from the consultation (see below) there are a number of polymers that are classified for irritancy or corrosivity but not other adverse effects. These would be considered as polymers of low concern under the scheme proposed in COM (2015).

The criteria for H 2 effectively assume that, if the monomers and other substances present in the polymer are not classified, then the polymer is a polymer of low concern.

Elemental limitations

Rationale

The main rationale for the inclusion of the elemental limitations given in COM (2015) is that they are common amongst some schemes for ensuring a low hazard from an environmental point of view. A further provision related to perfluoroalkyl moieties was added to these criteria (EL 2) in line with a hazard assessment conducted by the USEPA but no further details were given.

This provision for perfluoroalkyl moieties is based on an amendment to the polymer exemption rule for the premanufacture notification requirements in the United States (USEPA, 2010). The amendment excludes certain perfluorinated polymers from being polymers of low concern. This exclusion includes polymers that contain any one or more of the following: Perfluoroalkyl sulfonates (PFAS), perfluoroalkyl carboxylates (PFAC), fluorotelomers, or perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule (affected polymers). The perfluoroalkyl moieties are those consisting of a CF3- or longer chain length. The USEPA has received information which suggests that polymers containing PFAS or PFAC may degrade and release fluorochemical residual compounds into the environment. Once released, PFAS or PFAC are expected to persist in the environment, may bioaccumulate, and may be highly toxic.

The USEPA also excludes from polymers of low concern those that contain fluorotelomers, or that contain perfluoroalkyl moieties consisting of a CF3- or longer chain length that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule. Initial studies have demonstrated toxic effects of certain compounds containing fluorotelomers (derived from the 2-(perfluorooctyl)ethyl alcohol (CAS No. 678–39–7)). Preliminary investigations have found that fluorotelomer alcohols were present in the air above several cities, indicating that these chemical substances may be widely distributed and that air may be a route of exposure. Based on the available data, EPA expects that polymers containing fluorotelomers or perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule may degrade in the environment thereby releasing fluorotelomer alcohols or other perfluoroalkyl–containing chemical substances. It is possible that, once released, such moieties may potentially degrade to form PFAS or PFAC.

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[168] It is important to note that the CLP Regulation does not include any obligation to conduct new testing for the purposes of classification. The absence of classification in the Inventory therefore does not distinguish between lack of hazard and lack of data.

- The Danish Environmental Protection Agency (2013) reached similar conclusions about the potential of certain perfluoroalkyl-containing substances to degrade to from PFAS or PFAC. The Danish Environmental Protection Agency (2013) considered that fluorinated polymers could be considered in the following three main groups;
- Fluoropolymers. These have carbon polymer backbone with the fluorine atoms attached directly to the carbon backbone. These polymers do not lead to the formation of long-chain PFAS or PFAC as a result of degradation;
- Perfluoropolyethers. These have a polyether polymer backbone with the fluorine atoms directly attached to the carbon in the polymer backbone. These polymers do not lead to the formation of long-chain PFAS or PFAC as a result of degradation; and
- Side-chain-fluorinated polymers. These have a non-fluorinated polymer backbone with fluorinated side chains[169]. Depending on the side chain, these types of polymers can potentially lead to the formation of PFAS substances as a result of degradation.

Comparison with other approaches

With the exception of the clause for perfluoroalkyl groups, similar elemental limitations are used in the schemes in the United States, Canada and Australia.

The Japan CSCL has criteria related to metals other than Na, Mg, K and Ca, and the presence of As and Se in the chemical structure.

In China, heavy metals are not allowed in polymers of low concern with average molecular weights between 1000 and 10 000 Da.

No elemental limitations are used in the schemes in Korea, Taiwan, Philippines and New Zealand.

Issues/limitations

The rationale for inclusion of elemental limitations in the proposal in COM (2015) is unclear but appears to be based on commonality amongst the various schemes.

Cationicity

Rationale

The rationale given in COM (2015) is that aquatic toxicity and adverse human health effects (related mainly to inhalation concerns) have been identified for cationic polymers during polymer risk assessments conducted by the USEPA. The concern is thought to be highest for polymers that are either water-soluble or dispersible in water as either micro- or macro-dispersions. Health concerns are related to inhalation of cationic polymers which can then bind irreversibly to the lung membranes (anionic) resulting in acute and chronic lung toxicity.

Comparison with other approaches

Similar criteria for cationic polymers appear in the schemes from the United States, Canada, Australia, Korea K-REACH, and China. However, China does not contain exceptions for solid polymers or polymers with a low cationic density.

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[169] The Danish Environmental Protection Agency (2013) notes that under the REACH terminology, the fluorinated side chains may be considered as “other reactants” and, as such, would already be subject to their own registration requirements if they are used in amounts of 1 tonne or more per year.

No criteria for cationic polymers are included in the schemes from Japan, Taiwan, Philippines or New Zealand.

Issues/limitations

None.

Degradability

Rationale

The rationale given in COM (2015) for this criterion is that degradable polymers can convert into smaller compounds which are able to cross biological membranes with the potential to present an environmental and/or health hazard.

Comparison with other approaches

Similar degradability criteria are included in the schemes from the United States, Canada and Australia. The Japan CSCL also considers that a polymer of low concern must be found to be stable.

No degradability criteria are considered in the schemes from Korea, Taiwan, China, the Philippines or New Zealand.

Issues/limitations

The degradability criterion, as it is written in COM (2015), is open to interpretation and makes no distinction between polymers that are “readily biodegradable” and which may be completely mineralised and those that may degrade to more hazardous products.

The exclusion of degradable polymers from being considered as polymers of low concern may negatively impact on innovation and encourage the development of non-biodegradable polymers over biodegradable polymers. This needs to be considered carefully in any criteria developed for polymers requiring registration.

Water absorption

Rationale

The rationale given in COM (2015) for this criterion is based on concerns over carcinogenicity for high molecular weight water-absorbing polymers that have been seen a two-year inhalation study in rats. The concern is that similar effects could occur with other water-absorbing polymers

Comparison with other approaches

Similar criteria are included in the schemes from the United States and Australia. The criterion is not included in any of the other schemes considered.

Issues/limitations

There appears to be only a limited number of studies with high molecular weight polyacrylate polymers that demonstrate carcinogenicity. The general applicability of the findings to other polymers that absorb high amounts of water is unclear. This is discussed further later in relation to development of criteria for PRR.

Polyesters

Rationale

The rationale for this given in COM (2015) is that polyesters manufactured from certain specific alcohols and acids are known to be of low toxicity regardless of the molecular weight or oligomer content. The proposed list is based on approved lists used in the schemes used in the United States, Canada and Australia. However, a number of substances were removed from these lists as they can be considered to be toxic.

Comparison with other approaches

A broadly similar approach is used in the schemes in the United States, Canada and Australia. The scheme in China considers polyesters as polymers of low concern if they contain at least two carboxylic ester bonds in polymeric molecules and at least one carboxylic ester bond combined with internal monomers.

There are no specific considerations for polyesters in the schemes from Japan, Korea, Taiwan, the Philippines and New Zealand.

Issues/limitations

During the consultation it was noted that the COM (2015) report omitted the three most important and globally used monomers used in polyethylene terephthalate (PET) manufacture: terephthalic acid (benzene 1,4-dicarboxylic acid; CAS 100-21-0), monoethylene glycol (ethane-1,2-diol; CAS 107-21-1) and dimethyl terephthalate (dimethyl 1,4-benzenedicarboxylate; CAS 120-61-6). These monomers are exempted in other global schemes (e.g. in the United States, Canada and Australia) and there is no obvious reason why they were omitted from the COM (2015) recommendations.

The available evidence upon which the criterion is based is not clear from COM (2015) or from the other global schemes. It is not consistent with the general approach to consider polyesters to be of low concern without evidence. This is discussed further in relation to development of criteria for PRR later in this report.

Molecular weight and oligomer content

Rationale

The rationale given in COM (2015) is based on schemes from other countries and, in particular, the OECD (2009) study. The OECD (2009) study suggested that the polymers with a potential health concern showed an increased incidence of high oligomer content and that this appeared to be related to oligomer contents of ≥5% for oligomers with molecular weights <1000 Da and ≥2% for oligomers with molecular weights <500 Da. However, the OECD (2009) study also found that many low concern polymers have molecular weights between 1000 and 10 000 Da with oligomer contents up to 30%. Therefore, in order to avoid exclusion of too many low hazard polymers from the polymers of low concern group, the cut-offs for low molecular oligomers present in the polymers were proposed pragmatically at <10% and <25% for oligomers with molecular weight of <500 Da and <1000 Da respectively for polymers with molecular weights between 1000 and 10 000 Da. In addition, restrictions on the reactive functional groups present in the polymer are also applied to polymers in this molecular weight range (see below).

For polymers with molecular weights ≥10 000 Da the limits on oligomer content were proposed as <2% for oligomers with molecular weights of <500 Da and <5% for oligomers with molecular weights of <1000 Da, with no restrictions on the nature and content of the reactive functional groups present.

Comparison with other approaches

The approach proposed in COM (2015) is broadly in line with schemes used in the United States, Australia Canada, China, Korea (K-REACH) and Taiwan. However, only the United States, China and Taiwan schemes have specific criteria on the active functional groups associated with the polymers with molecular weights in the range 1000 to 10 000 Da. The Taiwan scheme also has a criterion on the active functional groups present in polymers with molecular weights >10 000 Da.

The Japan CSCL has molecular weight criteria based on low molecular weight species. For polymers which are soluble in water or organic solvents, the criterion is based on <1% content for species with a molecular weight <1000 Da. This applicable to soluble polymers with molecular weights between 1000 and 10 000 Da and also polymers with molecular weights ≥10 000 Da.

The Japan ISHL has a criterion for exemption from notification for polymers with molecular weight ≥2,000 Da.

No criteria related to molecular weight are included in the schemes in the Philippines and New Zealand.

Issues/limitations

The cut-offs for low molecular weight oligomer contents appear to be a pragmatic choice for identification of polymers of low concern based on the available evidence/experience. However, there does appear to be an inconsistency between how these are applied in COM (2015) to polymers with molecular weights between 1000 and 10 000 Da compared to polymers with molecular weights ≥10 000 Da. For example, according to these criteria a polymer with high molecular weight >10 000 Da having a fraction of oligomer (<1000 Da) of 10% would not be considered to be a polymer of low concern whereas a polymer with molecular weight between 1000 and 10 000 Da but a higher fraction of oligomer (<1000 Da) of 20% would be considered as a polymer of low concern.

The COM (2015) report justifies the use of different cut-offs for the low molecular weight oligomer content of polymers within the different molecular weight ranges on the basis of the OECD (2009) study The OECD (2009) study found an increasing incidence of potential health concerns with increasing oligomer content, starting at 5% oligomer content for oligomers <1000 Da and 2% for oligomers <500 Da. This was used as the basis for the oligomer content for the polymers with molecular weights >10 000 Da.

COM (2015) justified the cut-offs for polymers with molecular weights between 1000 and 10 000 Da on the basis that the OECD (2009) also found that many low concern polymers have molecular weights between 1000 and 10 000 Da sometimes with relatively high oligomer contents. Therefore the cut-offs of 10% for oligomers <500 Da and 25% for oligomers <1000 Da were taken as a reasonable choice in COM (2015).

These same cut-offs are used in several other regulatory schemes, along with an assessment of the presence of reactive functional groups. According to COM (2015) these cut-offs are based on expertise from the various polymer-related registrations and assessments from the rest of the world, and that ECHA considered that these criteria would ensure adequate protection for the EU. However, COM (2015) notes that these cut-off levels may be adjusted should further information become available.

A further possible limitation is that, even if there are low molecular weight oligomers present, they may not necessarily be available for release from the polymer. This is, at least in part, an exposure-based consideration. In general terms the diffusion of a non-bound substance within a polymer is linked to the molecular weight of the substance. The potential for diffusion to the surface of the polymer (and hence potential for subsequent release from the polymer) generally tends to decline as the molecular weight increases. In addition, the potential release from the polymer may also be influenced by polymer characteristics such as degree of cross-linking, rigidity etc. (for example increasing cross-linking and/or rigidity may be expected to reduce the potential for release of lower molecular weight substances present). However, it is important to note that there are examples of additives with molecular weights <1000 Da that are known to be released from polymer matrices (e.g. phthalates from PVC, brominated flame retardants from plastics[170]) and so it is not possible to conclude that the low molecular weight oligomers present in the polymer are not available for release in all cases (with subsequent potential for exposure of man or the environment).

There may be analytical challenges associated with reliable determination of the amounts of low molecular weight constituents present in polymers. For example, it may not always be possible to distinguish between 500 Da and 1000 Da accurately as the results for common methods such as gel permeation chromatography (GPC) can be influenced by the standards, detector and solvent system used. In addition, molecular weight distributions by GPC can only be measured on the fractions of the polymer that are soluble in the chosen solvent. During the consultation it was also stated that for some polymers such as aqueous acrylate dispersions it is almost impossible to determine a molecular weight with reasonable effort.

Reactive functional groups

Rationale

The rationale given in COM (2015) for including reactive functional groups is that some polymers could pose a hazard to health or the environment owing to their reactivity e.g. polymers that are alkylating agents or polymers which are electrophilic in nature. The proposed categories of reactive function groups given in COM (2015) are based on work conducted in the United States, EU, Australia and Canada. In addition, a study of reactivity at a molecular level was conducted and reported in Annex 4 of COM (2015).

Comparison with other approaches

A similar approach to categorisation of reactive functional groups is included in the schemes in the United States, Australia and Canada. The low-concern and moderate-concern groups proposed in COM (2015) are in line with the low- and moderate concern groups in these schemes. However, COM (2015) proposed including in the high-concern group a number of reactive functional groups (acid halides, acid anhydrides, aldehydes, hemiacetals, methylolamides, methylolamines, methylolureas, methoxy- and ethoxysilanes, allyl ethers, conjugated olefins, cyanates, epoxides, imines, and unsubstituted positions ortho or para to phenolic hydroxyl) that are in the moderate-concern groups in the United States and Canada, as a precautionary approach and citing a lack of evidence to support a lower hazard category[171].

The Japan CSCL has a criterion based on the following functional groups in the monomers: double bond (carbon to carbon), triple bond (carbon to carbon), double bond (nitrogen to nitrogen), triple bond (nitrogen to nitrogen), aziridine group, amino group, epoxy group, sulphone group, hydrazine group, phenol group, fluoro group.

The Taiwan TCSCA does not allow any active functional groups to be present in polymers of low concern.

In China, the following are not allowed in polymers of low concern with average molecular weights between 1000 and 10 000 Da: cyan groups, acrylic esters, aziridine, isocyanate, thio-isocyanate, vinyl sulphone.

No criteria for reactive functional groups are included in the schemes in Korea, the Philippines and New Zealand.

The FGEW cut-off proposed in the COM (2015) approach are the most stringent amongst those used in the studied countries.

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[170] For example, REACH restrictions apply to several phthalates in plastics used in toys and childcare articles, and the use of decabromodiphenyl ether and octabromodiphenyl ether in polymers (see Annex XVII of REACH).

[171] The EC(2015) study reports that NICNAS (the Australian Competent Authority) noted that they had no data that these RFG were of moderate concern and the OECD study shows that epoxides and unsubstituted positions ortho or para to phenolic hydroxyls are cause for health concerns.

Issues/limitations

The available experimental evidence for the criterion is not clear. However, the theoretical background to the criterion is based on sound science[172].

Other

The TCCA in Korea considers a polymer to be a polymer of low concern if the polymer is non-ionic with a number average molecular weight ≥1000 Da and where all of the starting monomers/reactants are listed in the Korean Existing Chemical Substance Inventory (KECI) and not listed on the toxic chemicals listing published by the National Institute of Environmental Research (NIER), and is not synthesised from toxic chemicals, observational chemicals or new chemicals and epoxy-compounds, and the water solubility is ≤5 mg/g at pH 2, 7 and 9. Non-ionic Polymers with a number average molecular weight of ≥10 000 Da are considered as polymers of low concern.

Summary

The proposed criteria given in COM (2015) are for identification of polymers of low concern. Generally similar criteria are included in one or more other schemes word-wide for identification of polymers of low concern. A summary of the rationale behind the criteria proposed in COM (2015) along with a comparison with other schemes and possible issues/limitations in considering these in relation to identification of polymers requiring registration is given in Table C2.

Table C2 Summary of the rationale for the COM (2015) proposed criteria for polymers of low concern

Criterion	Rationale	Comparison with other schemes world-wide	Possible issues/limitations
Definition of a polymer	Taken from the REACH Regulation and is consistent with the OECD definition of a polymer.	Generally consistent with the OECD definition. Two schemes also include a clause related to the number average molecular weight.	None identified.
Hazard information	Polymers, monomers and other substances present in the polymer labelled as hazardous in the most serious hazard classes are ruled out from being polymers of low concern.	Several of the approaches do not directly take into account the classification of the polymer.	The proposal in COM (2015) does not consider irritancy or corrosivity as part of the relevant hazard classes. The hazard properties of the polymer may be substantially different from that of the monomers and other substances.
Elemental limitations	Based on commonality amongst other schemes.	Similar elemental limitations are used in several other schemes.	The rationale for inclusion in the COM (2015) proposal is not clear other than it is included in other schemes.
Cationicity	Aquatic toxicity and adverse effects on human health via inhalation have been identified.	Similar criteria appear in several schemes.	None identified.

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[172] The COM (2015) report states that "The proposed categorisation was submitted to ECHA which received it favourably, with eminent toxicologists considering it is in line with the EPA learnings and that the approach in SAR (structure-activity relationship, see Annex 4) on which the proposal is based is sound."

Criterion	Rationale	Comparison with other schemes world-wide	Possible issues/limitations
Degradability	Degradable polymers can convert into smaller compounds which are able to cross biological membranes.	Similar criteria appear in several schemes.	No distinction is made between polymers that are readily biodegradable and those that may degrade to more hazardous products. The exclusion of degradable polymers from being considered as a polymer of low concern may encourage the development of non-biodegradable polymers over biodegradable polymers.
Water absorption	Based on concerns over carcinogenicity for high molecular weight water-absorbing polymers.	Similar criteria are included in two other schemes.	Finding is based on a limited number of studies with high molecular weight polyacrylate polymers. The general applicability of the findings is unclear.
Polyesters	Polyesters made from certain specific alcohols and acids are known to be of low toxicity.	A broadly similar approach is used in three schemes, and a further scheme considers polyesters to be polymers of low concerns if they contain certain structural elements.	The available evidence for the criterion is not clear.
Molecular weight and oligomer content	Based on schemes in other countries and, in particular, the OECD (2009) study.	Broadly in line with approaches in other schemes.	The cut-offs for low molecular weight oligomer contents appear to be a pragmatic choice for identification of polymers of low concern based on the available evidence/experience. The criterion does not consider whether the oligomers can actually be released.
Reactive functional groups	Some polymers could pose a hazard to health or the environment based on their reactivity.	A broadly similar approach is used in three schemes. Other schemes also do not allow specific (or in one case all) reactive functional groups to be present.	The available experimental evidence with polymers for the criterion is not clear in the COM (2015) report. However, the theoretical background to the criterion is explained in the COM (2015) report.

References for Appendix C

Danish Environmental Protection Agency (2013). Survey of PFOS, PFOA and other perfluoroalkyl and polyfluoroalkyl substances. Part of the LOUS-review. Environmental Project No. 1475, 2013. Danish Ministry of the Environment, The Danish Environmental Protection Agency. https://www2.mst.dk/Udgiv/publications/2013/04/978-87-93026-03-2.pdf (accessed 29th October 2019).

COM (2015). Technical assistance related to the review of REACH with regard to the registration requirements on polymer. Final Report. European Commission, 2015.

ECHA (2012). Guidance for monomers and polymers. European Chemicals Agency, Version 2.0, April 2012.

OECD (2009). Data analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern. Organisation for Economic Co-operation and Development, ENV/JM/MONO(2009)1, 27th January 2009.

USEPA (2010). 40 CFR Part 723. Premanufacture Notification Exemption for Polymers; Amendment of Polymer Exemption Rule to Exclude Certain Perfluorinated Polymers. United States Environmental Protection Agency. Federal Register, Vol. 75, No. 17, January 27, 2010, p4295-4305.

Appendix D
CESIO (2019) information on surfactants in the EU

During the consultation CESIO[173] (2019) made available further information on the polymeric surfactants used within the EU. CESIO is an industry association which represents companies manufacturing and marketing surfactants or their organic intermediates.

Recommendations for the harmonised self-classification and labelling of surfactants have been published (CESIO, 2017). These are based on the hazard information available to CESIO Member companies and recommended classifications for the main surfactants manufactured or supplied in the EU are given based on weight of evidence and expert judgement. The recommended classifications are reviewed every two years.

The CESIO (2017) report considers the surfactants under the following families: alcohol ethoxylates; alkyl ether sulfates, alkyl sulfates, other anionic surfactants and other surfactants. Within each family, the surfactants are further sub-grouped based on chemistry (for example chemical name, carbon chain length, degree of ethoxylation or propoxylation etc. as relevant). It is important to note that report makes no distinction between non-polymeric surfactants and polymeric surfactants within these broad groups and subgroups.

As an example, the alcohol ethoxylates (a major family of nonionic surfactants) is sub-divided into 25 groups (covering 31 CAS Numbers) based on the alcohol chain length (or range of chain lengths) present and these are then further sub-divided into ranges of ethoxylation degree covered by the recommended classification (for example <2.5 EO[174], ≥2.4-≤4 EO, >4-≤5 EO, >5-<10 EO, 10 EO, >10-≤15 EO and >15 EO; the actual ranges vary slightly with alcohol chain length). This resulted in a total of 211 sub-groups of alcohol ethoxylates to which a recommended classification has been assigned. Similar approaches are used for the other surfactant families using grouping relevant to the particular surfactant chemistry.

A broad overview of the recommended classifications for the surfactant families that may[175] contain surfactants that meet the REACH definition of a polymer is given in Table D1. The CESIO (2017) report should be consulted for the actual classifications recommended to the specific sub-groups within each family.

Table D1 Overview of classifications for surfactant families that may contain polymeric substances from the CESIO (2017) report

Family		**Environmental hazard class and hazard statement[176]**	**Health hazard class and hazard statement[18]**
Alcohol ethoxylates (nonionic surfactant)	Alcohol chain lengths between C_8 and C_{11}	For ≥2.5 EO groups generally not classified for environmental hazard under CLP. Under the GHS, substances with up to around 15 EO groups (and in some cases up to 40 EO	For ≥2.5-15 EO groups generally classified as Eye Irrit. 2 (H319) or Eye Dam. 1 (H318). For >5-<10 EO groups also Acute Tox. 4 (H302).

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[173] Comité Européen des Agents de Surface et de leurs Intermédiaires Organiques - European Committee of organic surfactants and their organic intermediates.

[174] Alcohol ethoxylates with <2.5 ethylene oxide groups are not polymers under the REACH definition and have already been registered under REACH.

[175] The CESIO (2017) report contains information on a large number of surfactants but does not specifically distinguish between polymeric surfactants and non-polymeric surfactants. The table gives examples of groups of surfactants which may contain members which may meet the REACH definition of a polymer. Whether or not a specific surfactant meets the REACH definition of a polymer will need to be considered by the manufacturer/importer on a case-by-case basis.

[176] When no advice or no recommendation is given this means that the data base is not sufficient for giving a classification recommendation.

Family		Environmental hazard class and hazard statement[176]	Health hazard class and hazard statement[18]
		groups classified as Acute 2 (H401) or Acute 3 (H402)[177].	For 10-15 EO groups no advice is given for acute toxicity. For >15 EO groups no advice is given for all endpoints.
	Alcohol chain lengths between C_{11} and C_{16}.	For ≥2.5- 5 EO groups classified as Acute 1 (H400) and Chronic 3 (H412). For 5-15 EO groups classified as Chronic 3 (H412). For >15-40 EO groups not classified under CLP but under GHS classified as either Acute 2 (H401) or Acute 3 (H402)18. For >40 EO groups not classified for environmental hazard.	For ≥2.5-20 EO groups generally classified as Eye Irrit. 1 (H318), Eye Irrit. 2 (H319) or Eye Dam. 1 (H318). For ≥7-<15 EO groups also Acute Tox 4 (H302). For >15 EO groups no advice is given for acute toxicity and for >20 EO groups no advice is given for all endpoints.
	Alcohol chain lengths between C_{16} and C_{20}.	For ≥2.5-5 EO groups classified as Chronic 2 (H411) under CLP. For >5-10 EO classified as Acute 1 (H400) and Chronic 3 (H412) under CLP. For >10 EO not classified for environmental hazard.	For ≥2.5-7 EO groups not classified. For >7-15 EO groups classified as Acute Tox 4 (H302). Additionally, for >11-25 EO groups classified as either Eye Dam. 1 (H318) or Eye Irrit. 2 (H319). For >25 EO no classification advice is given.
Alkyl ether sulfates and salts (anionic surfactant)	Alkyl chain lengths between C_8 and C_{10}, C_9 and C_{11}, C_{10} and C_{12} and C_{10} and C_{16}.	For ≥2.5 to 50 EO groups. Not classified under CLP but classified as either Acute 2 (H401) or Acute 3 (H402) under GHS18. For >50 EO groups not classified for environmental effects.	For ≥2.5 to >50 EO groups no recommendations given.
	Alkyl chain length of C_{12}.	For ≥2.5 - ≤11 EO groups Chronic 3 (H412) under CLP. For ≥12 – 50 EO groups not classified under CLP but Acute 3 (H402) under GHS18. For >50 EO groups not classified for environmental effects.	For ≥2.5 EO groups no recommendations are given except or 12 EO groups which is not classified for health hazard.
	Alkyl chain length of C_{12} to C_{13}.	For ≥2.5-≤10 EO groups Chronic 3 (H412) under CLP. For >10 – 50 EO groups not classified under CLP but Acute 3 (H402) under GHS[18] For >50 EO groups not classified for environmental effects.	For ≥2.5 EO groups no recommendations are given for human health hazard.
	Alkyl chain length of C_{12} to C_{14}.	For ≥2.5 – ≤50 EO groups not classified under CLP but Acute 2 (H401) or Acute 3 (H402) under GHS[18]. For >50 EO groups not classified for environmental effects.	For ≥2.5 EO groups no recommendations are given for human health hazard.

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[177] This indicates that toxicity has been demonstrated in acute aquatic toxicity tests but at concentrations above the level that would trigger classification under CLP.

Family		Environmental hazard class and hazard statement[176]	Health hazard class and hazard statement[18]
	Alkyl chain length of C_{12} to C_{18}.	For ≥2.5-≤10 EO groups Chronic 3 (H412) under CLP. For >10 – 50 EO groups not classified under CLP but Acute 3 (H402) under GHS[18] For >50 EO groups not classified for environmental effects.	For ≥2.5 EO groups no recommendations are given for human health hazard.
	Classification recommendations are not affected by the salt/counter ion present.		
Alkyl sulfates	These are not likely to be polymers within the REACH definition.		
Anionic surfactants, other	Alkylether carboxylic acids and salts (C_8 to C_{18})	For >2.5-10 EO groups not classified for environmental hazard under CLP. Under GHS >2.5-10 EO classified as Acute 2 (H401) or Acute 3 (H402)18.	For >2.5-10 EO groups classified as Eye Dam. 1 (H318) under CLP.
	The report also contains information on other, probably non-polymeric, surfactants in this family.		
Other surfactants	Amines, coco alkyl, ethoxylate (C_{12-18})	For ≥5-10 EO no recommendation for environmental classification. For ≥10-20 EO groups classified as Chronic 3 (H412).	For ≥5 EO groups generally classified as Acute Tox. 4 (H302), Eye Dam. 1 (H318) and in some cases Skin Irrit. 2 (H315).
	Tallow amine ethoxylates (C_{16-18})	For ≥5-50 EO groups generally classified as either Acute 1 (H400) and Chronic 1 (H410) or Chronic 2 (H411)	For ≥5 - <15 EO groups generally classified as Acute Tox. 4 (H302) along with Eye Dam. 1 (H315) and/or Skin Irrit. 2 (H315). For 15 EO groups additionally classified as Acute Tox. 2 (H330). No recommendation is given for >15-50 EO groups.
	Oleylamine ethoxylate (C18)	For 3-12 EO groups classified as Acute 1 (H400) and Chronic 1 (H410). For 20 EO classified as Chronic 2 (H411).	For 3-20 EO groups classified as Acute Tox. 4 (H302) along with either Skin Corr. 1C (H314), Skin Irrit. 2 (H315) and/or Eye Dam. 1 (H318)
	Stearylamine ethoxylate (C18)	For 8-15 EO groups classified as Acute 1 (H400) and Chronic 1 (H410). For 25 EO classified as Chronic 2 (H411).	No recommendations are given for health classification.
	Amines, C_{20-22} alkyl, ethoxylated	No recommendation given for 34 EO groups.	For 34 EO groups classified as Acute Tox 4. (H302) and Eye Irrit. 2 (H319).

Family		Environmental hazard class and hazard statement[176]	Health hazard class and hazard statement[18]
	Octy or nonylphenol ethoxylate	>2.5 -30 EO groups generally classified as Chronic 2 (H411) or Chronic 3 (H412). For >30 EO groups no recommendations are given.	For up to 15 EO groups Acute Tox 4. (H302) along with Skin Irrit. 2 (H315), Eye Dam. 1 (H318) and/or Eye Irrt. 2 (H319). For >15 EO groups not classified for health hazard.
	Fatty acid ethoxylates (C_8-C_{18})	For up to 10 EO groups no recommendations given for environmental hazard. For C_{18} and ≥10 EO groups Chronic 3 (H412).	Not classified for C_{8-18}. For C18 unsaturated no recommendations given.
	Fatty acid EO glycerol esters (C_{12} to C_{18})	No environmental classification under CLP for up to 17 EO groups. For C12-14 and up to 17 EO groups classified as Acute 3 (H402) under GHS[18]	Not classified for health hazard.
	Sorbitan ethoxylated fatty acid esters (C_{12} to C_{18})	C12 with up to 20 EO not classified for environmental hazard. C18 unsaturated with 20 EO groups classified as Chronic 3 (H412).	Not classified for health hazard.
	The report also contains information on other, probably non-polymeric, surfactants in this family. Contains several oligomeric substances.		

The information from CESIO indicates that most of the health hazards associated with polymeric surfactants relate to irritation or corrosive properties. However acute toxicity is associated with some products, particularly where 10-20 ethoxylate groups are present (examples for lower and higher numbers of ethylene oxide groups also exist). However, it is also important to note that no classification advice/recommendation is given in the CESIO (2017) report for many of the surfactants, particularly those with high numbers of ethoxylate groups.

For the environment, hazards related to acute or chronic toxicity are evident. From the CESIO (2017) data it is apparent that hazards to the aquatic environment are generally absent in surfactants with >50 ethoxylate groups but below this number the hazard is dependent upon the surfactant family, the alkyl (or hydrophobic group) chain length and the number of ethoxylate groups present.

The molecular weight of the ethoxylate repeat unit ($-C_2H_4O-$) is 44 Da and so polymers with at least 50 ethoxylate groups would have molecular weights of at least $44 \times 50 = 2{,}200$ Da, excluding the molecular weight of the hydrophobic group. This suggests that the most hazardous surfactants would have molecular weights below around 2,300-2,500 Da depending upon the hydrophobic group.

References for Appendix D

CESIO (2017). CESIO Recommendations for the harmonized classification and labelling of surfactants. Brussels, March 2017. https://www.cesio.eu/images/content/CESIO_CL_Recommendations_Brochure_Updated.pdf (accessed on 9th September 2019).

CESIO (2019). Presentation by CESIO REACH and Polymers Task Force, 29th August 2019. CESIO Surfactants Europe.

Appendix E
Confidential Annex

Appendix F
Cationic polymers

Cationic polymers as a broad group are known to lead to measurable toxicity to aquatic organisms in laboratory tests when they are soluble or dispersible in water. USEPA (2012) and Boethling and Nabholz (1997) outline methods that can be used to predict the aquatic toxicity of cationic polymers and these are discussed below. The experimental data behind these predictive methods is summarised in Boethling and Nabholz (1997), although the exact identities of the polymers tested is not given.

USEPA (2012) and Boethling and Nabholz (1997) considers structure activity relationships (SARs) for carbon-based, silicon-based and natural-based polymer backbones. The toxicity seen to aquatic organisms is related to the overall charge density of the molecule but there are several factors that can influence the estimated aquatic toxicity of cationic polymers.

- Cationic atom. Nitrogen, in the form of primary, secondary and tertiary amine groups or quaternary ammonium groups, is the most common group that is, or could become, cationic (>99% of cationic polymers contain one or more of these groups). Other cationic groups that may be present in cationic polymers include phosphonium or sulfonium groups;
- Percent amine nitrogen (%-aN) can be used to represent the percentage of cationic atoms within the polymer for polymers based on nitrogen-containing cationic groups. This is used as the basis for the SARs given in USEPA (2012) and Boethling and Nabholz (1997); and
- Polymer backbone. USEPA (2012) considers the following types: carbon-based, silicon-based or natural-based (for example chitin, starch, tannin).

The SARs relate the toxic effect levels to %a-N. The toxic effect concentration is predicted to decrease (higher toxicity) as the %a-N increases up to a %a-N of 3.5% to 4.5%, after which the toxic effect concentration remains approximately constant with a further increase in %a-N.

The available SARs for acute toxicity (L(E)C_{50}) to fish and Daphnids are shown in Figure 1 and Figure 2. For alga SARs are available for the acute toxicity (EC_{50}) and also the chronic toxicity value (ChV[178]) and these are shown in Figure 3.

The SARs shown are from USEPA (2012), essentially the same SARs are given in Boethling and Nabholz, 1997). SARs are currently not available for silicon-based polymers for acute toxicity to Daphnids and algae, and SARs are currently not available for natural-based polymers for acute toxicity to fish and acute and chronic toxicity to algae.

The SARs were based on experimental data for the following numbers of polymers (Boethling and Nabholz, 1997). The regression correlation coefficient (R^2) is also given were relevant.

- Fish acute toxicity:
  - Carbon-based backbone:
    - 19 polymers, $R^2 = 0.66$ for %a-N ≤3.5%; and
    - 34 polymers for %a-N >3.5%.
- Silicon-based backbone:
  - 4 polymers, $R^2 = 0.73$ for %a-N ≤3.5%

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[178] ChV is the geometric mean of the lowest observed effect concentration (LOEC) and the no observed effect concentrations (NOEC).

    - 1 polymer for %a-N >3.5%;
    - Natural based backbone:
        - No SAR derived for %a-N ≤3.5%. Boethling and Nabholz (1997) indicates that these polymers have either similar toxicity to carbon-based backbone polymers or lower toxicity; and
        - No SAR derived for %a-N >3.5%. Data available for one substance indicated less toxicity than for carbon-based backbone polymers.

- Daphnid acute toxicity:
    - Carbon-based backbone:
        - 7 polymers, $R^2 = 0.90$ for %a-N ≤3.5%; and
        - 13 polymers for %a-N >3.5%.
    - Silicon-based backbone:
        - No SAR derived for either %a-N ≤3.5% or >3.5%. Boethling and Nabholz (1997) indicates that these polymers have either similar toxicity to carbon-based backbone polymers or lower toxicity.
    - Natural-based backbone:
        - 6 polymers, $R^2 = 0.82$ for %a-N ≤4.3%; and
        - 1 polymer for %a-N >4.3%.

- Green algal acute toxicity:
    - Carbon-based backbone:
        - 5 polymers, $R^2 = 0.54$ for %a-N ≤3.5%; and
        - 12 polymers for %a-N >3.5%.
    - Silicon-based backbone:
        - No SAR derived for either %a-N ≤3.5% or >3.5%. Boethling and Nabholz (1997) indicates that these polymers have either similar toxicity to carbon-based backbone polymers or lower toxicity.
    - Natural-based backbone:
        - No SAR derived for either %a-N ≤3.5% or >3.5%. Boethling and Nabholz (1997) indicates that these polymers generally have lower toxicity to carbon-based backbone polymers with the same charge density.

- Green algal chronic toxicity (ChV):
    - Carbon-based backbone:
        - 5 polymers, $R^2 = 0.53$ for %a-N ≤3.5%; and
        - 11 polymers for %a-N >3.5%.

- Silicon-based backbone:
    - Data for one polymer indicating a similar toxicity to carbon-based backbone polymers.
- Natural-based backbone:
    - No SAR derived for either %a-N ≤3.5% or >3.5%. Boethling and Nabholz (1997) indicates that these polymers generally have lower toxicity compared to carbon-based backbone polymers with the same charge density.

It is important to note that some of the SAR are based on very few substances (notably those for silicon-based and natural-based polymers) and so this introduces more uncertainty over the predicted ecotoxicity.

Figure F1 SARs for prediction of acute toxicity to fish for polycationic polymers

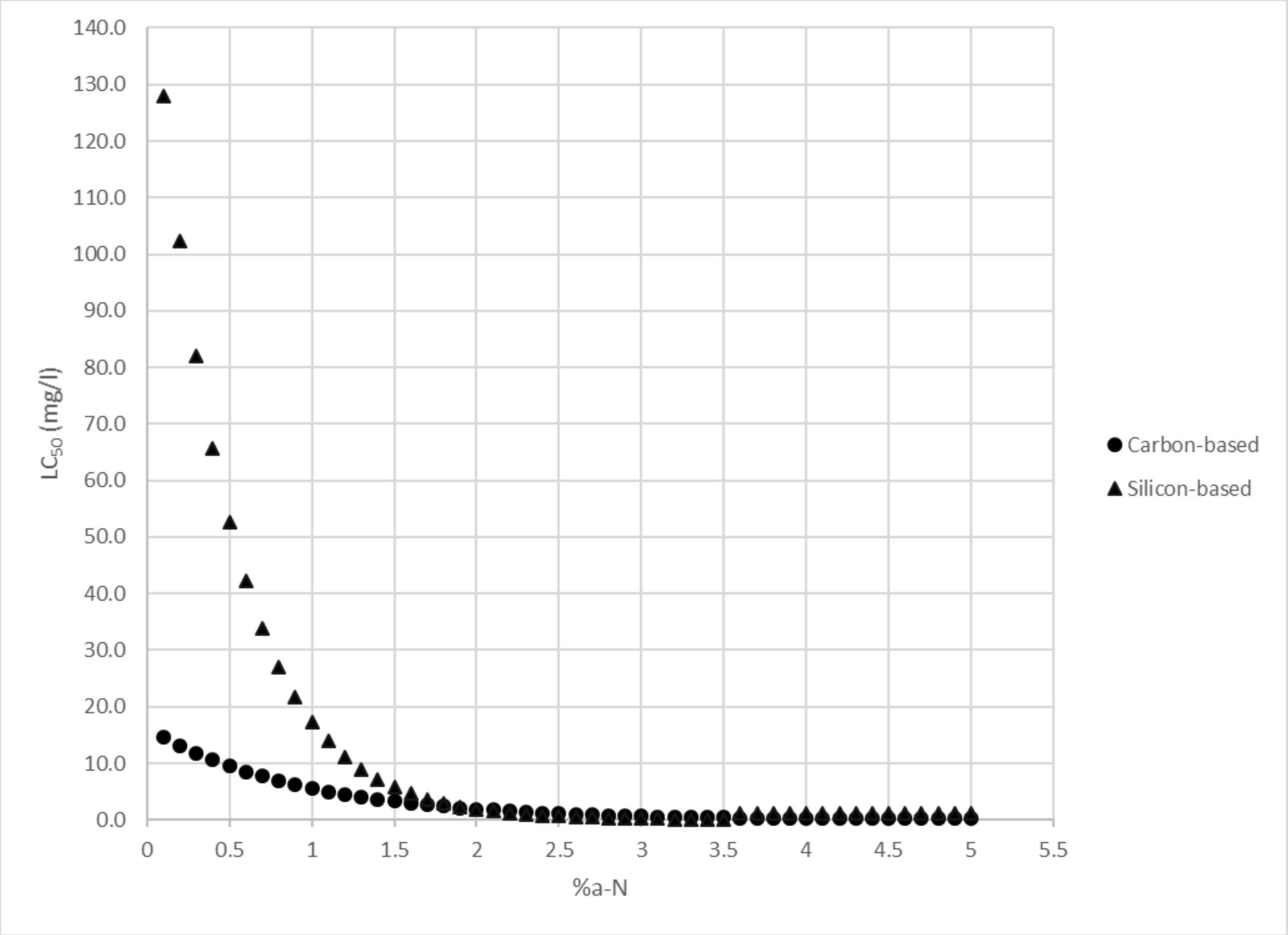


Figure F2 SARs for prediction of acute toxicity to Daphnids for polycationic polymers

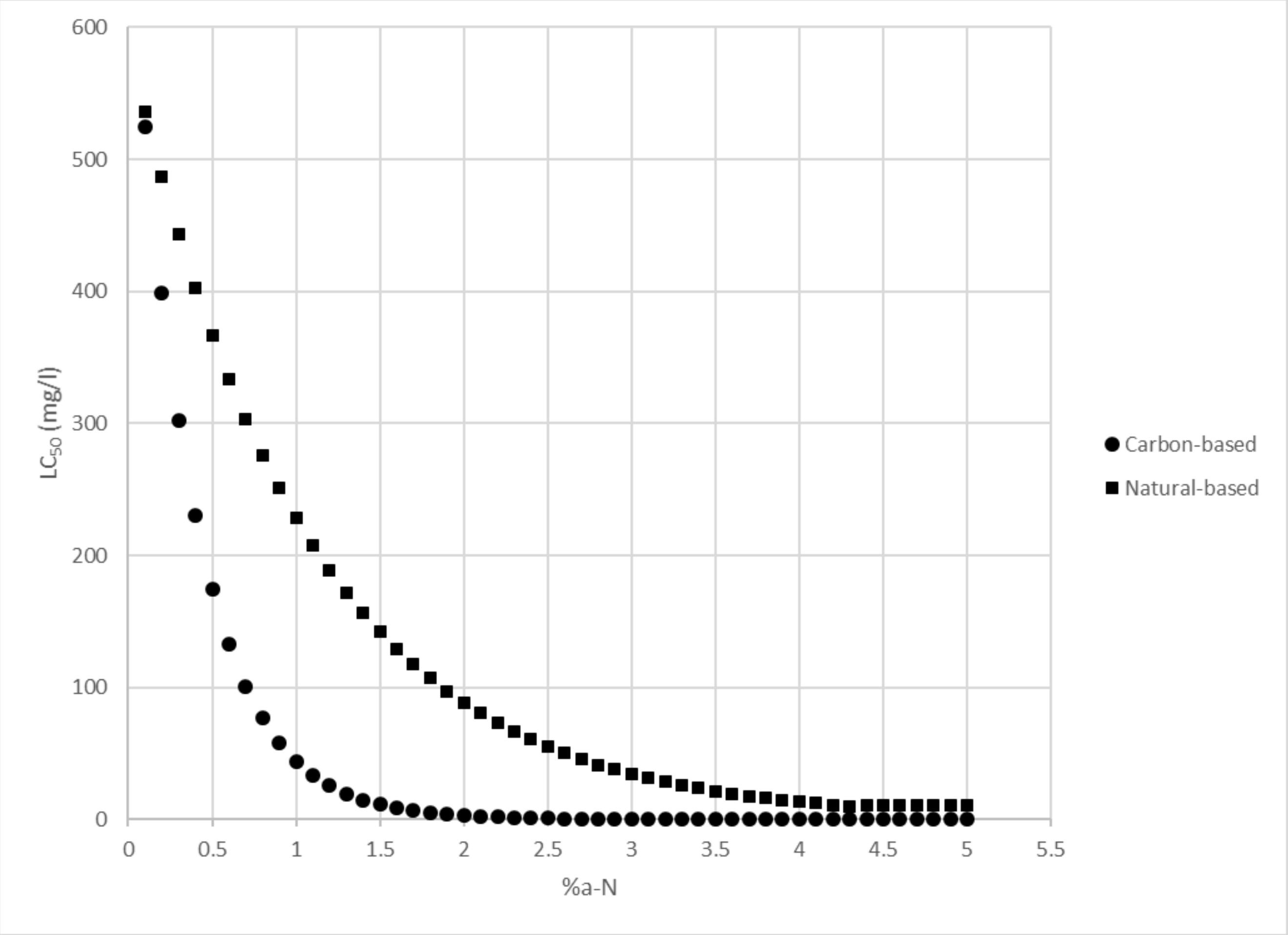
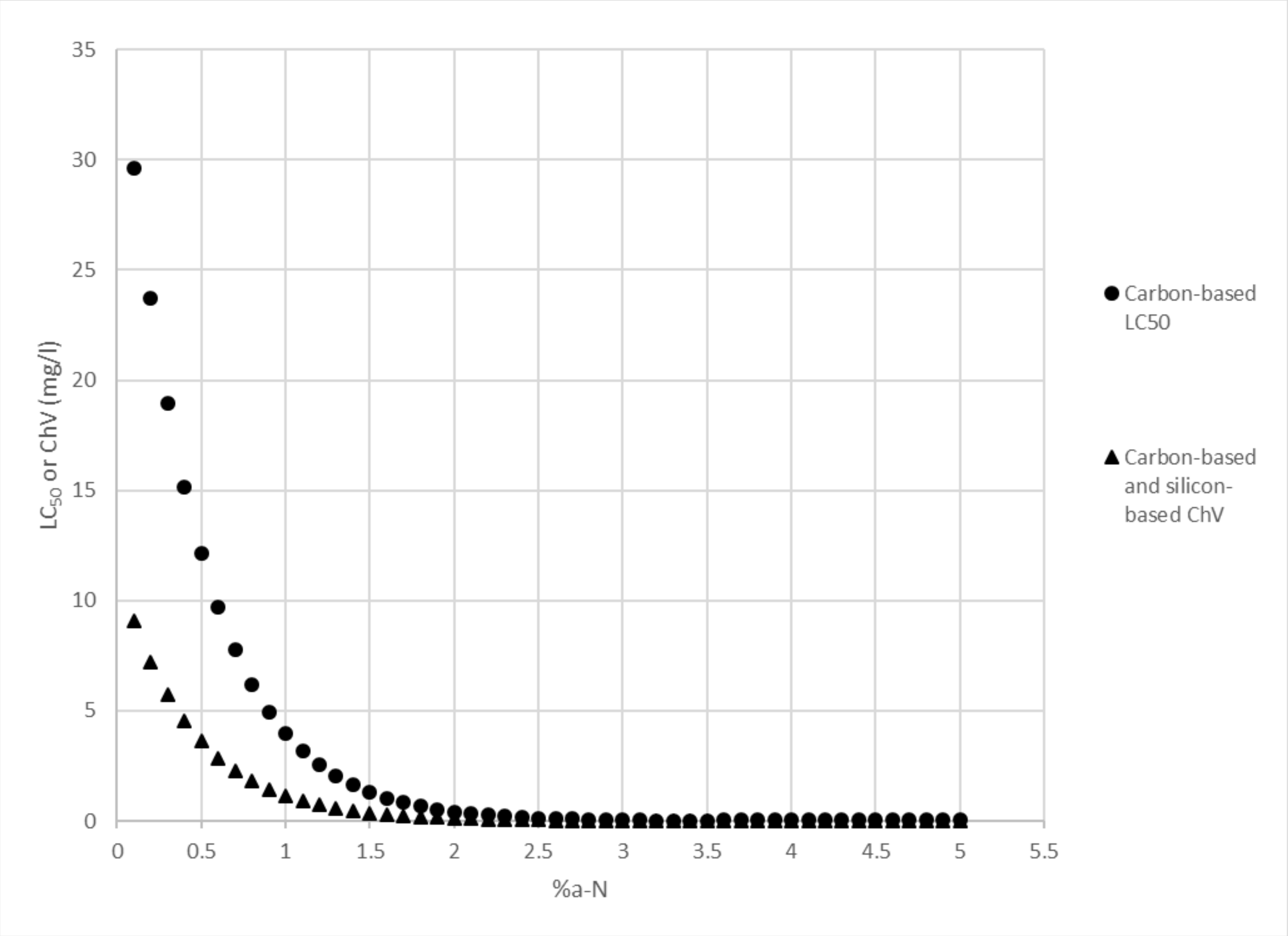


Figure F3 SARs for prediction of acute and chronic toxicity to algae



For the prediction of chronic toxicity to fish and Daphnids, USEPA (2012) suggests that this can be predicted from the acute toxicity by application of an acute to chronic ratio of 18 for fish or 14 for Daphnids (the same ratios are used for all three polymer backbone groups). According to Boethling and Nabholz (1997) the ratio of 18 for fish is derived from a single fish early life stage toxicity study and the ratio for Daphnids of 14 is derived from a single 21-day Daphnia magna reproduction test. Therefore, the extrapolation of acute toxicity to chronic toxicity for cationic polymers in general is uncertain.

Importantly, USEPA (2012) and Boethling and Nabholz (1997) consider that there is no molecular weight limit for toxicity to aquatic organisms, and report that some polycationic polymers with molecular weights >1000,000 Da are toxic to aquatic organisms. The reason for this is that the toxicity is not related to absorption of the polymer within the organism but rather from adsorption on the respiratory membranes of aquatic organisms.

Using a suggested cut-off of ≤100 mg/L for acute toxicity as being a property of the polymer that would be requiring registration then it can be seen that cationic polymers would meet this cut-off (e.g. based on the predicted algal toxicity in Figure 3.2) at all values of %a-N. This suggests strongly that all cationic polymers should be considered as polymers requiring registration.

Support for this comes from the data from the analysis of the DSD dataset carried out in Task 1.1 which contained several cationic polymers that were classified as hazardous

Further confidential information on the hazards associated with certain cationic polymers was provided by Industry at a late stage in the current project. Unfortunately there was insufficient time to take these data fully into account in this review but the data showed that such cationic polymers may be hazardous to the aquatic environment, and at concentrations similar to those predicted by Boethling and Nabholz (1997). These data could be useful in any further refinement of the above SARs (confidentiality issues aside).

It is also relevant to consider the form of the polymer. In terms of hazards to the environment the most concern would be associated with those cationic polymers that are either soluble in water or dispersible in water. Insoluble polymers would not lead to significant exposure to aquatic organisms. However, for insoluble polymers, inhalation exposure to sprays/dust/powders could potentially occur in some applications and this could be requiring registration in relation to human exposure.

The approach outlined in USEPA (2012) and Boethling and Nabholz (1997) also takes into account mitigation factors (MF). These are used to take into account that dissolved organic carbon (DOC), particularly humic acid and other acidic substances, reduces the toxicity of cationic polymers in the aquatic environment. Laboratory studies usually have relatively low levels of DOC compared with the natural environment and so the results from standard aquatic toxicity tests may overestimate the toxicity of the cationic polymers to organisms in the environment. These factors, whilst important, are more relevant to the risk assessment of cationic polymers (i.e. as to whether the polymer presents a risk to the environment from a specific use) than understanding of the intrinsic hazards of the polymers. Furthermore, similar mitigation considerations are not necessarily specific to cationic polymers, for example the toxicity of non-polymeric cationic substances may also be similarly mitigated by the presence of DOC, and this needs to be considered on a case-by-case basis as part of a detailed risk assessment. Therefore, it is proposed that mitigation factors are not taken into account when deciding if a cationic polymer is a polymer requiring registration or not but that such mitigation factors are taken into account in any subsequent risk/safety assessment requirements following registration.

The above predictive methods apply to cationic polymers where nitrogen is the basis of the cationic group. Much less information appears to be available on cationic polymers based on phosphonium, sulfonium or other cationic groups, although USEPA (2012) suggests that the %a-N in the above SARs can be replaced by the percentage of other cationic atoms within the polymer. As the mechanism of toxicity of cationic polymers in general is related to adsorption to respiratory surfaces there is no reason to suspect that cationic polymers based on cationic groups other than nitrogen-based would be of a lower concern than those with nitrogen-based cationic groups. Therefore, any requirement to include cationic polymers as polymers requiring registration for registration under REACH should equally apply to all cationic groups.

In terms of human health concerns from cationic polymers, much less publicly available information appears to be available. COM (2015) considered that the human health concerns from cationic polymers are related to inhalation of cationic polymers which can then bind irreversibly to the lung membranes (which are anionic) resulting in acute and chronic lung toxicity.

The overall conclusion is that cationic polymers should be considered as polymers requiring registration. Such polymers will typically contain one or more of the following groups.

- Primary, secondary and tertiary amine groups or quaternary ammonium groups; and
- Phosphonium or sulfonium groups, or other groups that are, or can become, cationic.

The cationic polymers that would be of highest concern are those that are soluble or dispersible in water, as these can potentially lead to exposure of aquatic organisms following release/use. For human exposure the highest concern would be extended to cationic polymers where inhalation exposure to sprays, dusts or powders could occur.

References for Appendix F

Boethling R S and Nabholz J V (1997). Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, Hamilton, John D. and Sutcliffe, Roger (eds.), (1997) Van Nostrand Reinhold.

COM (2015). Technical assistance related to the review of REACH with regard to the registration requirements on polymer. Final Report. European Commission, 2015.

USEPA (2012). Methodology document for the Ecological Structure-Activity Relationship Model (ECOSAR) Class Program. Estimating toxicity of industrial chemicals to aquatic organisms using the ECOSAR (Ecological Structure Activity Relationship) Class Program. MS-Windows Version 1.11. Contributors: K Mayo-Bean, K Moran, B Meylan and P Ranslow. United States Environmental Protection Agency, Syracuse Research Corporation and Consortium for Environmental Risk Management, May 2012. https://www.epa.gov/sites/production/files/2015-09/documents/ecosartechfinal.pdf (accessed 14th November 2018).

Appendix G
Polymer types and structural features requiring registration

Introduction

This appendix gives an overview of the different kinds of polymer that exist. This illustrates the complexity of this area and the breadth of different structures that can fall under the term 'polymer'.

For organic polymers, an overview of the common types of polymer is presented in Section 9.5 pf this appendix This includes a summary of the functional groups present and a discussion of whether they are potentially indicative of a PRR.

Inorganic and hybrid polymers do not contain functional groups requiring registration according to the proposed criteria under Task 1 in section 3 of the core report (although some structures may be 'requiring registration' due to ionisation or low molecular weight). However, comparatively little is known about most of these polymers, even when compared with organic polymers and further consideration of these structures may be needed.

Definitions of polymer types are taken from Billmeyer (1984), Callister (1997), Callister & Rethwisch (2010), Harris (1981), Moulijn et al (2001) and Sperling (2006). Polymer structures and names for Section 6 were identified using CROW (2018) and Wypych (2016).

Types of Polymers

Homopolymers

A homopolymer is made by linking only one kind of monomer.

Copolymers

A copolymer is formed when two or more different monomers are joined in the same polymer chain.

Alternating copolymers

The two monomers alternate (form an ABABAB pattern) in the polymer chain. There are two different types of alternating copolymers depending upon the polymerisation mechanism.

Step-growth condensation polymers (ABABABA)

A step-growth condensation polymer is formed by condensation reactions between the functional groups of two monomers (for example an amine and a carboxylic acid).

Addition alternating copolymers (ABABABA)

An addition alternating copolymer is formed by addition reactions between two different monomers. No small molecules are generated.

Random copolymers

The two monomers (A and B) may follow in any order. It is unlikely that the monomer ratio will be exactly 1:1. The monomer ratio depends upon properties of the monomers, polymerisation conditions, and the relative rates of polymerisation of the monomers. Initially the more reactive monomer is incorporated more than the less reactive one.

—A—A—B—A—B—B—A—B—A—A—B—B—B—A—

The Mayo-Lewis equation can be used to predict the composition of the polymer product for all initial mole fractions of monomer.

Block copolymers

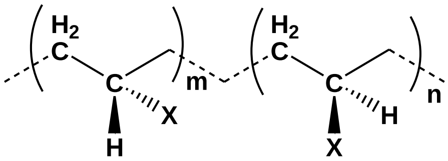
Two or more homopolymer subunits linked by covalent bonds. A Junction Block may be required to join the homopolymers together. This can be considered as two or more homopolymers joined together at one of the ends.

—A—A—A—A—A—A—A—B—B—B—B—B—B—B—

These are termed either diblock (with two blocks), triblock (with three blocks), or tetrablock (with four blocks) etc.

Stereoblock copolymers

These are where one or more copolymers with different stereochemistry are joined together.



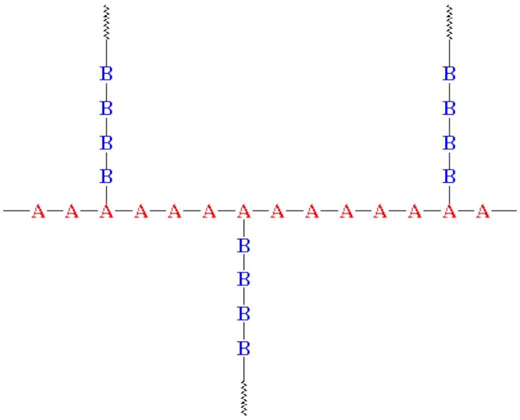
A stereoblock vinyl copolymer.

Periodic copolymers

Periodic copolymers have two (or more) monomers in a repeating sequence. For example, the repeat pattern of $(A\text{-}B\text{-}A\text{-}B\text{-}B\text{-}A\text{-}A\text{-}A\text{-}A\text{-}B\text{-}B\text{-}B)_n$.

Graft copolymers

Chains of a polymer made of monomer B are grafted onto a polymer chain of monomer A.



For example, high-impact polystyrene (HIPS) has a polystyrene backbone with chains of polybutadiene grafted on. The polystyrene gives the material rigidity and the rubbery polybutadiene chains give it resilience, so it is less brittle.

Naming Conventions

It is recommended that the ECHA naming convention for polymers should follow those of the American Chemical Society (ACS) and IUPAC. These organisations have proposed similar standardised naming conventions where the name of the polymers reflects the monomer(s) from which they are synthesised rather than the precise nature of the repeating subunit. For example, the polymer synthesised from ethylene is called polyethylene, retaining the -ene suffix even though the double bond is removed during the polymerisation process.

Table G1 Examples of naming conventions

Common name	ACS name	IUPAC name
Poly(ethylene oxide) or PEO	Poly(oxyethylene)	Poly(oxyethene)
Poly(ethylene terephthalate) or PET	Poly(oxy-1,2-ethanediyloxycarbonyl-1,4-phenylenecarbonyl)	Poly(oxyetheneoxyterephthaloyl)
Nylon 6	Poly[amino(1-oxo-1,6-hexanediyl)]	Poly[amino(1-oxohexan-1,6-diyl)]

Polymer Characteristics

The sections below summarise some of the different ways in which polymers can be characterised.

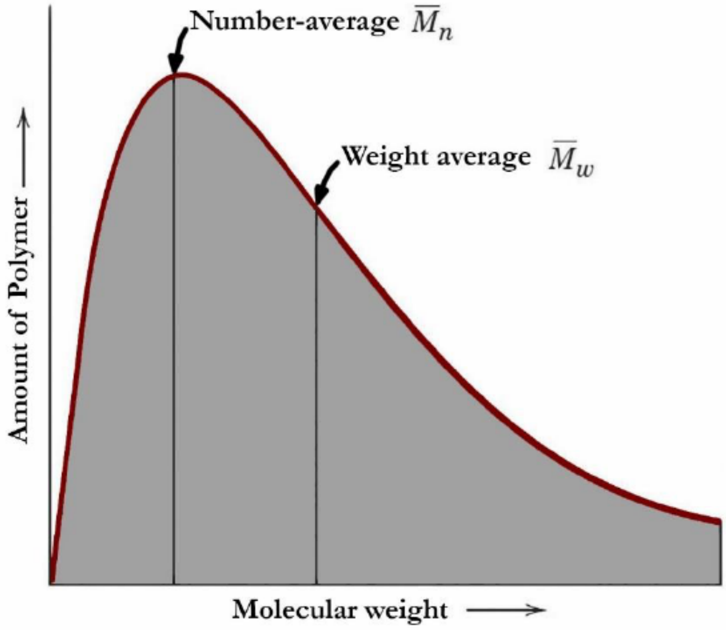
A polymer with the same repeat units may have very different characteristics depending on the conditions of the polymerisation. The mechanical properties of a polymer can differ significantly depending on variables like the extent and type of branching, crystal structure, and molecular weight.

It is also important to remember that most polymers are used as formulations with solvents, stabilisers, colourants, residual monomer, etc. Although these components should be registered separately under REACH, they can be very significant for mechanical, physicochemical and degradation properties and much existing (eco)toxicological data will be for the formulation.

Molecular Weight of the Polymer

The molecular weight of a polymer may be characterised using either the Number Average Molecular Weight or the Weight Average Molecular Weight. These two quantities can differ significantly. The number average lies near the peak of the weight-distribution curve and is always lower than the weight average molecular weight.

Figure G2 Distribution of molecular weight within a polymer



Number Average Molecular Weight $\overline{\boldsymbol{M}}_{\boldsymbol{n}}$

Some methods of molecular weight measurements count the number of molecules in a known mass of material. This leads to the number average molecular weight, $\overline{\boldsymbol{M}}_{\boldsymbol{n}}$, obtained by dividing the chains into a series of ranges and then determining the number fraction of chains with each size range.

$$\overline{M}_n = \sum x_i \, M_i$$

Where M_i = the mean (middle) molecular weight of the size range i

x_i = the fraction of the total number of chains within the corresponding size range.

Weight Average Molecular Weight $\overline{\boldsymbol{M}}_{\boldsymbol{w}}$

The weight fraction of molecules within the various size ranges are obtained by absolute methods of analysis.

$$\overline{M}_w = \sum w_i \, M_i$$

Where M_i = the mean molecular weight within a size range i

w_i = the weight fraction of molecules within the same size interval.

Degree of Polymerisation (DP)

This represents the number of polymer units in a chain. This could be expressed either as number average (DP_m) or weight average (DP_w) degrees of polymerisation.

$$DP_m = \frac{\overline{M}_n}{m} \qquad \text{OR} \qquad DP_w = \frac{\overline{M}_w}{m}$$

Where $\overline{M}_m$ = Number Average Molecular Weight

$\overline{M}_w$ = Weight Average Molecular Weight

m = Repeat unit molecular weight.

Typical Ranges ($\overline{\boldsymbol{M}}_{\boldsymbol{w}}/\overline{\boldsymbol{M}}_{\boldsymbol{m}}$)

The quantity ($\overline{M}_w/\overline{M}_m$)is a useful measure of the breadth of the molecular weight distribution curve and is the most common parameter quoted to describe it.

Table G2 Typical Ranges of ($\overline{\boldsymbol{M}}_{\boldsymbol{w}}/\overline{\boldsymbol{M}}_{\boldsymbol{m}}$)Ratio in Synthetic Polymers[179]

Polymer	**Range**
Hypothetical monodisperse polymer	1000
Actual monodisperse and living polymers	1.01-1.05
Addition polymer terminated by coupling	1.5
Addition polymer terminated by disproportionation	2.0
Condensation polymer	2.0
High conversion vinyl polymers	2-5

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[179] Billmeyer, Fred W. (1984) Textbook of Polymer Science, John Wiley & Sons, p18.

Polymer	Range
Polymers made with auto-acceleration	5-10
Addition polymers prepared by co-ordination polymerisation	8-30
Branched polymers	20-50

Molecular Structure of Polymers

The physical characteristics of a polymer depend not only on its molecular weight and shape, but also on differences in the structure of the molecular chains. It should be noted that polymers are not normally of only one distinct structure type. For example, a predominantly linear polymer might have some limited branching and crosslinking.

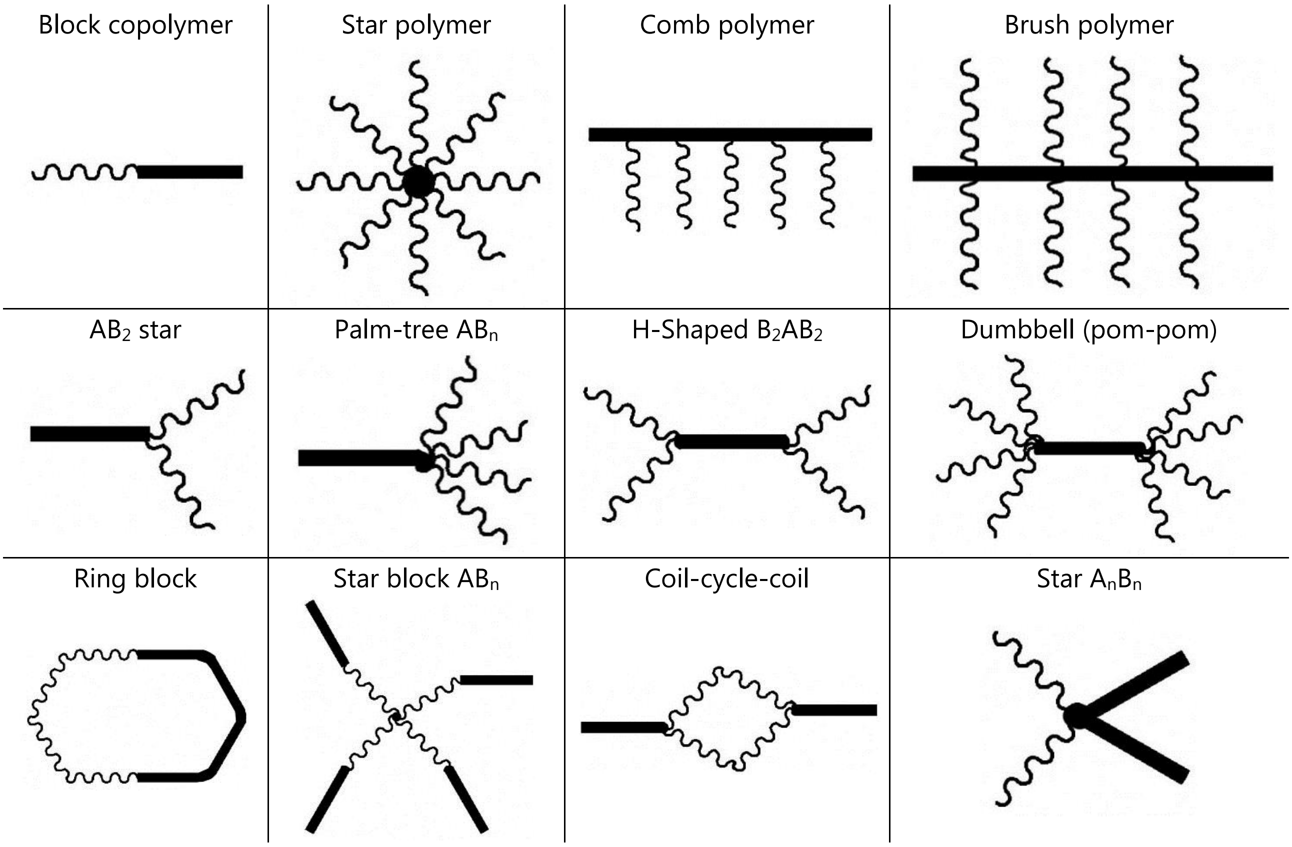
Linear Polymers

The polymer units are joined together end to end in a single chain. These chains are long and flexible. There may be extensive van der Waals bonding between the chains. Linear polymers can be reshaped by heating to an elevated temperature.

Branched Polymers

Polymers with side-chains connected to the main chain. The chain packing efficiency is reduced with the formation of side branches, which results in a lowering of the polymer density.

Figure G3 Types of branched copolymers



Crosslinked Polymers

Adjacent linear chains are joined to each other at various positions by covalent bonds. The crosslinking is either achieved during synthesis or by a non-reversible chemical reaction, normally carried out at an elevated temperature.

Network Polymers / Thermoset Resins

This is a highly crosslinked polymer with many trifunctional or more polymer units that form three dimensional networks instead of the linear chain framework of bi-functional polymer units. The epoxides and phenol-formaldehyde belong to this group. These cannot be reshaped at an elevated temperature and at high temperature thermal decomposition occurs.

Elastomers

These can be deformed quite severely by a small stress but regain their original shape on removal of the stress. For example, rubber and synthetic rubber.

Thermoplastics

Most linear and branched polymers can take on new shapes by the application of heat or pressure so are often termed to be a thermoplastic.

Thermoplastic Fibres

These linear polymers can be drawn (pulled out) into strands with considerable tensile strength and durability.

Molecular Configuration of Polymers

Geometric isomers

These have a double bond between chain carbon atoms. It is not possible by simple chain bond rotation to convert trans to cis, or vice versa.

Cis

The R groups are on the same side of the chain.

Trans

The R groups are on the opposite side the chain.

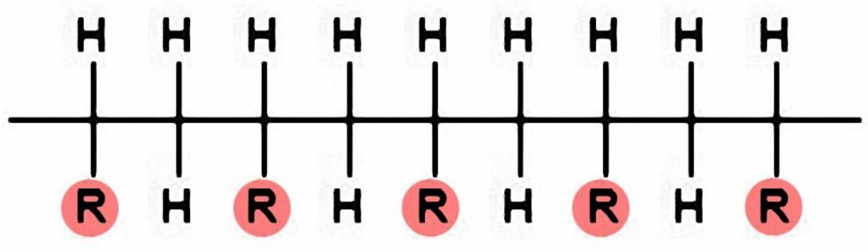
Stereoisomers

Stereoisomerism denotes the situation in which atoms are linked together in the same order but differ in their spatial arrangements. The conversion from one stereoisomer to another is not possible by a simple rotation about a single chain bond. The predominant form depends upon the method of synthesis.

Isotactic

All R groups are situated on the same side of the chain.

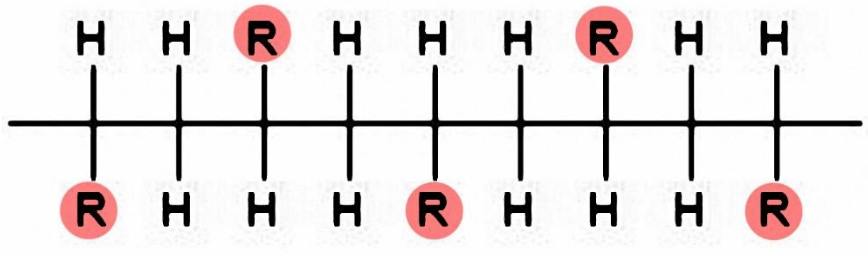
Figure G4 Isotactic



Syndiotactic

The R groups are on alternating sides of the chain.

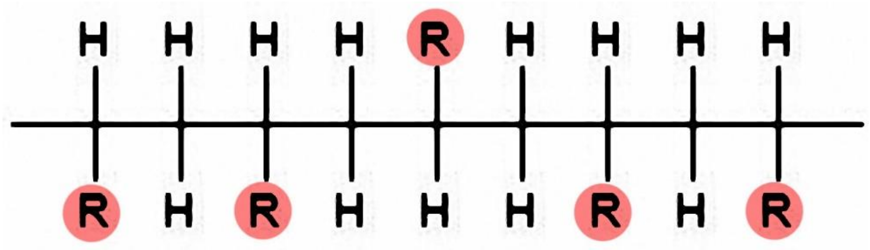
Figure G5 Syndiotactic



Atactic

The R groups are in random positions.

Figure G5 Atactic



Polymer Shape and Crystallinity

This is the degree of twist, coiling and bending. The polymer molecule assumes many different conformations in rapid succession due to thermal energy in dilute solution where the polymer chain is surrounded by small molecules or in the melt where it is in an environment of similar chains. As the polymer melt is cooled, the polymer chains are restrained by increasingly strong interchain forces.

Glass-transition temperature

This is the temperature where the polymeric material undergoes a marked change in properties with the virtual cessation of local molecular motion. Below their glass-transition temperature, amorphous polymers have many of the properties associated with ordinary glasses including hardness, stiffness, brittleness and transparency.

Crystalline melting point

Some polymers can crystallise at temperatures below their crystalline melting point. The crystalline melting point can be raised by increasing the intermolecular forces through the selection of highly polar polymers or by using inherently stiff polymer chains. These plastics are capable of replacing metals and ceramics in engineering applications.

Degree of Crystallinity

The density of a crystalline polymer is greater than an amorphous one of the same material and molecular weight because the chains are more closely packed together in the crystalline structure. The degree of crystallinity of a polymer depends on the rate of cooling during solidification and the chain configuration. For the chains to move and align themselves there must be sufficient time. Linear polymers crystallise easily due to the lack of restrictions to prevent chain alignment. Side branches interfere with crystallisation resulting in branched polymers never being highly crystalline; network polymers are totally amorphous. This may be determined from accurate density measurements.

$$\%\ Crystallinity = \frac{\rho_c\,(\rho_s - \rho_a)}{\rho_s\,(\rho_c - \rho_a)} \times\ 100$$

Where ρ_s = Density of a specimen for which the % crystallinity is to be determined

ρ_c = Density of a perfectly crystalline polymer

ρ_c = Density of totally amorphous polymer

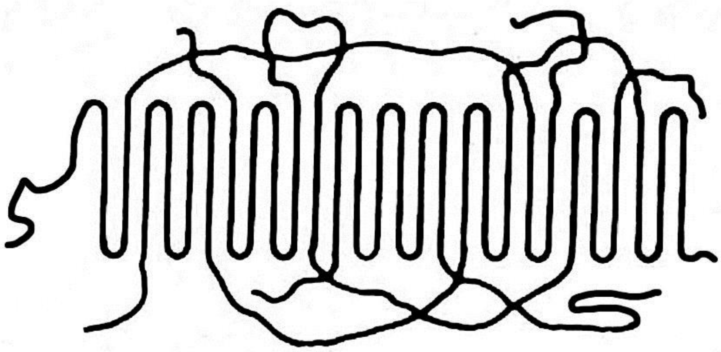
Crystalline polymers

These have a high level of symmetry or a simple polymer backbone, for example polyethylene and polytetrafluoroethylene. Crystalline polymers are strong, tough, stiff and generally more solvent resistant than non-crystalline polymers. The properties of crystalline polymer fibres can be further improved by the process of drawing or orientation. This results in an increase in strength, stiffness and dimensional stability.

Spherulites

The spherulites consists of an aggregate of ribbonlike chain-folded crystallites (also known as lamellae or lamellar crystals) and some amorphous material. Polyethylene, polypropylene, polyvinyl chloride, polytetrafluoroethyelene and nylon form a spherulite structure when they crystallise from a melt. Spherulites can be considered analogous to grains of polycrystalline metals and ceramics.

Figure G6 Schematic two-dimensional representation of lamellae



Crystallites or Micelles

These are small crystalline regions that have a precise alignment that are embedded within the amorphous matrix composed of randomly orientated molecules.

Semi-crystalline polymers

These have crystalline and amorphous regions.

Amorphous polymers

These have asymmetric or bulky pendant groups that inhibit packing and the solid is disordered.

Conjugated microporous polymers (CMPs)

These are amorphous porous conjugated polymers that are conductors, mechanical rigid, and insoluble. They are used in gas storage, heterogeneous catalysis, light emitting, light harvesting, and electric energy storage.

Forms of Polymers

Organic Polymers

In 1929, W.H. Corothers suggested the classification of polymers into two groups; **condensation** and **addition** polymers.

- **Condensation polymers** lack certain atoms present in the monomer from which they are formed (or to which it can be degraded). For example, a polyester is formed by condensation reactions between two bifunctional monomers with the elimination of water; and
- **Addition polymers** are those in which this loss of a small molecule does not take place. The most important group of addition polymers are those synthesised from unsaturated vinyl monomers.

Probably a more useful method of distinguishing polymers is by mechanism. There are two main polymerisation mechanisms.

- **Chain-growth Polymerisation** (addition polymerisation) where the reaction occurs with successive addition of monomer to the reactive end of the polymer. The most important group is the polymerisation of the vinyl monomers (e.g. ethene, propene, styrene and vinyl chloride). A high molecular weight product is produced initially while the monomer quantity decreases slowly over time. The reaction is fast, irreversible and moderately to highly exothermic.
    - **Free radical polymerisation** using an initiator such as peroxides (-O-O-) or azo compounds (-N=N-);
    - **Ionic (anionic or cationic) polymerisation**; and
    - **Co-ordination polymerisation** normally involves using a transition metal catalyst such as the Ziegler-Natta Catalyst and the Phillips catalyst.
- **Step-growth Polymerisation** reactions occur between the functional groups (-OH, -COOH, -NH$_2$ etc.) of any two molecules (either monomer or polymer). The molecular weight is not normally as high as with chain-growth polymerisation and small amounts of unreacted monomer is present after the start of the reaction. The reaction is slow, equilibrium-limited and isothermal to slightly exothermic. These can be split into addition polymers and condensation polymers.
    - **Addition polymers** where no molecules are evolved during the polymerisation; and
    - **Condensation polymers** where small molecules such as water are evolved.

Table G3 Distinguishing features of chain- and step-growth polymerisation

Chain-growth polymerisation	**Step-growth polymerisation**
Only growth reaction adds repeating units one at a time to the chain.	Any two molecular species present can react.
Monomer concentration decreases steadily throughout the reaction.	Monomer disappears early in reaction; at degree of polymerisation 10, less than 1% monomer remains.
Long polymer chains are formed at once; polymer molecular weight changes little throughout reaction.	Polymer molecular weight rises steadily throughout reaction.
Long reaction times give high yields but affect molecular weight little.	Long reaction times are essential to obtain high molecular weights.
Reaction mixture contains only monomer, long polymer chains and about 10^{-8} growing chains.	At any stage all molecular species are present in a calculable distribution.

Other polymerisation mechanisms include

- **Ring Opening Condensation** introduces a heteroatom into the polymer backbone, e.g. the ring opening of an epoxide to form poly(ethylene oxide); and
- **Nucleophilic Substitution** reactions are used in the production of polysulfide rubbers from aliphatic dichlorides and sodium sulfide.

There are hundreds of homopolymers and alternating copolymers where the molar ratio of the two monomers is 1:1.

Biodegradable Polymers

There are two main sources of biodegradable polymers.

- Agro-polymers are biodegradable polymers made from polysaccharides derived from potato/ wood starch, animal protein based upon whey or plant derived gluten. These include polyhydroxybutyrate and polylactic acid.
- Biopolyesters are biodegradable polymers derived from microorganisms or synthetically made from either natural or synthetic monomers.

Reactive functional groups

One possible criterion for a ‘polymer requiring registration’ is the presence of reactive functional groups within the polymer chain. Different functional groups have been identified as being ‘requiring registration’ by different regulatory regimes.

Natural Biopolymers

Biopolymers are produced by living organisms. The three main classes of biopolymers are:

- Polynucleotides (RNA and DNA), which are long polymers composed of 13 or more nucleotide monomers;
- Polypeptides, which are short polymers of amino acids;
- Polysaccharides, which are often linear bonded polymeric carbohydrate structures.

Other examples of biopolymers include rubber, suberin, melanin and lignin.

Modified natural polymers

Natural polymers can be modified by oxidation, cross-linking and end-capping. Examples are:

- Nitrocellulose from the reaction of nitric acid and cellulose;
- Vulcanised rubber from heating natural rubber in the presence of sulphur.

Inorganic Polymers

Inorganic polymers do not contain carbon atoms in the backbone. These are formed by:

- Step-growth polymerisation: e.g Polysiloxanes;
- Chain-growth polymerisation: e.g. Polysilanes; and
- Ring-opening polymerisation: e.g. Poly(dichlorophosphazene).

Hetero-chain

Heterochain polymers have more than one type of atom in the main chain. Typically, two different atoms alternating along the main chain.

- **Silicon (Si) based:**
  - Polysiloxanes with Si and O main chain centres, -Si-O-Si-O-; and
  - Polysilazanes with Si and N main chain centres are unstable to water so there are no commercial applications.
- **Phosphorous (P based):**
  - Polyphosphazenes with the -P-N-P-N- backbone. Generated by ring-opening polymerisation of hexachlorophosphazene followed by substitution of the P-Cl groups by alkoxide. Used as elastomers.
- **Boron-Nitrogen (B-based):**
  - Boron-nitrogen polymers have -B-N-B-N- backbones, e.g. polyborazylenes, and polyaminoboranes.
- **Sulphur-Nitrogen (S-based):**
  - Polythiazyls with -S-N-S-N- backbone and lack substituents on the main chain atoms. These exhibit high electrical conductivity and are superconductors below 0.26 K.

Homo-chain polymers

These have only one kind of atom in the main chain.

- .**Polysilanes**, e.g. Poly(dimethylsilane) is prepared by reduction of dimethyldichlorosilane and subsequent pyrolysis gives SiC fibres;
- **Polygermanes**, $(R_2Ge)_n$; and
- **Polystannanes**, $(R_2Sn)_n$.

Smart inorganic polymers (SIPs)

Inorganic polymers with tuneable (smart) with stimuli responsive physical properties such as shape, conductivity, rheology, redox, photo-emissive, magnetic, self-healing and catalytic properties. This emerging technology has been applied such as optoelectronics, energy storage, industrial chemistry and biology.

Hybrid Polymers

Hybrid polymers contain inorganic atoms and carbon atoms in the backbone. These include:

- Silicon peptide biopolymers;
- Ether polymers formed from epoxides; and
- Polysulphide polymers.

Ionic and Polar Polymers

Ferroelectric polymers

These are Crystalline polar polymers that maintain a permanent electric polarisation that can be reversed, or switched, in an external electric field (ferroelectric). For example, polyvinylidene fluoride (PVDF) is used in acoustic transducers and electromechanical actuators because of their inherent piezoelectric response, and as heat sensors because of their inherent pyroelectric response.

Ionomer

A polymer with both electrically neutral repeating units and ionised units (usually no more than 15 mole percent) covalently bonded to the polymer backbone as pendant group moieties. Uses for ionomers include golf ball covers, semipermeable membranes, sealing tape and thermoplastic elastomers. Common example ionomers include:

- Polystyrene sulfonate;
- Sulfonated tetrafluoroethylene-based fluoropolymer-copolymer;
- Nitrile rubber; and
- A copolymer of ethylene and methacrylic acid used as a coating and packaging material.

Polyelectrolytes [Polyionic polymers]

These contain greater than 80% ionic groups covalently bonded to the polymer backbone.

Ionenes

A polymer with ionic groups as part of the actual polymer backbone.

Investigation into Functionality

One possible criterion for a Polymer requiring registration' is the presence of reactive functional groups. Different functional groups have been identified as being 'requiring registration' by different regulatory regimes.

This investigation focuses on synthetic organic polymers. The natural polymers and modified natural polymers and inorganic (hetero- or homo-chain), hybrid, and transition-metal polymers that exist are not covered here.

The information presented in this section represents an initial investigation into the functional groups present in organic polymers that may be associated with health hazards. The different classes of polymer have been identified based on CROW (2018) and Wypych (2016).

The simplified molecular input line entry system (SMILES) for the repeat unit was generated and a six-carbon alkyl chain was added to each end; these 'extended SMILES' are small enough to allow computational calculations while containing all functional groups associated with the polymer. The set of extended SMILES were Profiled using the OECD QSAR toolbox[180]. This was intended as a first-pass attempt to identify functional groups that may be associated with human health hazards.

Tables A4 - A8 list the polymer classes, with an example from each class. The monomer and the repeat unit are then identified, and the functional groups present are discussed. It should be noted that in all cases the

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[180] https://www.qsartoolbox.org/

monomer contains functional groups that are reacted during polymerisation and are no longer present in the polymer. In many cases, it is not possible for the functionality of the monomer to be regenerated during degradation of the polymer. Therefore, the relevance of hazard data for the monomer is limited (except in terms of the possibility for unreacted monomer to be present).

It should be noted that:

- The Profilers[181] in the QSAR Toolbox are intended for grouping of chemicals for read-across, not to predict toxicity in themselves;
- The Toxic hazard classification by Cramer profilers' High (Class III) classification is meant to cover substances with chemical structures that permit no strong initial presumption of safety[182]. This alert has not been included in the tables below unless the Cramer classification decision tree indicates that a group associated with toxicity is present. Alerts from the Repeated Dose (HESS) profiler that indicate similarity to a substance with known toxicity have also been excluded because the similarity would not be relevant for the polymer structure;
- Alerts with a boundary condition relating to molecular weight or carbon chain length have been excluded, but such conditions are not specified for most profilers. Even if a functional group is strongly associated with toxicity, the high molecular weight of polymers may mean that the substance is not bioavailable, and toxicity that would be expected for a small molecule is not expressed. There is very little experimental data for polymeric material to allow any predictions of possible toxicity to be validated.

There is also a comment in the tables about whether the polymers contain functional groups listed in the current proposed criteria for a polymer requiring registration. These comments relate only to the criteria linked to structural features. Polymers with low molecular weight, high oligomer content or meeting exposure criteria would be identified as polymers requiring registration using the criteria suggested in the main report regardless of the structural features present.

Table A4 covers chain-growth homopolymers. In chain-growth polymerisation (addition polymerisation) the polymerisation reaction occurs with successive addition of monomer to the reactive end of the polymer. The most important group is the polymerisation of the vinyl monomers (e.g. ethene, propene, styrene and vinyl chloride). A high molecular weight product is produced initially while the monomer quantity decreases slowly over time; some monomer may remain even at long reaction times. The reaction is fast, irreversible and moderately to highly exothermic. No reactive groups are left at chain ends after termination of the reaction. The monomer units would not be regenerated upon degradation of the polymer.

Table A5 shows condensation step-growth polymers. The polymers shown here have two monomers and form an ABABAB co-polymer. In step-growth polymerisation, bifunctional (or multifunctional) monomers react to form first dimers, then trimers, longer oligomers and then polymers. A small molecule such as water is evolved during each reaction. A high extent of reaction is required to achieve high molecular weight, but monomer is lost rapidly early in the reaction. The ends of the polymer chain remain active, with the functional groups that are present in the monomers. The monomer functionality could be regenerated upon degradation of the polymer.

Table A6 and A7 show ring opening polymers where a heteroatom is introduced into the polymer backbone, e.g. the ring opening of an epoxide to form poly(ethylene oxide).

Table A8 shows other alternating co-polymers including addition polymers.

Only homopolymers and ABABAB copolymers are covered below; many different co-polymers exist. However, the criteria for identifying functional groups requiring registration are also relevant for copolymers. Some

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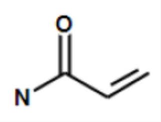
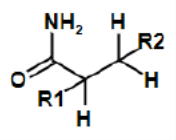
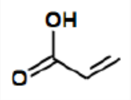
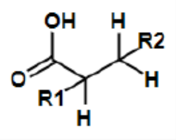
[181] The Profilers in the QSAR Toolbox are used to identify potential structural analogues. These are used by the QSAR Toolbox to identify suitable read-across data or structural alerts for the molecule.

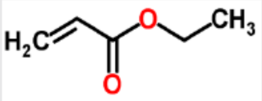
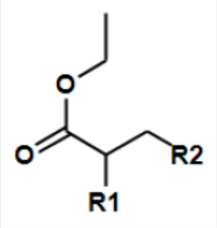
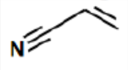
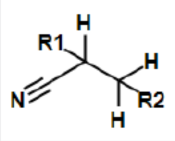
[182] The Cramer Classification Class III contains substances were the possibility of toxicity cannot be ruled out based on structural features.

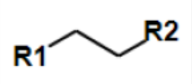
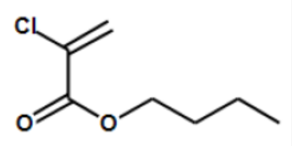
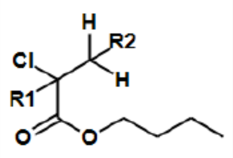
examples of common copolymers (acrylonitrile, acrylic acid, vinyl acetate, halogenated and polystyrene copolymers) were investigated and (as expected) gave the same structural alerts for toxicity in the QSAR Toolbox as homopolymers with each the same monomer types.

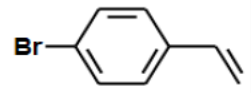
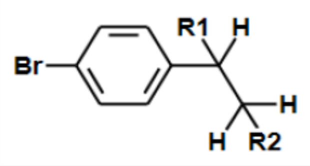
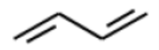
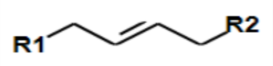
Chain Growth Homopolymers

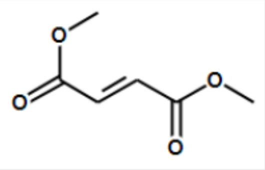
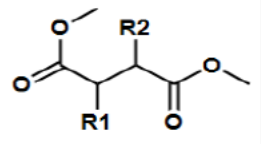
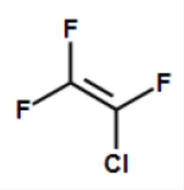
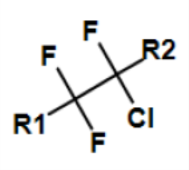
Table G4 Chain growth homopolymers

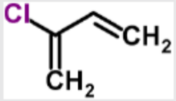
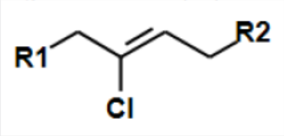
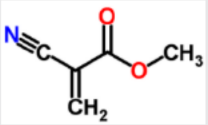
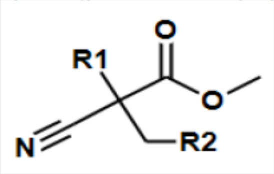
Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyacrylamides				
Poly(acrylamide)	The monomer is acrylamide or an acrylamide ester.  Acrylamide	The C=C double bond of the acrylamide is lost, leaving an alkyl chain with pendant amide or amide ester groups. The acrylamide functionality would not be regenerated upon degradation of the polymer. 	No evidence of significant toxicity.	These are water-absorbing polymers. Amide is not in the list of functional groups requiring registration.
Polyacrylates (Polypropenoates)				
Poly(acrylic acid)	The monomer is acrylic acid.  Acrylic acid	The C=C double bond of the acrylic acid is lost, leaving an alkyl chain with pendant carboxylic acid. The acrylic acid functionality would not be regenerated upon degradation of the polymer. 	No evidence of significant toxicity for this class in general.	Not in general. Poly(acrylic acid) has pendant carboxylic acid groups. Carboxylic acid is identified as a functional group of low concern but it is expected to become anionic in a natural aquatic environment and may be requiring registration for this reason.

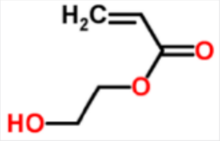
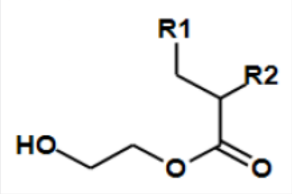
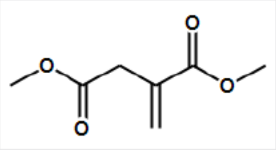
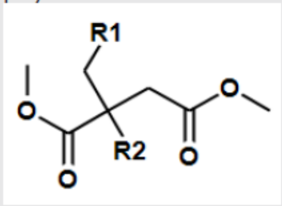
Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Poly(ethyl acrylate)	The monomer is an acrylate ester. 	The C=C double bond of the acrylate ester is lost, leaving an alkyl chain with pendant ester groups. The acrylic acid functionality would not be regenerated upon degradation of the polymer. 	No evidence of significant toxicity for this class in general. Some substances in the group have structural features (for example, cyano) that have structural alerts.	Not in general. High concern functional groups may be part of the pendant group (for example, the cyano group in poly(2-cyanoethyl acrylate) and poly(cyanomethyl acrylate)).
Polynitriles				
Poly(acrylonitrile)	The monomer contains nitrile and alkene groups; there is conjugation between these two groups.  Acrylonitrile	The alkene functionality and the conjugation are lost, leaving an alkane chain with pendant nitrile groups. The alkene functionality would not be regenerated upon degradation of the polymer. 	The aliphatic nitrile group may be associated with hepatotoxicity (Hess Profiler) and is a functional group associated with enhanced toxicity in the Toxic Hazard Classification by Cramer profiler. All supporting data for these profilers relates to very small molecules and may not be applicable to polymers.	No. Unconjugated nitrile groups are classed as "low concern"

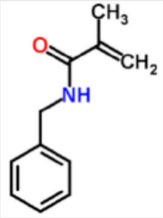
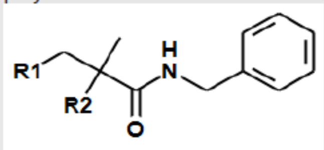
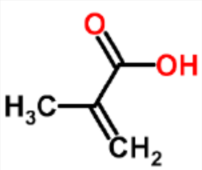
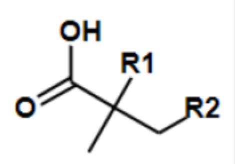
Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyalkenes (Polyolefins)				
Poly(ethylene)	The monomer is an alkene. $H_2C{=}CH_2$ Ethylene	The alkene group is lost, leaving an alkane chain. The alkene functionality would not be regenerated upon degradation of the polymer. 	No alerts.	No.
Poly(2-chloroacrylates) / (Poly(2-chloro propenoates)				
Poly(butyl-α-chloroacrylate)	The monomers are 2-chloroacrylate esters.  propyl-alpha-chloroacrylate	The C=C double bond of the acrylate is lost, leaving an alkyl chain with pendant ester and chloro groups. The acrylate functionality would not be regenerated upon degradation of the polymer. 	No evidence of significant toxicity.	Ester is not included in the list functional groups requiring registration. Halogens (except reactive halogen containing groups such as benzylic or allylic halides) are a group of low concern.

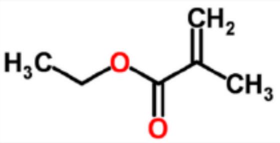
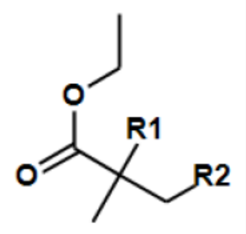
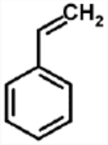
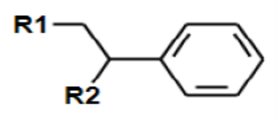
Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyhalostyrenes (Brominated Chlorinated and Fluorinated Styrenes)				
Poly(4-bromostyrene)	The monomers are halogenated styrenes.  4-bromostyrene	The alkene group reacts, leaving an alkane chain with pendant halophenyl groups. The alkene group would not be regenerated upon degradation of the polymer. 	There is some evidence that halogenated aromatic compounds may be carcinogenic and show repeated dose toxicity. Two 4-Alkylchlorobenzene substances also have an alert relating to oestrogen receptor binding. It is not known whether these alerts are relevant for polymers.	No. Halogens (except reactive halogen containing groups such as benzylic or allylic halides) are a group of low concern. Phenyl groups are not included in the list of groups requiring registration.
Polydienes (Diene Elastomers)				
Poly(1,4-butadiene)	The monomer contains two conjugated C=C double bonds.  Butadiene	One C=C double bond per monomer is lost during polymerisation, leaving a carbon chain with alkene groups that are not conjugated. The alkene group would not be regenerated upon degradation of the polymer. 	No relevant alerts.	No. "Ordinary" unconjugated olefinic groups are of low-concern.

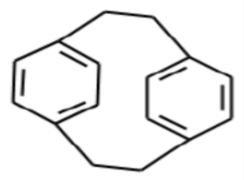
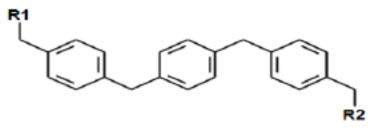
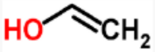
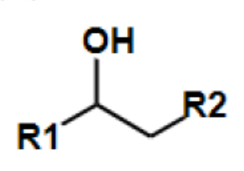
Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyfumarates (Polybutenedioates)				
Poly(dimethyl fumarate)	The monomer is a dialkyl fumarate (dialkyl butenadioate)  Dimethylfumarate	The C=C double bond of the fumarate group is reacted, leaving butanedioate groups. This results in an alkyl chain with pendant ester groups. The fumarate group would not be regenerated upon degradation of the polymer. 	No evidence of significant toxicity.	No. Butanedioic acid groups are of low concern; butanedioate groups are not included in the list of functional groups requiring registration.
Polyhaloolefins				
Poly(chlorotrifluoroethylene)	The monomer is generally ethene substituted with up to four halogens.  Chlorotrifluoroethene	The alkene functionality is lost, leaving a halogenated alkane chain. The alkene functionality would not be regenerated upon degradation of the polymer. 	Structural alerts associated with genetic toxicity, carcinogenicity and sensitisation have been identified for substances in this group. The alerts identified depend on the number and identity of the halide groups. The relevance of these alerts for polymers is not clear.	No. Halogens are a group of low concern (except reactive halogen containing groups such as benzylic or allylic halides).

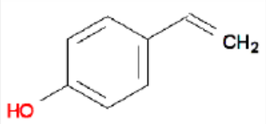
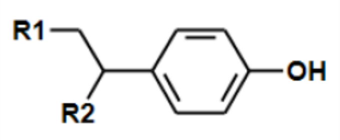
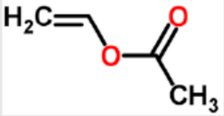
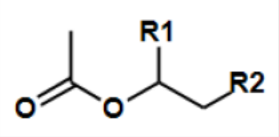
Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyhalodienes (Chlorinated and Brominated Dienes)				
Poly(1-chloro-1-butenylene) (Polychloroprene)	The monomer contains two conjugated C=C double bonds and a halide group.  Chloroprene (2-Chloro-1,3-butadiene)	One C=C double bond per monomer is lost during polymerisation, leaving a carbon chain with halo-alkene groups that are not conjugated. The alkene group would not be regenerated upon degradation of the polymer.  	These structures have alerts relating to mutagenicity, carcinogenicity and repeated dose toxicity. These are related to the haloalkene group. The relevance of these alerts for polymers is not clear.	No. "Ordinary" unconjugated olefinic groups and halogens (except reactive halogen containing groups such as benzylic or allylic halides) are in the low-concern group.
Polycyanoacrylates				
Poly(methyl cyanoacrylate)	The monomer is an alkyl cyanoacrylate.  Methyl 2-cyanoacrylate	The C=C double bond of the acrylate reacts, leaving an alkyl chain with pendant alkyl ester and nitrile (cyano) groups. The acrylate group would not be regenerated upon degradation of the polymer.  	The aliphatic nitrile group may be associated with hepatotoxicity (Hess Profiler) and is a functional group associated with enhanced toxicity in the Toxic Hazard Classification by Cramer profiler. All supporting data for these profilers relates to very small molecules and may not be applicable to polymers.	No. Nitrile groups are of low-concern. Esters are not included in the list of functional groups requiring registration.

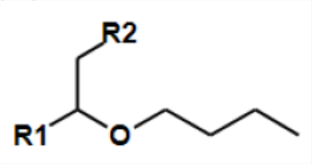
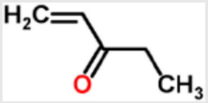
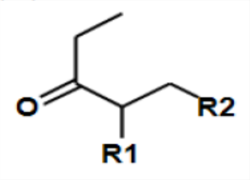
Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyhydroxy(meth) acrylates				
Poly(2-hydroxyethyl acrylate)	The monomer contains (meth)acrylate and alcohol functionality.  2-Hydroxyethyl acrylate	The C=C double bond of the acrylate reacts, leaving an alkyl chain with pendant groups containing ester and hydroxyl functionality. The acrylate group would not be regenerated upon degradation of the polymer.  	These structures have an alert for *in vivo* mutagenicity (H-acceptor-path3-H-acceptor). This relates to parts of the chain that have the structure O-C-C-O.	No. Aliphatic hydroxyl groups are of low concern. Esters are not included in the list of functional groups requiring registration.
Polyitaconates (Polymethylene succinates)				
Poly[dimethyl itaconate]	The monomer is a dialkyl itaconate. It therefore contains acrylate and ester functionality.  Dimethyl itaconate	The C=C double bond of the itaconate is reacted, leaving butanedioate groups. This results in an alkyl chain with pendant ester groups. The itaconate group would not be regenerated upon degradation of the polymer.  	No evidence of significant toxicity.	No. Butanedioic acid groups are of low concern; butanedioate groups are not included in the list of functional groups requiring registration.

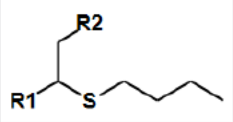
Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polymethacrylamides				
Poly(N-benzyl methacrylamide)	The monomer is a methacrylamide.  N-Benzyl-2-methylacrylamide	The C=C double bond of the methacrylamide is reacted, leaving an alkyl chain with pendant amide groups. The methacrylamide group would not be regenerated upon degradation of the polymer. 	No evidence of significant toxicity.	These are water-absorbing polymers. Amide is not included in the list of functional groups requiring registration.
Polymethacrylates				
Poly(methacrylic acid)	The monomer is methacrylic acid.  Methacrylic acid	The C=C double bond of the methacrylic acid is reacted, leaving an alkyl chain with pendant carboxylic acid. The methacrylic acid group would not be regenerated upon degradation of the polymer. 	In general, no evidence of significant toxicity.	Not in general. The carboxylic acid group is identified as a functional group of low concern.

Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Poly(ethyl methacrylate)	The monomer is methacrylic acid.  Ethyl methacylate	The C=C double bond of the methacrylate is reacted, leaving an alkyl chain with pendant ester groups. The R' group of the ester (RCO_2R') may be alkyl, aryl, haloalkyl or hydroxyalkyl. The methacrylate group would not be regenerated upon degradation of the polymer. 	In general, no evidence of significant toxicity. The ester groups may be associated with skin irritation. It is not known whether this would be applicable to polymer structures. There may be alerts associated with the R' group of the ester.	Not in general.
Polystyrenes (Polyphenylethylenes)				
Polystyrene	The monomer is styrene or styrene with an alkyl or alkoxy substituent.  Styrene	The alkene bond of styrene is reacted, leaving an alkane chain with pendant phenyl groups. The alkene group would not be regenerated upon degradation of the polymer. 	No relevant alerts.	No.

Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyphenylenes				
Poly(p-xylene)	The monomers contain phenylene groups. 	The polymers have phenyl groups as part of the chain, giving phenylene or xylene type structures. The cyclic monomers would not be regenerated upon degradation of the polymer.  	Aromatic hydrocarbons with ≥2 aromatic rings are associated with liver enzyme induction. It is not known whether this would be relevant for polymer structures.	No.
Polyvinyl alcohols & Derivatives				
Poly(vinyl alcohol)	The monomers contain both vinyl (alkene) and alcohol (hydroxy) groups.  1-Hydroxyethylene ((hypothetical monomer, tautomerises to acetaldehyde))	The alkene group reacts leaving an alkyl chain with a hydroxy-containing pendant group. The alkene group would not be regenerated upon degradation of the polymer.  	Not in general.	Not in general.

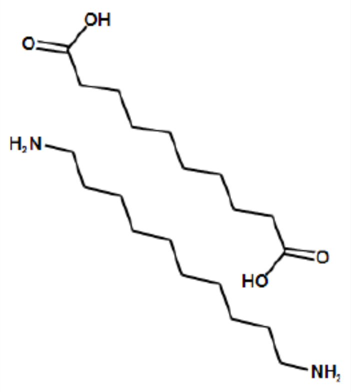
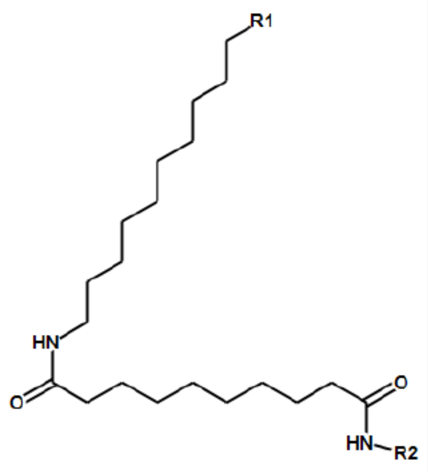
Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Poly(4-vinyl phenol)	The monomers contain both vinyl (alkene) and alcohol (hydroxy) groups.  4-Hydroxystyrene	The alkene group reacts leaving an alkyl chain with a hydroxy-containing pendant group. The alkene group would not be regenerated upon degradation of the polymer. 	No general alerts. The phenol group in Poly(4-vinyl phenol) is linked to various alerts.	Not in general. Poly(4-vinyl phenol) contains an unsubstituted para-phenolic hydroxy group, which is in high-concern group.
Polyvinyl Esters				
Poly(vinyl acetate)	The monomers are vinyl esters.  Vinyl acetate	The vinyl group reacts leaving an alkyl chain with pendant ester groups. The alkene (vinyl) group would not be regenerated upon degradation of the polymer. 	In general, no evidence of significant toxicity. The ester groups may be associated with skin irritation. It is not known whether this would be applicable to polymer structures.	No.

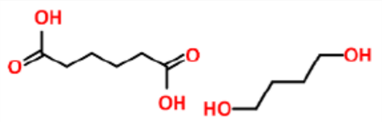
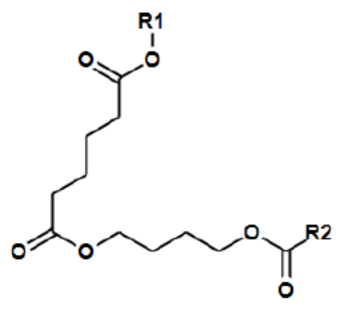
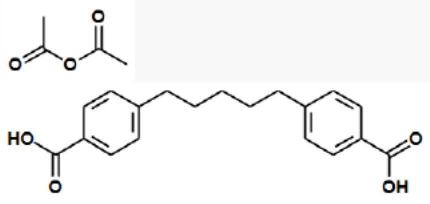
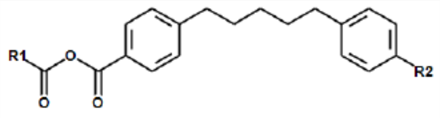
Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyvinyl Ethers				
Poly(butyl vinyl ether)	The monomers are vinyl ethers.  Butyl vinyl ether	The vinyl group reacts leaving an alkyl chain with pendant ether groups. The alkene (vinyl) group would not be regenerated upon degradation of the polymer.  	No relevant alerts.	No.
Polyvinyl Ketones (and Vinyl Pyrrolidone)				
Poly(vinyl ethyl ketone)	The monomers are vinyl ketones.  Vinyl ethyl ketone	The vinyl group reacts leaving an alkyl chain with pendant ketone groups. The alkene (vinyl) group would not be regenerated upon degradation of the polymer.  	No general alerts. Individual structures may be associated with alerts (for example pyrrolidine).	No.

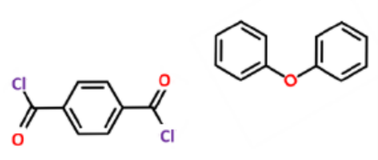
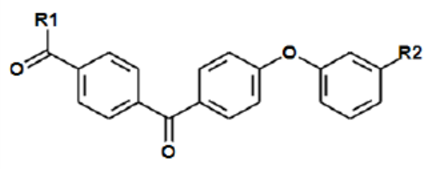
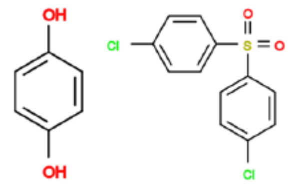
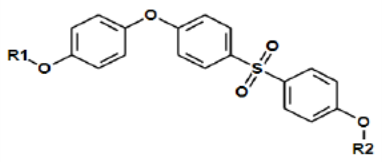
Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyvinyl Sulfides (Polyvinyl thioethers)				
Poly(vinyl butyl sulfide)	The monomers are vinyl sulphides.  Butyl vinyl thioether	The vinyl group reacts leaving an alkyl chain with pendant thioether groups. The alkene (vinyl) group would not be regenerated upon degradation of the polymer. 	Some sulfide structures have been shown to cause toxicity in the liver (an alert in Repeated Dose (HESS) appears for all substances). It is not known whether this would be applicable to polymer structures.	No. Thiols are of low concern. Thioethers are not included in the list of functional groups requiring registration.

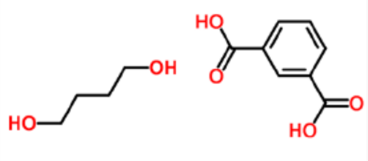
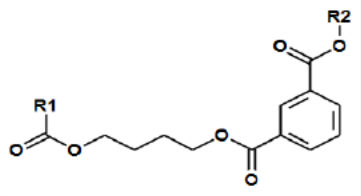
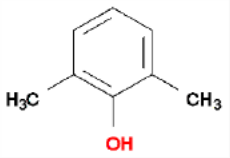
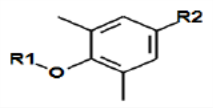
Step-growth polymers (ABABAB)

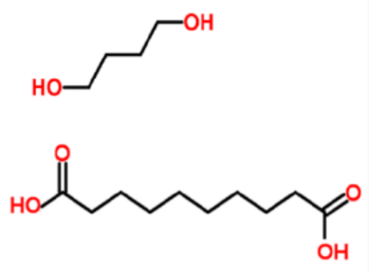
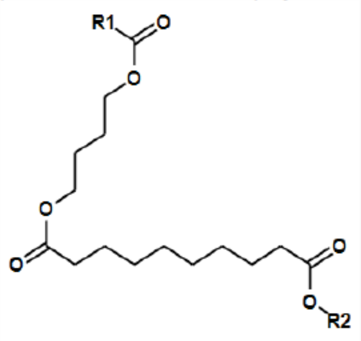
Table G5 Step-growth polymers (ABABAB)

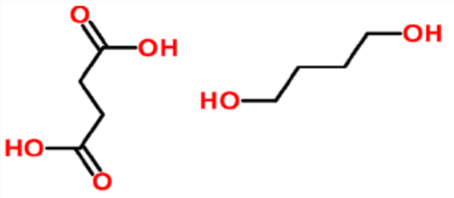
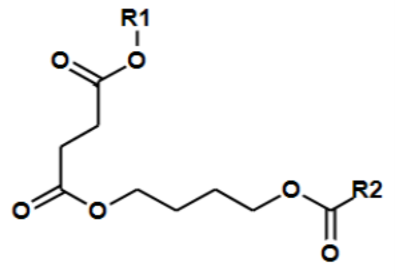
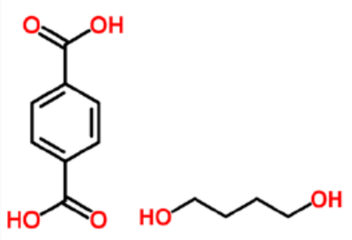
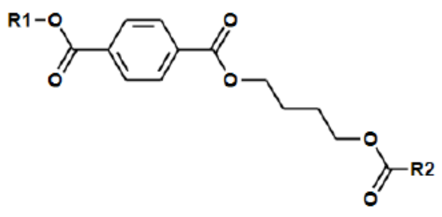
Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyamides (polylactams)				
Nylon 10,10	Monomer 1 contains carboxylic acid groups; monomer 2 contains primary amine groups.  Sebacic Acid; 1,10-decanediamine	The carboxylic acid group is reacted with the primary amine to form an amide link (with loss of water). An amine or carboxylic acid may be present at each end of the polymer chain.  	In general, no evidence of significant toxicity.	No functional groups requiring registration. The end groups (carboxylic acid and amine) are expected to become charged in the natural environment. Therefore, these could be amphoteric polymers.

Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyesters				
Poly(butylene adipate)	The monomers are a dicarboxylic acid and a dialcohol.  Adipic acid; 1,4-butylene glycol	The carboxylic acid group is reacted with the alcohol to form an ester link (with loss of water). A carboxylic or alcohol group may be present at each end of the polymer chain. 	There is some evidence that butyl diesters may be non-genotoxic carcinogens. Ethylene glycol derived polymers have an alert from in vivo mutagenicity (Micronucleus) alerts by ISS (H-acceptor-path3-H-acceptor).	Polyesters are excluded if the monomers are from an approved list. Adipic acid is not on this list (ECHA, 2015). Polymers that are not excluded could be anionic polymers requiring registration due to the presence of the ionising carboxylic acid end group.
Polyanhydrides				
Poly(p-pentamethylenedibenzoic anhydride)	The monomers are acetic anhydride and a dicarboxylic acid.  Acetic anhydride; p,p'-pentamethylenedibenzoic acid	The carboxylic acid and anhydride groups react (with loss of water), resulting in acid anhydride groups as part of the polymer chain. A carboxylic acid or anhydride group may be present at each end of the polymer chain. 	No evidence of significant toxicity.	Yes. Acid anhydride is a functional group that is in the high-concern group.

Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyketones (Polyetherketones)				
PEKK - Poly(ether ketone ketone)	A number of different monomer types are found.  Diphenyl ether; terephthaloyl chloride	The polymer contains ketone groups along the polymer chain; it may also contain ether groups and phenylene groups. The functional groups of the monomer may be present at the ends of the polymer chain. 	Not in general. The two aryl compounds have an alert for in vivo mutagenicity only.	No. The ketone group is not mentioned as a functional group requiring registration.
Polyethersulfones (Polysulfone)				
Poly(ether sulfone)	The first monomer contains two hydroxyphenyl groups and the second monomer contains two chlorophenyl groups.  Bis(4-chlorophenyl)sulfone; Hydroquinone	The polymer chain contains aryl sulfone and aryl ether groups. The functional groups of the monomer may be present at the ends of the polymer chain. 	Not in general. Substances with the 1-phenoxy-benzene group have an alert for in vivo mutagenicity (Micronucleus) alerts by ISS.	Vinyl sulfones and analogous compounds are functional groups in the high -concern group. An aryl sulfone might be considered analogous of a vinyl sulfone.

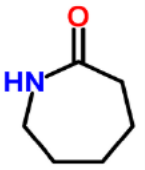
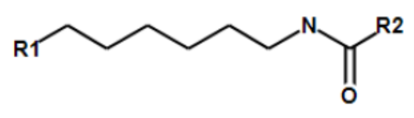
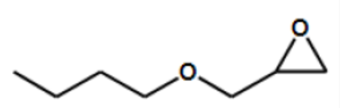
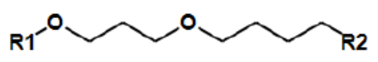
Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyisophthalate				
Poly(butylene isophthalate)	One monomer contains two alcohol groups; the other monomer is isophthalic acid (1,3-benzenedicarboxylic acid).  1,4-Butanediol; Isophthalic acid	The carboxylic acid groups of the phthalic acid react with the alcohol groups of the other monomer (with loss of water) to give phthalate ester links. A carboxylic acid or alcohol group may be present at each end of the polymer chain.  	Not in general. Aryl esters (formed when the first monomer has aryl alcohol groups) have alerts relating to sensitisation. Ethylene glycol derived polymers have an alert from in vivo mutagenicity (Micronucleus) alerts by ISS (H-acceptor-path3-H-acceptor).	No. These are polyesters. Isophthalic acid is on the list of approved polyester reactants (ECHA 2015). 1,4-butanediol is also on this list but other monomers in this class (Ethylene glycol, Bisphenol A) are not. The polymers contain no functional groups requiring registration but the carboxylic acid will ionise in the natural environment, so these may be anionic polymers.
Polyphenylethers (Polyphenyleneoxide)				
Poly(2,6-dimethyl-p-phenylene oxide)	The monomer is an alkyl or aryl substituted phenol.  2,6-Xylenol	The phenolic hydroxy group is reacted, leaving an aryl ether.  	The phenoxybenzene structural features results in an alert for in vivo mutagenicity.	No.

Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polysebacates				
Poly(butylene sebacate)	One monomer is sebacic acid (decanedioic acid); the other is an alkanediol.  Sebacic acid; 1,4-butanediol	The carboxylic acid groups of the sebacic acid react with the alcohol groups of the other monomer (with loss of water) to give ester links. A carboxylic acid or alcohol group may be present at each end of the polymer chain.  	Not in general. Ethylene glycol derived polymers have an alert for in vivo mutagenicity (Micronucleus) alerts by ISS (H-acceptor-path3-H-acceptor).	No. These are polyesters. Sebacic acid is on the list of approved polyester reactants (ECHA 2015). 1,4-Butanediol is also on this list but other monomers in this class (ethylene glycol, 1,6-hexanediol) are not. The polymers contain no functional groups requiring registration but the carboxylic acid will ionise in the natural environment, so these may be anionic polymers.

Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polysuccinates				
Poly(1,4-butylene succinate)	One monomer is succinic acid (1,4-butanedioic acid); the other is an alkanediol.  Succinic acid, 1,4-Butanediol	The carboxylic acid groups of the succinic acid react with the alcohol groups of the other monomer (with loss of water) to give ester links. A carboxylic acid or alcohol group may be present at each end of the polymer chain. 	Not in general. Ethylene glycol derived polymers have an alert for in vivo mutagenicity (Micronucleus) alerts by ISS (H-acceptor-path3-H-acceptor).	No. These are polyesters. Succinic acid is on the list of approved polyester reactants (ECHA 2015). 1,4-Butanediol is also on this list but other monomers in this class (ethylene glycol, 1,6-hexanediol, 1,3-propanediol) are not. The polymers contain no functional groups requiring registration but the carboxylic acid will ionise in the natural environment, so these may be anionic polymers.
Polyterephthalates				
Poly(butylene terephthalate)	One monomer is terephthalic acid (1,4-benzenedioic acid); the other contains two alcohol groups.  Terephthalic acid; 1,4-butanediol	The carboxylic acid groups of the terephthalic acid react with the alcohol groups of the other monomer (with loss of water) to give terephthalate ester links. A carboxylic acid or alcohol group may be present at each end of the polymer chain. 	Not in general. Aryl esters (formed when the first monomer has aryl alcohol groups) have alerts relating to sensitisation. Ethylene glycol derived polymers have an alert for in vivo mutagenicity (Micronucleus) alerts by ISS (H-acceptor-path3-H-acceptor).	These are polyesters, however terephthalic acid and some of the alcohol monomers are not on the list of approved polyester reactants (ECHA 2015). The polymers contain no functional groups requiring registration but the carboxylic acid will ionise in the natural environment, so these may be anionic polymers.

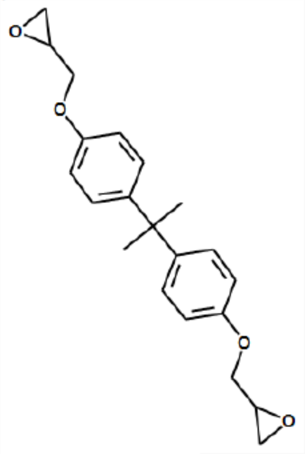
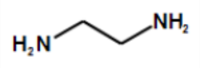
Ring Opening Step Growth Polymer

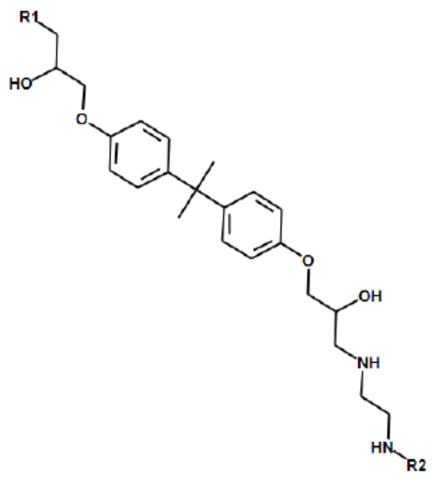
Table G6 Ring opening step growth polymers

Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyamides (Polylactams)				
Nylon 6 - Poly(caprolactam)	The monomer is a lactam (cyclic amide).  Caprolactam	Ring opening polymerisation produces an alkane chain with amide linkages.  	No evidence of significant toxicity.	No functional groups requiring registration.
Polyglycols (Polyethers)				
Poly(3-butoxypropylene oxide)	The monomers are glycidyl ethers & cyclic ethers.  2-(Butoxymethyl)oxirane, n-butyl glycidyl ether	The epoxy or cyclic ether reacts, leaving a polyether chain. Pendant groups (for example halide or alkyl halide) may be present depending on the structure of the monomer.  	In general, there is no evidence of significant toxicity for polyglycols. The two structures with pendant halide or alkyl halide groups have some alerts relating to skin sensitisation, genetic toxicity and carcinogenicity.	No.

Ring Opening alternating step growth copolymer

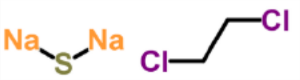
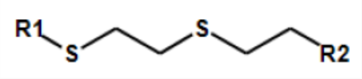
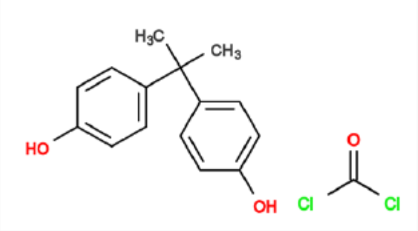
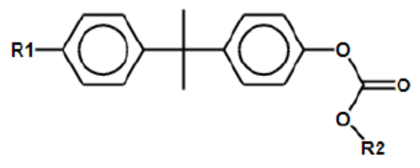
Table G7 Ring opening alternating copolymers

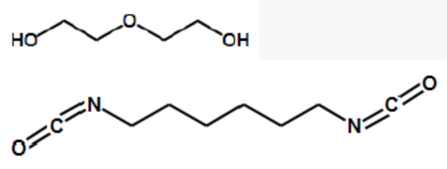
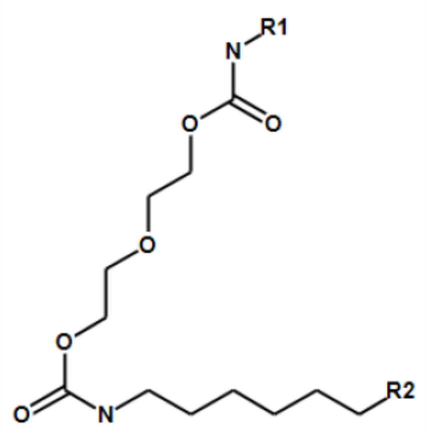
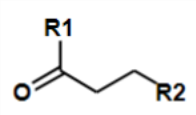
Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyepoxides (epoxy resins)				
Poly(bis-A diglycidyl ether- alt - ethylenediamine)	Monomer 1 contains epoxide groups (and may contain other groups such as ether and phenyl). Monomer 2 contains other functional groups such as primary amine, phenol or thiol.  	The epoxide functions react with the functional groups of the second monomer. In the example substance, the amine and epoxy groups react to generate a secondary amine as part of the polymer chain and a pendant alcohol group. The ether and phenyl groups remain in the polymer chain. The epoxide group would not be present at chain ends due to its high reactivity; the functional group from the other monomer may be present. The epoxide group would not be regenerated upon degradation of the polymer.	These structures have an alert for *in vivo* mutagenicity (H-acceptor-path3-H-acceptor). This relates to parts of the chain that have the structure X-C-C-X, where X is O or N.	Amines will protonate in a natural environment; therefore, if the second monomer is an amine, the polymer could be cationic.

Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
				

Other Alternating Copolymers (ABABAB)

Table G8 Other alternating copolymers (ABABAB)

Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polysulfides / Polythioethers				
Poly(ethylene sulfide)	The monomers are disodium sulfide and a dichloroalkane or dichlorobenzene.  1,2-Dichloroethane; Disodium sulfide	A thioether chain is formed. Chloride and sodium are not part of the polymer. Terminal thiol and alkyl chloride groups are present prior to curing.  	Some sulfide structures have been shown to cause toxicity in the liver (an alert in Repeated Dose (HESS) appears for all substances). It is not known whether this would be applicable to polymer structures.	No. Thiols are a group of low-concern; thioether is unclear not included in the list of functional groups.
Polycarbonates				
Poly(bisphenol A carbonate)	A number of different monomer types are found.  Bisphenol A; Phosgene	The polymer contains carbonate groups along the polymer chain; it may also contain other groups that are present in the monomer (for example, thioether, phenylene and chlorophenylene). Monomer groups may be regenerated upon degradation of the polymer.  	There is no evidence for significant toxicity in aliphatic polycarbonates. Aromatic polycarbonates may have various alerts, particularly those related to sensitisation. Other groups present in some monomers (such as thioether) could be associated with alerts.	No.

Example polymer	Monomer(s)	Repeat unit/monomer residue	Structural alerts associated with the repeating unit	Polymer requiring registration according to proposed criteria identified in Task 1.2 of the main report?
Polyurethanes				
Poly[(diethylene glycol)-alt-(1,6-hexamethylene diisocyanate)]	The first monomer contains two alcohol groups; the second monomer contains two isocyanate groups. The monomers may also contain other groups within the chain such as ether or phenylene.  Diethylene glycol; 1,6-Hexamethylene diisocyanate	The alcohol and isocyanate groups react to form a carbamate (urethane) link. Other groups such as ether or phenylene may also form part of the chain. Isocyanate or alcohol groups could be present at chain ends.  	Carbamate structures may have alerts relating to sensitisation, genotoxicity and carcinogenicity. It is not known whether these alerts would be relevant for polymer structures.	The carbamate group is not included in the list of functional groups requiring registration. Alcohols are a low-concern group. Isocyanates are a group of high concern.
Polyketones (Polyetherketones)				
Poly(ethyleneketone)	The monomers are an alkene and carbon monoxide. $H_2C{=}CH_2$ $\bar{C}{\equiv}O^{+}$ Ethylene; carbon monoxide	A carbon chain with ketone groups along the chain is formed.  	No relevant alerts.	No. The ketone group is not mentioned a functional group requiring registration.

References for Appendix G

Billmeyer, Fred W. (1984) *Textbook of Polymer Science,* John Wiley & Sons.

Callister, William D. (1997) *Material Science and Engineering, An Introduction,* 4th Edition, John Wiley & Sons Inc.

Callister, William D. and David G. Rethwisch (2010) *Material Science and Engineering, An Introduction,* 8th Edition, John Wiley & Sons Inc.

CROW (2018): *The Polymer Database*, *Chemical Retrieval on the Web,* https://polymerdatabase.com/home.html [Accessed 28/11/2018]

Harris, Frank W. (1981) "Introduction to Polymer Chemistry," *J. of Chemical Education*, 58(11) 837-843

Moulijn JA, Makkee M and van Diepen A (2001) *Chemical Process Technology,* John Wiley & Sons.

Sperling, L.H. (2006) *Introduction to Physical Polymer Science,* John Wiley & Sons.

Wypych G (2016): *Handbook of Polymers,* Chemtec Publishing, 2nd Edition Toronto.

Appendix H
Suggested approved list of polyester reactants

Proposed list of approved polyester reactants (based on COM, 2015).

Reactant type	CAS Registry Number and Name		
Monobasic Acids and Natural Oils	111-14-8] Heptanoic acid [112-05-0] Nonanoic acid [142-62-1] Hexanoic acid [143-07-7] Dodecanoic acid [3302-10-1] Hexanoic acid, 3,3,5-trimethyl- [8001-20-5]* Tung oil [8001-21-6]* Sunflower oil [8001-22-7]* Soybean oil [8001-23-8]* Safflower oil [8001-26-1]* Linseed oil [8001-29-4]* Cottonseed oil [8001-30-7]* Corn oil [8001-31-8]* Coconut oil [8002-50-4]* Fats and glyceridic oils, menhaden	[8016-35-1]* Fats and glyceridic oils, oiticica [8023-79-8]* Palm kernel oil [8024-09-7]* Oils, walnut [61788-47-4]* Fatty acids, coco [61788-66-7]* Fatty acids, vegetable-oil [61788-89-4]* Fatty acids, C18-unsatd., dimers [61789-44-4]* Fatty acids, castor oil [61789-45-5]* Fatty acids, dehydrated castor oil [61790-12-3]* Fatty acids, tall-oil [67701-08-0]* Fatty acids, C16-18 and C18-unsatd. [67701-30-8]* Glycerides, C16-18 and C18-unsatd. [68132-21-8]* Oils, perilla	[68153-06-0]* Fats and glyceridic oils, herring [68308-53-2]* Fatty acids, soya [68424-45-3]* Fatty acids, linseed oil [84625-38-7]* Fatty acids, sunflower-oil [68649-95-6]* Linseed oil, oxidized [68953-27-5]* Fatty acids, sunflower-oil, conjugated [91078-92-1]* Fats and glyceridic oils, babassu [93165-34-5]* Fatty acids, safflower-oil [93334-41-9]* Fats and glyceridic oils, sardine [120962-03-0]* Canola oil [128952-11-4]* Fats and glyceridic oils, anchovy [No Registry #]* Fatty acids, tall-oil, conjugated [No Registry #]* Oils, cannabis
Dibasic and Tribasic Acids and Esters	[100-21-0]** Benzene 1,4-dicarboxylic acid [106-65-0] Butanedioic acid, dimethyl ester [106-79-6] Decanedioic acid, dimethyl ester [110-15-6] Butanedioic acid [110-17-8] 2-Butenedioic acid (E)- [110-40-7] Decanedioic acid, diethyl ester [111-16-0] Heptanedioic acid [111-20-6] Decanedioic acid [120-62-6]** Dimethyl 1,4-benzenedicarboxylate	[121-91-5] 1,3-Benzenedicarboxylic acid [123-25-1] Butanedioic acid, diethyl ester [123-99-9] Nonanedioic acid [143-07-7] Dodecanoic acid [505-48-6] Octanedioic acid [528-44-9] 1,2,4-Benzenetricarboxylic acid [624-17-9] Nonanedioic acid, diethyl ester [693-23-2] Dodecanedioic acid	[1459-93-4] 1,3-Benzenedicarboxylic acid, dimethyl ester [1732-08-7] Heptanedioic acid, dimethyl ester [1732-09-8] Octanedioic acid, dimethyl ester [1732-10-1] Nonanedioic acid, dimethyl ester [1852-04-6] Undecanedioic acid [61788-89-4] Fatty acids, C18-unsaturated, dimers *

Reactant type	CAS Registry Number and Name		
Polyols	[56-81-5] 1,2,3-Propanetriol [77-85-0] 1,3-Propanediol, 2-(hydroxymethyl)-2-methyl- [77-99-6] 1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)- [105-08-8] 1,4-Cyclohexanedimethanol [107-21-1]** Ethane-1,2-diol	[107-88-0] 1,3-Butanediol [110-63-4] 1,4-Butanediol [111-46-6] Ethanol, 2,2′-oxybis- [115-77-5] 1,3-Propanediol, 2,2-bis(hydroxymethyl)- [126-30-7] 1,3-Propanediol, 2,2-dimethyl-	[144-19-4] 1,3-Pentanediol, 2,2,4-trimethyl- [2163-42-0] 1,3-Propanediol, 2-methyl [25119-62-4] 2-Propen-1-ol, polymer with ethenylbenzene [25618-55-7] 1,2,3-Propanetriol, homopolymer
Modifiers	110-99-6] Acetic acid, 2,2′-oxybis- [111-27-3] 1-Hexanol [112-34-5] Ethanol, 2-(2-butoxyethoxy)- [13393-93-6] 1-Phenanthrenemethanol, tetradecahydro-1,4a-dimethyl-7-(1- methylethyl)- [25036-25-3] Phenol, 4,4′-(1-methylethylidene)bis-, polymer with 2,2′-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]-bis[oxirane]	[72318-84-4]* Methanol, hydrolysis products with trichlorohexylsilane and trichlorophenylsilane [68037-90-1]* Silsesquioxanes, Ph Pr [68440-65-3]* Siloxanes and silicones, di-Me, di-Ph, polymers with Ph silsesquioxanes, methoxy-terminated	[68957-04-0]* Siloxanes and silicones, di-Me, methoxy Ph, polymers with Ph silsesquioxanes, methoxy-terminated [68957-06-2]* Siloxanes and silicones, Me Ph, methoxy Ph, polymers with Ph silsesquioxanes, methoxy- and Ph-terminated

Notes *Indicates that the substances is a UVCB substance.
**Indicates that the substance was not included in COM (2015) but is recommended to be included for the PRR criteria.

Appendix I
Assumptions for generating information and testing

The table below shows assumptions used in Task 4 to calculate the costs of generating information and testing for PRRs. As set out in the main report, where it is assumed that data waiving would occur, the associated costs of polymer registration are not assumed to be zero, but to be a percentage of the cost of undertaking each test.

Table I1 Assumptions for generating information and testing

Property	Annex no or Polymer specific	% waiving for Type 1	% waiving for Type 2	% waiving for Type 3	% requiring information for Type 1	% requiring information for Type 2	% requiring information for Type 3	% requiring new test for type 1	% requiring new test for type 2	% requiring new test for type 3	Weighted cost Type 1	Weighted cost Type 2	Weighted cost Type 3
Identity of PRRs													
Name or other identifier of each substance	VII (≥1tpa)				100 %	100 %	100 %	5%	5%	5%	€ -	€ -	€ -
Names in IUPAC nomenclature[1] or other international chemical name(s)	VII (≥1tpa)				40%	40%	40%	38%	38%	38%	€ -	€ -	€ -
Other names (usual name, trade name, abbreviation)	VII (≥1tpa)				100 %	100 %	100 %	5%	5%	5%	€ -	€ -	€ -
EINECS or ELINCS number	VII (≥1tpa)				0%	0%	0%	0%	0%	0%	€ -	€ -	€ -
CAS name and CAS number	VII (≥1tpa)				40%	40%	40%	38%	38%	38%	€ -	€ -	€ -
Other identity code	VII (≥1tpa)				100 %	100 %	100 %	5%	5%	5%	€ -	€ -	€ -
Molecular and structural formula (including SMILES notation)	VII (≥1tpa)				40%	40%	40%	38%	38%	38%	€ -	€ -	€ -
Molecular weight or molecular weight range	VII (≥1tpa)				100 %	100 %	100 %	5%	5%	5%	€ -	€ -	€ -

Property	Annex no or Polymer specific	% waiving for Type 1	% waiving for Type 2	% waiving for Type 3	% requiring information for Type 1	% requiring information for Type 2	% requiring information for Type 3	% requiring new test for type 1	% requiring new test for type 2	% requiring new test for type 3	Weighted cost Type 1	Weighted cost Type 2	Weighted cost Type 3
Number average and weight average molecular weight	P (≥1tpa)				100%	100%	100%	5%	5%	5%	€ -	€ -	€ -
GPC data (or equivalent) and molecular weight distribution (MWD)	P (≥1tpa)				100%	100%	100%	60%	60%	60%	€ 5,340	€ 5,340	€ 5,340
Identity of repeat units	P (≥1tpa)				100%	100%	100%	5%	5%	5%	€ -	€ -	€ -
Proportion of different repeat units	P (≥1tpa)				100%	100%	100%	5%	5%	5%	€ -	€ -	€ -
Distribution of repeat units or groups of repeat units	P (≥1tpa)				40%	40%	40%	2%	2%	2%	€ -	€ -	€ -
Chain length mean and distribution	P (≥1tpa)				40%	40%	40%	2%	2%	2%	€ -	€ -	€ -
Degree of crosslinking	P (≥1tpa)				40%	40%	40%	2%	2%	2%	€ -	€ -	€ -
Functional group molar concentration	P (≥1tpa)				100%	100%	100%	60%	60%	60%	€ -	€ -	€ -
Availability of monomeric functional groups for further chemical reaction or interaction with surrounding media	P (≥1tpa)				40%	40%	40%	2%	2%	2%	€ -	€ -	€ -
Polydispersity	P (≥1tpa)				100%	100%	100%	60%	60%	60%	€ -	€ -	€ -
Degree of purity (w/w %)	VII (≥1tpa)				40%	40%	40%	24%	24%	24%	€ -	€ -	€ -
Nature of impurities, including by-products	VII (≥1tpa)				100%	100%	100%	5%	5%	5%	€ -	€ -	€ -
Weight percentage of main impurities	VII (≥1tpa)				100%	100%	100%	5%	5%	5%	€ -	€ -	€ -
Nature and order of magnitude of any additives	VII (≥1tpa)				100%	100%	100%	95%	95%	95%	€ -	€ -	€ -
Spectral data (UV, IR, Raman, NMR or MS)	VII (≥1tpa)				100%	100%	100%	95%	95%	95%	€ -	€ -	€ -

Property	Annex no or Polymer specific	% waiving for Type 1	% waiving for Type 2	% waiving for Type 3	% requiring information for Type 1	% requiring information for Type 2	% requiring information for Type 3	% requiring new test for type 1	% requiring new test for type 2	% requiring new test for type 3	Weighted cost Type 1	Weighted cost Type 2	Weighted cost Type 3
High pressure liquid chromatogram, gas chromatogram	VII (≥1tpa)				40%	40%	40%	38%	38%	38%	€ -	€ -	€ -
Description of analytical methods	VII (≥1tpa)				100 %	100 %	100 %	5%	5%	5%	€ -	€ -	€ -
Identity of nonreacted monomers	P (≥1tpa)				100 %	100 %	100 %	5%	5%	5%	€ -	€ -	€ -
Weight percentage of non-reacted monomers	P (≥1tpa)				40%	40%	40%	2%	2%	2%	€ -	€ -	€ -
Manufacturing description	VII (≥1tpa)				100 %	100 %	100 %	5%	5%	5%	€ -	€ -	€ -
Physio-chemical properties													
Cure regime	P (≥1tpa)				100 %	100 %	100 %	5%	5%	5%	€ -	€ -	€ -
Physical form	VII (1-10tpa)				100 %	100 %	100 %	5%	5%	5%	€ 50	€ 50	€ 50
Melting/freezing point	VII (1-10tpa)				40%	40%	40%	2%	2%	2%	€ 20	€ 20	€ 20
Boiling point	VII (1-10tpa)				40%	40%	40%	2%	2%	2%	€ 22	€ 22	€ 22
Decomposition temperature	P (≥1tpa)				100 %	100 %	100 %	95%	95%	95%	€ 833	€ 833	€ 833
Relative density	VII (1-10tpa)				100 %	100 %	100 %	5%	5%	5%	€ 53	€ 53	€ 53
Vapour pressure	VII (1-10tpa)				40%	40%	40%	38%	38%	38%	€ 1,221	€ 1,221	€ 1,221
Surface tension of an aqueous solution	VII (1-10tpa)				40%	40%	40%	38%	38%	38%	€ 441	€ 441	€ 441
Solubility (water, solvents, oils)	VII (1-10tpa)				100 %	100 %	100 %	5%	5%	5%	€ 244	€ 244	€ 244
Partition coefficient	VII (1-10tpa)				100 %	100 %	100 %	95%	95%	95%	€ 4,900	€ 4,900	€ 4,900
Water extractivity	P (≥1tpa)				100 %	100 %	100 %	5%	5%	5%	€ 345	€ 345	€ 345

Property	Annex no or Polymer specific	% waiving for Type 1	% waiving for Type 2	% waiving for Type 3	% requiring information for Type 1	% requiring information for Type 2	% requiring information for Type 3	% requiring new test for type 1	% requiring new test for type 2	% requiring new test for type 3	Weighted cost Type 1	Weighted cost Type 2	Weighted cost Type 3
Flash-point	VII (1-10tpa)				40%	40%	40%	38%	38%	38%	€ 375	€ 375	€ 375
Flammability	VII (1-10tpa)				40%	40%	40%	2%	2%	2%	€ 35	€ 35	€ 35
Explosive properties	VII (1-10tpa)				40%	40%	40%	38%	38%	38%	€ 1,296	€ 1,296	€ 1,296
Self-ignition temperature	VII (1-10tpa)				40%	40%	40%	2%	2%	2%	€ 47	€ 47	€ 47
Oxidising properties	VII (1-10tpa)				40%	40%	40%	38%	38%	38%	€ 1,551	€ 1,551	€ 1,551
Granulometry/morphology (solids only)	VII (1-10tpa)				100%	100%	100%	95%	95%	95%	€ 1,894	€ 1,894	€ 1,894
Stability in organic solvents and identity of relevant degradation products	IX (100-1000tpa)				100%	100%	100%	5%	5%	5%	€ 435	€ 435	€ 435
Dissociation constant	IX (100-1000tpa)				40%	40%	40%	2%	2%	2%	€ 85	€ 85	€ 85
Viscosity	IX (100-1000tpa)				40%	40%	40%	2%	2%	2%	€ 31	€ 31	€ 31
Environmental fate and behaviours													
Degradation (ready biodegradation)	VII (1-10tpa)				100%	100%	100%	95%	95%	95%	€ 4,480	€ 4,480	€ 4,480
Fate and behaviour in the environment (adsorption/desorption screening)	VIII (10-100tpa)				100%	100%	100%	95%	95%	95%	€ 8,233	€ 8,233	€ 8,233
Degradation (abiotic hydrolysis as function of pH)	VIII (10-100tpa)				40%	40%	40%	38%	38%	38%	€ 2,850	€ 2,850	€ 2,850
Degradation (further abiotic testing if need identified by CSA)	VIII (10-100tpa)				100%	100%	100%	95%	95%	95%	€ 3,135	€ 3,135	€ 3,135
Degradation (biotic simulation – ultimate degradation in surface water)	IX (100-1000tpa)				100%	100%	100%	95%	95%	95%	€ 3,515	€ 3,515	€ 3,515

Property	Annex no or Polymer specific	% waiving for Type 1	% waiving for Type 2	% waiving for Type 3	% requiring information for Type 1	% requiring information for Type 2	% requiring information for Type 3	% requiring new test for type 1	% requiring new test for type 2	% requiring new test for type 3	Weighted cost Type 1	Weighted cost Type 2	Weighted cost Type 3
Degradation (biotic soil simulation testing (for substances with a high potential for adsorption to soil)	IX (100-1000tpa)	100%	100%	100%	0%	0%	0%	0%	0%	0%	€ -	€ -	€ -
Degradation (biotic sediment simulation testing (for substances with a high potential for adsorption to sediment)	IX (100-1000tpa)	100%	100%	100%	0%	0%	0%	0%	0%	0%	€ -	€ -	€ -
Degradation (biotic identification of degradation products)	IX (100-1000tpa)	100%	100%	100%	0%	0%	0%	0%	0%	0%	€ -	€ -	€ -
Degradation (further biotic testing if need identified by CSA)	IX (100-1000tpa)	100%	100%	100%	0%	0%	0%	0%	0%	0%	€ -	€ -	€ -
Fate and behaviour in the environment (bioaccumulation in aquatic species, preferably fish)	IX (100-1000tpa)				100%	100%	100%	95%	95%	95%	€ 68,154	€ 68,154	€ 68,154
Fate and behaviour in the environment (further adsorption/desorption if warranted from screening under Annex VIII)	IX (100-1000tpa)				100%	100%	100%	95%	95%	95%	€ 5,415	€ 5,415	€ 5,415
Fate and behaviour in the environment (further environmental fate and behaviour of substance or degradation products if need identified by CSA)	X (≥1000tpa)				100%	100%	100%	95%	95%	95%	€ 3,031	€ 3,031	€ 3,031
Mammalian toxicology													
Skin irritation or skin corrosion (in vitro)	VII (1-10tpa)				100%	100%	100%	95%	95%	95%	€ 2,286	€ 2,286	€ 2,286
Eye irritation (in vitro)	VII (1-10tpa)				100%	100%	100%	95%	95%	95%	€ 1,626	€ 1,626	€ 1,626

Property	Annex no or Polymer specific	% waiving for Type 1	% waiving for Type 2	% waiving for Type 3	% requiring information for Type 1	% requiring information for Type 2	% requiring information for Type 3	% requiring new test for type 1	% requiring new test for type 2	% requiring new test for type 3	Weighted cost Type 1	Weighted cost Type 2	Weighted cost Type 3
Skin sensitisation (in vitro/in chimico)	VII (1-10tpa)				100%	100%	100%	95%	95%	95%	€ 5,267	€ 5,267	€ 5,267
Mutagenicity (in vitro gene mutation in bacteria)	VII (1-10tpa)				100%	100%	100%	95%	95%	95%	€ 3,536	€ 3,536	€ 3,536
Acute toxicity (oral)	VII (1-10tpa)				100%	100%	100%	95%	95%	95%	€ 1,848	€ 1,848	€ 1,848
Mutagenicity (in vitro cytogenicity study in mammalian cells or in vitro micronucleus study)	VIII (10-100tpa)				100%	100%	100%	95%	95%	95%	€ 14,206	€ 14,206	€ 14,206
Mutagenicity (in vitro gene mutation study in mammalian cells, if other tests negative)	VIII (10-100tpa)				100%	100%	100%	95%	95%	95%	€ 15,780	€ 15,780	€ 15,780
Acute toxicity (inhalation)	VIII (10-100tpa)	50%	95%	95%	50%	5%	5%	48%	5%	5%	€ 6,608	€ 661	€ 661
Repeated dose toxicity (in vivo short-term (28 days))	VIII (10-100tpa)	50%	95%	95%	50%	5%	5%	48%	5%	5%	€ 26,039	€ 2,604	€ 2,604
Reproductive toxicity (in vivo screening (OECD 421 or 422))	VIII (10-100tpa)	50%	95%	95%	50%	5%	5%	48%	5%	5%	€ 54,150	€ 5,415	€ 5,415
Toxicokinetics (assessment of available information)	VIII (10-100tpa)				100%	100%	100%	95%	95%	95%	€ 1,235	€ 1,235	€ 1,235
Repeated dose toxicity (in vivo sub-chronic (90 days)	IX (100-1000tpa)	80%	98%	98%	20%	2%	2%	19%	2%	2%	€ 38,962	€ 3,896	€ 3,896
Reproductive toxicity (prenatal developmental toxicity) in one species	IX (100-1000tpa)	80%	98%	98%	20%	2%	2%	19%	2%	2%	€ 17,144	€ 1,714	€ 1,714
Reproductive toxicity (Extended 1 generation reproductive, with exceptions)	X (≥1000tpa)	80%	98%	98%	20%	2%	2%	19%	2%	2%	€ 96,900	€ 9,690	€ 9,690

Property	Annex no or Polymer specific	% waiving for Type 1	% waiving for Type 2	% waiving for Type 3	% requiring information for Type 1	% requiring information for Type 2	% requiring information for Type 3	% requiring new test for type 1	% requiring new test for type 2	% requiring new test for type 3	Weighted cost Type 1	Weighted cost Type 2	Weighted cost Type 3
Reproductive toxicity (prenatal developmental toxicity) in a second species	X (≥1000tpa)	80%	98%	98%	20%	2%	2%	19%	2%	2%	€ 26,196	€ 2,620	€ 2,620
Mutagenicity (in vitro somatic cell study if positive genotoxicity study)	X (≥1000tpa)				100%	100%	100%	95%	95%	95%	€ 3,292	€ 3,292	€ 3,292
Repeated dose toxicity (in vivo sub-chronic (≥ 12 months), if justified from other studies)	X (≥1000tpa)	80%	98%	98%	20%	2%	2%	19%	2%	2%	€ 152,950	€ 15,295	€ 15,295
Carcinogenicity study	X (≥1000tpa)	80%	98%	98%	20%	2%	2%	19%	2%	2%	€ 115,862	€ 11,586	€ 11,586
Acute toxicity (dermal)	VIII (10-100tpa)	50%	95%	95%	50%	5%	5%	48%	5%	5%	€ 1,217	€ 122	€ 122

Appendix J
Further information for the assessment of benefits

J1 Overview

This appendix provides further information on the assumptions made in the benefit assessment of this study. The approach used to assess the benefits from registering PRRs follows the steps taken in the COM (2017) study to 'gather further information to be used in support of an Impact Assessment of potential options, in particular possible amendments of REACH annexes, to modify requirements for registration of low tonnage substances (1-10t/year) and the CSA/CSR requirement for CMR substances in the framework of REACH'. Additional details can be consulted in the original study, on pages 76 to 87 of the main report. It was agreed at the start of the project that the approach to estimation of benefits should follow the approach in the COM (2017) study.

The table below summarises the human health and environmental outcomes linked to each hazardous property used in the analysis.

Table J1 Human health and environmental outcomes linked to hazardous properties

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

J2 Valuation of individual human health outcomes

The study adopts an approach based on the cost-of-illness to estimate the economic value of the human health benefits associated with registration. This covers medical treatment costs, productivity losses and, where available, individual willingness to pay (WTP) to avoid the disease/discomfort considered.

Table J2 Monetary values applied to metrics

Substance properties	**Valuation metric used**	**Monetary Value applied to metric**
Substances classified for skin/eye damage and irritation	Medical treatment cost + Productivity loss + WTP to avoid a single episode of mild acute dermatitis = Cost of a case of mild acute dermatitis	€ 0 + € 390 + € 277 € 667
Substances classified for skin sensitisation	Medical treatment cost + Productivity loss + WTP to avoid a single episode of case of chronic dermatitis = Cost of a case of severe chronic dermatitis	€ 2,100 + € 2,100 + € 1,055 € 5,255
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	Medical treatment cost + Productivity loss Cost of a 'poisoning event'	€ 1,370 + € 1,500 + = € 2,870
Substances with long-term toxicity information	Medical treatment cost + Productivity loss Kidney disease of short-term duration	€ 4,500+ € 6,000 = € 10,500
Substances with a classification for STOT RE 1 or 2	Medical treatment cost per year+ Productivity loss per year Annual cost of a case of chronic kidney disease Total cost of a case of chronic kidney disease assuming 10 years of treatment	€ 40,300+ €6,000 = € 46,300 per year € 380,400
Prevention of one cancer exposure per year over a period of 40 years	Latency = 15 years Survival/treatment period (years) = 5 years Fatality rate at end of period = 47% Annual cost per patient (€) = € 14,966 VSL (€) = € 4,000,000 VCM (€) = € 410,000	€22,673,090

J3 Valuation of individual environmental outcomes

Aquatic toxicity

The study uses the willingness to pay of UK households for improving the quality of water bodies to different Water Framework Directive Status levels, i.e. bad, poor, moderate, and good, in order to provide indicative values for water quality improvements. The study assumes that three components will be affected, namely fish, other animals (such as invertebrates) and plant communities.

It is assumed that the identification of acute aquatic toxic substances that do not currently have an associated ‘Predicted No Effect Concentrations’ (reflecting concentrations at which no (adverse) impact is observed) would result in the quality of water bodies improving from “bad” to “poor” at a value of €12,250 per km^2 river per year. The definition of PNECs would result in the setting of more stringent environmental risk management measures, with the effect of improving the quality of water bodies from "bad" to "moderate" at a value of €26,380 per km^2 river per year. The assumptions on km^2 waterbody improved are shown further down in this appendix.

PBTs and vPvBs

The study identifies a range of €1,000 - €50,000 per kg PBT substituted, remediated or emission reduced, as follows:

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

Estimates of the environmental releases eliminated for PBTs and vPvBs are presented further down in this annex.

J4 Adverse health effects avoided/unit environmental impacts avoided per substance identified through registration

This section provides an estimate of number of adverse health effects avoided and environmental impacts avoided for every substance identified. In particular, the approach identifies the number of substances for which adverse health effects would be newly identified through the introduction of a registration requirement. The study assumes that, for every substance identified, one case per year of the corresponding representative disease/disorder or environmental impact outcome would be prevented. This is considered an extremely conservative estimate, by the author of the impact assessment on the low tonnage substances.

There are significant uncertainties in assessing how accurate the scenarios described below are. However, to derive better estimates would require far better information on the extent of use of different polymers than stakeholders were able to provide in the course of this study. It is believed that the approach on the 1-10t study provides a reasonable basis for this Task, despite the significant uncertainty ranges presented in the results. Note that insufficient information from the literature or from stakeholders was available for the current study to derive more robust estimates of the number of people exposed per substance.

Numbers of workers exposed

The COM (2017) study provides estimates of the numbers of potentially exposed individuals at different stages of the value chain (including manufacturers and two layers of downstream users, in order to simplify the assessment. These numbers are reproduced below, noting that separate estimates are provided for substances with some ‘dispersive’ uses.

Thus, for example, for substances with no dispersive uses, there would be a total of 14,423 workers exposed per substance under the medium scenario.

Table J3 Average number of potentially exposed individuals per substance (by use)

Uses	Scenario	Manufacture	DU1 use non-dispersive	DU2 use non-dispersive	DU1 use dispersive	DU2 use dispersive
Substances with no dispersive uses	**Low**	12	100	500	0	0
	Medium	23	900	13,500	0	0
	High	46	6,000	180,000	0	0
Substances with 40% of uses being dispersive	**Low**	12	60	300	40	200
	Medium	23	540	8,100	360	5,400
	High	46	3,600	108,000	2,400	72,000

Source: COM (2017), methodology annex.

Estimation of ill effects from acute exposure

The study assumes that the total number of cases of acute ill health associated with exposure to the substances considered with as yet unidentified acute hazardous properties is as follows:

Table J4 Number of cases per year per substance identified

Scenario	Total number of cases over 40 years per substance	Number of cases per year per substance identified	Percentage of total exposed population suffering from an acute disease/disorder per year
Low	920	23	1.8%
Medium	2,520	63	0.2%
High	5,040	126	0.03%

Source: COM (2017) study on impact assessment for low tonnage substances. Numbers of cases over 40 years calculated by Wood by multiplying number of cases per year by 40, for consistency with data in Table J4.

Estimation of ill effects from repeated exposure

The study provides an estimate of the cumulative probability that a disease outcome is triggered per individual per year and potential exposed population and, in turn, the number of expected cases triggered per substance per year.

Table J5 Number of cases per year per substance identified

Scenario	Total number of chronic cases over 40 years per substance	Number of cases per year per substance	Percentage of total exposed population suffering from a chronic disease/disorder per year
Low	29	0.7	0.06%
Medium	88	2.2	0.008%
High	573	14.3	0.004%

Source: COM (2017) study on impact assessment for low tonnage substances. Note that the percentage of the total exposed population values are understood to refer to the same total exposed population as in Table J3. Data have been rounded so the total exposed population cannot be calculated from the above figures. See the methodology paper for COM (2017) for more detail on the total exposed population per substance.

J5 Environmental impacts

Aquatic toxicity

The environmental benefits of identifying substances that are toxic to the aquatic environment are presented in € per km^2 waterbody improved, with the following ranges:

- Low: 2 km^2 'improved' per substance newly identified as having aquatic hazards;
- Medium: 5 km^2 'improved' per substance; and
- High: 10 km^2 'improved' per substance.

PBTs and vPvBs

The following table provides an overview of estimates of the environmental releases eliminated of PBTs and vPvBs.

Table J6 Estimates of environmental releases eliminated

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

Source: COM (2017) study to 'gather further information to be used in support of an Impact Assessment of potential options, in particular possible amendments of REACH annexes, to modify requirements for registration of low tonnage substances (1-10t/year) and the CSA/CSR requirement for CMR substances in the framework of REACH'

J6 Annual damage costs avoided for substances newly identified with hazardous properties

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

- The monetary value applicable to the representative outcome (set out in the previous sections); and
- The number of cases of the representative outcome that are avoided per substance newly identified with each type of classification/property (defined in the next section).

J7 Percentage of total unique PRRs with hazardous properties

The impact assessment on low tonnage substances used statistics on fully registered substances in the Monte Carlo model to predict the numbers of substances that would be identified with hazardous properties if full *in vitro* and *in vivo* testing results were available. The estimates were based on data from actual registrations of other substances already submitted under REACH.

The percentage of total unique PRRs with hazardous properties assumes that the same percentages of PRR will have each hazardous property as was assumed for substances registered at 1-10t in COM (2017) and in turn the percentages that apply to other substances (in all tonnage bands) already registered under REACH, as this was the basis of the estimates in the 1-10t (COM, 2017) study. The number of unique PRR with each hazardous property was calculated by multiplying the percentage of PRR with each hazardous property by the number of PRR estimated in the Monte Carlo analysis for the cost estimates. These values are presented below.

Table J7 Percentage of PRR with hazardous properties

Hazardous properties covered	Damage metrics/ representative outcomes	Percentage of total unique PRRs with hazardous properties
Substances classified for skin/eye damage and irritation	Cases of mild acute dermatitis	22.1%
Substances classified for skin sensitisation	Cases of severe chronic dermatitis	12.0%
CM(R)s 1A/1B	NPV cancer over 40 years	2.4%
	Equivalent Annual Cost (EAC) cancer	
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	Poisoning events	27.3%
Substances with long-term toxicity information	Cases of kidney disease of short-term duration	7.4%
Substances that would have classification for STOT RE 1 or 2	Cases of chronic kidney disease of longer term duration	1.1%
Substances classified for acute aquatic toxicity	Improvement of WFD water body status from 'bad' to 'poor'	10.7%
Substances classified for acute aquatic toxicity with enough information for PNECs	Improvement of WFD water body status from 'bad' to 'moderate'	20.4%
PBTs/vPvBs non-diffuse	WTP to eliminate emissions of polymer PBTs	0.3%
PBTs/vPvBs non-diffuse	WTP to eliminate emissions of polymer PBTs	0.1%

J8 Assumed total numbers of cases/outcomes avoided per year

Based on the data in table J7, Table 5.13 in the main report provides estimates of the numbers of PRR with each hazardous property, based on the assumed 11,000 polymers that would be selected for registration. The table below provides details of the total numbers of cases/outcomes avoided per year, for information and context, This is based on the numbers per substance in Table 5.12 in the main report. Values for the 'medium' scenario are included, with the exception of environmental effects, for which the values for the 'low' scenario are used (in keeping with the 'best estimate' values in the main report).

Table J8 Total numbers of cases/outcomes avoided per year

Hazardous properties covered	**Damage metrics/ representative outcomes**	**Cases/outcomes avoided per year per substance**	**Number of unique PRRs with hazardous properties**	**Total cases/outcomes avoided per year**
Substances classified for skin/eye damage and irritation	Cases of mild acute dermatitis	63	2,430	153,090
Substances classified for skin sensitisation	Cases of severe chronic dermatitis	2.2	1,319	2,902
CM(R)s 1A/1B	Cancer cases	2.2	261	574
Substances with better information on exposure limits for oral and dermal/inhalation toxicity	Poisoning events	63	3,006	189,378 [Note 1]
Substances with long-term toxicity information	Cases of kidney disease of short-term duration	2.2	812	1,786
Substances that would have classification for STOT RE 1 or 2	Cases of chronic kidney disease of longer term duration	2.2	118	260
Substances classified for acute aquatic toxicity	Improvement of WFD water body Improvement of water body status from 'bad' to 'poor' (as per the Water Framework Directive, WFD)	2 km^2	1,172	2,344 km^2
Substances classified for acute aquatic toxicity with enough information for PNECs	Improvement of WFD water body status from 'bad' to 'moderate'	2 km^2	2,248	4,496 km^2
PBTs/vPvBs with no diffuse uses	Eliminated emissions of polymer PBTs	1,955 kg	31	60,605 kg
PBTs/vPvBs with one or more diffuse uses	Eliminated emissions of polymer PBTs	5,083 kg	11	55,913 kg

Notes: [1] It was noted in consultation on this draft report that in the EU there are on average 600 000 calls to poison centres per year, so this figure would seem to be a high proportion, given that many of the calls to poison centres concern children. However, it is also relevant to note that not all cases of poisoning result in calls to poison centres. The figure here represents a likelihood of encountering such a poisoning event across the EU population (446 million) of around 1 in 2400 per year.